

Risk Management Ethics

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FROM THE EDITOR

Risk Management Ethics

David Sine, D.Bioethics

This issue of the *AMA Journal of Ethics* is unique—not only because it’s about risk management ethics, but also because the contributors wrote their essays prior to a global pandemic that thrust ethical issues of access, justice, and inequity into the media spotlight. I wonder how different this content would read if these issues, which are the stock-in-trade of most biomedical ethicists, were at the forefront of the minds of writers and readers alike. Could a chapter be written about health technology and ethics that did not touch upon health disparities worsened by lack of **equitable access** to that technology? Or a chapter on **health financing** that would not point out that, for those without hope of attaining health insurance, discussions about payment for services are and will always be purely academic? Or could any chapter on risk management and ethics be written that did not mention poor US public health capacity, lack of supply chain resiliency, and unpreparedness that is laid bare for all to see?

My aim is to bring you writings by ethicists who work in the risk management space—or risk managers who work in the ethics space. And the contributors have done so. This *AMA Journal of Ethics* issue explores the thin gray crescent of overlap between these 2 professions. What we find in the product of that vocational Venn diagram is that ethicists remind us to be fair, while risk managers remind us to be prepared to be fair.

Differences between those 2 mindsets tend to be flimsy, as practitioners in both professions have internalized ethics in their own ways (ie, what one calls **patient autonomy**, the other calls **patient-centered care**). Risk managers tend not to discuss risk in a technical way all that often. It is true that if you attend a risk management conference, you can find more than a few breakout sessions on funding captive insurance programs, bond debt obligations, or even bundling and transferring claims risk. But if you head out to the lobby of that conference hotel, discussions you overhear will likely be about personal aspects of difficult claims, complex cases, or human error and how to make health care **safer for patients**. This issue reveals that risk managers have their own language but that many share with ethicists a need to prepare an organization, its policies, its practice, and its clinicians to meet the conditions in which health care can be just and safe for everyone.

David Sine, D.Bioethics is the chair of the Department of Bioethics at Kansas City University of Medicine and Biosciences in Missouri. He is also a certified professional health care risk manager and a former federal executive with experience in multiple disciplines, including enterprise risk management, organizational ethics, high reliability,

and patient safety. He earned a doctorate in biomedical ethics from Loyola University Chicago.

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CASE AND COMMENTARY

How Should Risk Managers Respond to Cases for Which No Risk Profile Exists?

Douglas E. Paull, MD, MS and Paul N. Uhlig, MD, MPA

Abstract

Rapid innovation makes some devices available for patient implantation prior to extensive preclinical trials. This article reviews information that risk managers can utilize to help patient-subjects and clinician-researchers make informed decisions about new device implantation in the absence of preclinical trial data. Novel devices should be regarded by risk managers as sources of unknowns with potential for procedural complications and other harms. Risk-benefit analyses during informed consent should include patient-subjects' preferences, experience of the implanting surgical team, disclosure of conflicts of interest, and postprocedure follow-up planning. Checklists can help risk managers facilitate critical conversations and decision making about whether to implant devices with no extant risk profile.

Case

MM is a 60-year-old man with hydrocephalus. His life was saved and his symptoms improved after Dr N implanted a shunt. Like many patients with shunt valves, MM experiences complications at the surgical site, the most pressing of which is the shunt valve's extrusion from the scalp wound. Dr N examines MM's scalp and remarks, "You're one of the patients who happens to have a lot of problems with their shunts. What you really need is a custom-made implant. If I could give you one, it would probably decrease chances of the shunt's failure, help mitigate skin breakdown on your scalp, and prevent the natural contours of your cranium from becoming deformed. I think you'd be a lot happier with a custom-fit shunt, if you agree to have me remove this one and replace it. You'd be the first patient to have a customized cranial implant. If you'd like to talk further about this, we can schedule some time tomorrow to talk about it more. In the meantime, I can present your case to my colleagues and get their ideas, too."

MM agreed to revisit Dr N's clinic the following day. In the morning, before multidisciplinary rounds, Dr N presented MM's case to the team at what team members call their weekly "innovation meeting," to discuss whether, when, and how to integrate new devices, materials, or techniques into practice. The team includes surgeons, surgical nurses, anesthesiologists, nurse anesthetists, case managers, and a risk manager. Dr N clarifies that MM's shunt valve would first be removed and then a

temporary shunt would be placed. MM would take a 14-day course of antibiotics. Then a contralateral craniectomy would accommodate implantation of the shunt valve system that the manufacturer would customize for MM's cranial measurements.

Team members at the meeting exchanged questions and responses. The risk manager took notes to share with colleagues in the hospital's office of general counsel and with other risk managers and left the meeting feeling concerned, as numerous questions about MM's safety remained unanswered—and perhaps unanswerable—until the first-in-human implantation of this device was complete.

Commentary

Growing demand for and explosive growth of technology led to US Food and Drug Administration (FDA) approval of more than 500 000 device models by the late 1990s.¹ Regulatory approval processes for new implantable devices differ from those for new medications and are not as rigorous.^{1,2} Devices deemed “substantially equivalent” to existing approved devices can be brought to market without clinical trials prior to first human use if approved through the FDA's 510k exemption process, despite being supported by only a limited amount of data.^{1,3} Variability in training and experience of the implanting team, variation in individual **patient-subject preferences** and risk tolerance,⁴ and possible conflicts of interest add additional layers of complexity to balancing patient safety with the need for innovation. Risk managers have critical roles in helping address decisions that patients and care teams must make about whether, when, and how to implant novel, untested devices. This commentary locates introduction of new devices within a framework of ethical principles in health care and introduces a decision matrix for evaluating new device implantation from an ethical perspective.

Clinical Risk-Benefit Analysis

Cerebrospinal fluid (CSF) shunts are lifesaving devices for patients with hydrocephalus caused by tumors, hemorrhage, or normal pressure hydrocephalus. However, morbidity of CSF shunt implantation is significant. Mechanical dysfunction and infection affect at least 17.2% and 6.1% of patients, respectively.⁵ The overall shunt revision rate has been estimated at 23.3%, with most revisions occurring within 6 months of the index implantation.⁵ Mortality for revision surgery is much higher than for first implantations (11.9 % vs 6.1%, respectively), and need for revision alone increases the incidence of subsequent shunt revision 9-fold.^{5,6} A new device, which could possibly decrease the risk of complications and shunt revision, could offer significant potential benefits for this patient.

Shunt customization involves embedding a rigid plastic casing made to fit the contours of a specific patient's skull. Two possible benefits of a low-profile customized shunt implantation are less scalp pressure and fewer dehiscence-related complications and revisions. Similar technology has already been utilized by neurosurgeons for other types of implanted devices, such as deep brain stimulators.⁶ These potential benefits appear significant in the case, in large part because the patient has already experienced dehiscence and a need for revision, which, as noted above, could increase this patient's morbidity and mortality risk. Identifying specific subpopulations of patients who could benefit most from implantation of a novel device is a key next step in MM and Dr N's risk-assessment process.⁴

Other risk factors to consider are whether the shunt and casing composition are like those of other devices used in neurosurgery, whether the surgical team is experienced in performing comparable procedures, and how risk of novel shunt placement might compare to risk of traditional shunt placement after a course of antibiotics. Material likeness of new to approved devices for which safe risk profiles have been established and analogous surgical experience are 2 of the most important elements in a risk manager's evaluation of risk in a case like this one.⁶

Ethical Risk-Benefit Analysis

New device implantation requires commitment to executing **informed consent processes** in ways that express respect for patient-subject autonomy. Patients and their families must be made aware of the rationale for using a new device for which there is little or no extant risk profile, the surgical team's experience with this or similar devices, alternatives such as implanting a device for which a risk profile is known and accepted, and potential conflicts of interest.^{3,7} Special consideration must be given to the **lack of clinical evidence** about a new device, gaps in knowledge about safety, and need for postimplant surveillance. Risk managers can help inform conversations about novel device implantation benefits and risks, identify patients or subgroups of patients that could benefit most from novel device implantation, and provide available information to build a risk-benefit profile for the device.⁴

Patient preferences. Patient perspectives on risk tolerance, for example, can differ from those of other stakeholders (eg, clinicians, manufacturers, regulators) for many reasons. In the case, a patient might choose to proceed with the new shunt in part due to the cosmetic appeal of the lower profile and an expectation of improved quality of life associated with this feature of the new device, whereas practitioners might focus more on technical or procedural considerations. Moreover, different patients are likely to have different attitudes about maximum acceptable risks and minimal acceptable benefits as well as different tolerance levels for uncertainty.⁴ Having already experienced failure of a traditional shunt, the patient in the case might be more tolerant of uncertainty and choose the new shunt, especially if the risk-benefit profiles of the new and traditional devices otherwise seem or are expected to be similar. On the other hand, because the new device requires removal of a small portion of skull to allow implantation of the novel embedded customized implant, the patient might not choose to take on additional or unknown risks of serious postoperative complications, such as epidural hematoma.

Perioperative care planning. When patient-subjects have capacity to make decisions, their wishes should be prioritized over advance directives or medical (physician) orders for life-sustaining treatment.⁸ Updating advance care planning documents to express patient-subjects' wishes and values is important, since patient-subjects can lose decision-making capacity during a procedure, illness, or hospitalization.⁹ Do-not-resuscitate (DNR) orders and policies must be navigated carefully when a patient-subject undergoes implantation of a new device, due to increased risk of cardiac or respiratory arrest.¹⁰ Deliberating about whether and when (especially during anesthetic airway intervention) a DNR order should be perioperatively suspended or continued¹⁰ must include patient or surrogate input. Decision making is easier when potential benefits of the novel device appear likely to—and potential risks appear less likely to—motivate expressed goals of care and when an advance directive fits the situation well.⁹ If conflict arises about how to interpret a patient-subject's wishes as represented in advance planning documents, for example, the clinical care team should obtain an ethics consultation.⁸

Anatomic location. Implanting a novel device in or around a patient-subject's brain obliges stakeholders to consider how a patient's identity and well-being can be affected,¹¹ especially if that device can be accessed or controlled by third parties. For example, shunts might be programmable to prevent over- or underdrainage of cerebrospinal fluid, especially in patients with normal pressure hydrocephalus.¹² Previous studies suggest that gaps between a physician-researcher's understanding and a patient-subject's perception of risks deserve attention and underscore the importance of effective communication.¹³ A risk manager can help elicit reflection, clarify concerns, and illuminate perspectives among all involved in decision making.

Commitment to transparency. Conflicts of interest, including financial conflicts and those related to the prestige of innovation, create a need for transparency about the experience and abilities of implanting team members and for disclosures about their personal and professional stakes in novel device implantation. Risk managers can help establish a relational environment in which these concerns can be discussed and in which any relevant data can be illuminated, considered, and addressed. One possible format for these discussions is interprofessional collaborative rounds, wherein clinical care team members, patients, and their families discuss a care plan and establish a shared mental model.¹⁴ Risk managers, clinical teams, patients, and families increasingly have access to databases of outcomes for related procedures and, as a result of the Sunshine Act, access to public databases of payments from device manufacturers to clinicians.³

Surveillance and communicating evolving knowledge. In new device implantation, a rich preclinical record of experience and evidence is missing, so a risk-profile is also missing, which creates a gap in knowledge for patient-subjects and clinician-investigators.³ Even approved devices can later be found to have previously unsuspected or unknown complications. A clinical team and organization have an ethical obligation to discuss providing or arranging for postimplantation surveillance to capture any safety issues that become apparent through patient-subjects' living with the novel device. Postimplantation surveillance thus should be discussed during an informed consent process. All stakeholders, including the patient-subject, should be engaged in surveillance and ongoing disclosures of potential conflicts of interest. Patients, clinicians, and manufacturers should report complications—and certainly adverse events—in the US Food and Drug Administration Manufacturer and User Facility Device Experience database or to the Medical Product Safety Network.³

Checklist

The authors have developed a checklist tool (see Table) to set the stage for informed consent or refusal conversations among stakeholders and prompt revelation of factors that can help motivate ethically informed decisions among patient-subjects and the clinical team. Higher scores yielded by use of the tool could be interpreted as supporting a decision to implant a new device for which there is no extant risk-profile. Lower scores would suggest ethical concerns and a need for pause and might prompt a risk manager to recommend an ethics consultation to help address those ethical concerns. This checklist could be applied to the above case.

Table. Checklist Tool for Ethically Implanting New Devices With Limited Clinical Trial Data^a

Factor	Item No.	Maximum Points	This Patient	Evidence of Greater Favorability	Evidence of Lesser Favorability
Regulatory	1	5	5	FDA approval	Investigational device exemption (eg, emergency)
	2	5	5	IRB approval	
Potential Benefits	3	5	4	Significant potential benefits function and quality of life, reduction in morbidity, and improved survival compared to current available device	Fewer potential benefits of new device compared to current available device
	4	5	3	Benefits long-lasting	Time course unknown
Potential Risks	5	5	3	New device either has similar expected risk or increased risk does not include serious harm compared to current device(s)	New device significantly increases risk of serious complication or death
	6	5	4	Any potential new complications are manageable	New complications introduced are difficult to treat
Device	7	5	0	Non-CNS location	Located near brain
	8	5	5	Functionality similar to devices in use	Novel functionality
	9	5	5	Not accessible	Accessible to third parties
	10	5	3	Implantation procedure similar to other procedures in routine clinical use	Implantation methods differ substantially from those currently in use
Surgeon/ Implanting Team	11	5	5	Has considerable experience implanting similar devices	Less experience with similar devices and implantations
	12	5	5	Has undergone additional training by the vendor with the new device	No or limited additional training with new device
	13	5	4	No conflicts of interest with the vendor and device	Potential conflict of interest (eg, royalties, paid speaker for device manufacturer)
Patient	14	5	5	Belongs to subpopulation of patients with disease most likely to benefit	No subpopulation more likely to benefit known or patient does not belong to the subpopulation likely to benefit the most

				Patient preferences known and include:	Patient preferences unknown or patient uncomfortable with:
	15	5	3	<ul style="list-style-type: none"> • Acceptance of maximum possible increase in risk 	<ul style="list-style-type: none"> • Maximum possible increase in risk
	16	5	3	<ul style="list-style-type: none"> • Acceptance of minimal possible increased benefit 	<ul style="list-style-type: none"> • Minimal possible increased benefit
	17	5	3	<ul style="list-style-type: none"> • Acceptance of degree of uncertainty associated with new device 	<ul style="list-style-type: none"> • Degree of uncertainty associated with new device
Postimplant Surveillance/Communication Plan	18	5	5	Implanting team or organization has the capacity to provide individual surveillance	Minimal capacity to provide individual surveillance
	19	5	5	Patient able/desires to participate in follow-up	Barriers to follow-up
	20	5	5	Processes in place to monitor implants in other patients and communicate outcomes to this patient	Unable to provide global follow-up and communication
Total Score		100	80		

Abbreviations: CNS, central nervous system; FDA, Food and Drug Administration; IRB, institutional review board.

^a Users may customize this tool by assigning more or less weight to different items.

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Douglas E. Paull, MD, MS is a board-certified general and cardiothoracic surgeon. He is an assistant professor at the Georgetown University School of Medicine in Washington, DC, where he teaches patient safety leadership in a graduate-level program. He also serves as a field representative for the Accreditation Council on Graduate Medical Education's Clinical Learning Environment Review program. He trained at New York Hospital-Cornell Medical Center and the University of North Carolina. His interests and publications encompass surgery, patient safety, and simulation.

Paul N. Uhlig, MD, MPA is a board-certified cardiothoracic surgeon and an associate professor in the Department of Pediatrics at the University of Kansas School of Medicine-Wichita. He is also a field representative for the Accreditation Council on Graduate Medical Education's Clinical Learning Environment Review program. His professional interests include collaborative care with active engagement of patients and families, interprofessional education, experiential learning, and patient safety. His research utilizes social science approaches to study and transform health care practice culture.

Editor's Note

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

CASE AND COMMENTARY

What Is an Ethically Informed Approach to Managing Patient Safety Risk During Discharge Planning?

John C. West, JD, MA

Abstract

Hospital discharge planning for patients who might not be safe at home— particularly those leaving against medical advice—can require risk managers to navigate the complex intersection of tort law, federal and state regulations, and clinical ethics. An overarching duty is to ensure that a patient is as safe as possible in the environment to which the patient is being discharged, although it's not always possible to formulate a safe discharge plan. When patients have decision-making capacity, they can make a decision to be in an environment that's not safe. When patients do not have decision-making capacity, it is not always legally permissible to hold them against their wishes to keep them in a safe environment, so some kind of discharge plan must be made. This article considers the role of a risk manager in navigating this set of circumstances.

Case

RQ is a 32-year-old man with end-stage multiple sclerosis (MS). He lived independently until 5 years ago, when his condition became worse and he had to be hospitalized several times. RQ was then cared for in his home by his parents and sister, with support from a home care agency. Early in his most recent hospitalization, RQ suffered severe respiratory distress, was intubated, and was placed on a ventilator. RQ's body language adamantly and persistently expressed that he did not want to be intubated. But Dr C, a pulmonologist in the intensive care unit (ICU), expressed confidence that RQ's current respiratory condition was temporary, with a solid chance of remission. No advance directive existed in RQ's electronic health record (EHR), and Dr C was convinced that RQ lacked decision-making capacity at this time. Dr C and RQ's parents agreed that ventilator support should continue.

As RQ's hospitalization continued, his condition deteriorated, and he became more agitated. RQ was sedated, a line was inserted for hyperalimentation (intravenous nutrition), and a tracheostomy tube was placed. He suffered several nosocomial infections, including methicillin-resistant staphylococcus aureus. After 80 days in the ICU, RQ's condition stabilized enough for him to be weaned from the ventilator. After 81 days, RQ plugged his tracheostomy tube to speak; he stated clearly and deliberately, "I

don't want any more machines and I don't want any more treatment here or anywhere. I want to go home, and I want to be by myself.”

To Dr C's and other caregivers' frustration, however, RQ's father insisted that all resuscitative measures, including mechanical ventilation, be implemented when RQ's respiratory status deteriorated again, which Dr C suspected could happen at any time. Based on their most recent conversations with RQ, Dr C and RQ's other caregivers agreed that an order to limit life-sustaining treatment should be placed in his EHR. Dr C explained to RQ's father, “RQ has decision-making capacity now, and he understands the risks of going home, so it's reasonable for us to explore discharge planning at this time.”

Enraged, RQ's father pointed at Dr C's chest and said, “Well, he can't go home. Something will happen to him and he'll be hurt, and I promise you'll be the first one we name when we sue this hospital.” Following this clear threat of legal action from RQ's father, RQ's care team now meet regularly with Mr J, one of the hospital's risk managers.

When discussing the timing and terms of RQ's discharge, Mr J stated, “Even with full assessment of his home environment, his deteriorating condition makes anywhere he's alone unsafe. Allowing him to exercise his right to self-determination is just too risky for us in this case. I wouldn't recommend discharge to any place other than a skilled nursing facility.”

Members of the team wondered what to do next.

Commentary

There are a number of avenues by which the issue of **safe discharge** can be addressed, but none of them offer an optimal solution to the problem. Discharging a patient is often a simple process: the patient has been restored to health and can return home to safely carry on with his or her life. While this covers the vast majority of cases, it does not cover all cases. The cases not covered by the foregoing scenario can be thorny and complex.

As a general rule, the Conditions of Participation for Hospitals, implemented by the Centers for Medicare and Medicaid Services (CMS), require that hospitals have a written discharge planning process for all patients. In general terms, CMS states that hospital discharge planning involves determining the appropriate posthospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his or her discharge destination; and beginning the process of meeting the patient's identified postdischarge needs.¹

These requirements must be tempered by reality, because there is only so much that a hospital can do to make the outside world safe for the soon-to-be discharged patient. For example, it might not be safe for a patient with a bandaged surgical incision to return home if his home does not have running water. Or it might not be safe for a patient recently recovered from pneumonia to be discharged to her home if her home does not have central heat. Hospitals have an obligation to explore all the alternatives and possibilities for a patient, but they can only do what is reasonable under the circumstances.

The hospital is not required to hold RQ simply because he is at risk for something that is not currently happening.² There must be a current medical condition that warrants hospitalization for him to remain hospitalized. This is true regardless of whether or not RQ has decision making capacity or is legally competent or incompetent. Consequently, the hospital has an obligation to discharge him, the only questions being where and how.

Options for RQ

Right to consent or refuse. RQ has clearly expressed his determination to be discharged during a period in which he had decision-making capacity. The right to consent to treatment involves the **right to refuse**. Any adult with decision-making capacity can refuse treatment, regardless of how ill-advised that decision might appear to an outside observer, such as a health care professional. Holding RQ without his consent might constitute false imprisonment, regardless of his father's wishes.³

Discharge against medical advice. If the clinicians feel that continuing the hospitalization is in RQ's best interest but RQ continues to feel that discharge is most appropriate, the hospital could consider discharging him. This would be evidence, if evidence is needed in the future, that the hospital was not abandoning RQ or rushing him out of the hospital for some reason and that the clinicians did not think that it was appropriate to discharge him when it was not.

If RQ Lacked Decision-Making Capacity

Even if RQ lacked decision-making capacity, the hospital only would have a limited ability to hold him. The test is normally whether a patient poses a risk to self or others. In this context, courts typically look at whether the patient is suicidal or homicidal. It is only in rare cases that courts have imposed a duty when the patient is incapable of caring for himself or herself. The duty to hold and treat a patient was found in *Thomas v Christ Hospital and Medical Center*, in which a patient was suffering from steroid-induced psychosis.⁴ This is a far cry from RQ's situation. As one court has put it, hospitals do not have a duty to do that which they have no legal right to do.⁵

Advance directives. If RQ lacked decision-making capacity during discharge planning, he might have formulated an advance directive during a period in which he had decision-making capacity. If RQ had designated what his wishes were or designated a **surrogate decision maker** during a period in which he had decision-making capacity, that designation must be followed. In the vast majority of states,^{6,7} such a designation is presumed to be valid (absent knowledge to the contrary), and any clinician who follows the patient's wishes or the surrogate's directions will be immune from liability. Thus, if RQ had designated a surrogate decision maker (other than his father), the clinicians should follow the surrogate's directions.

Guardianship. If the care team felt that RQ lacked the decision-making capacity necessary to formulate an advance directive and would not regain it, the hospital might be able to petition a court for a guardian of his person. This is normally not done unless the patient is incompetent. Just because someone lacks decision-making capacity for particular decisions during a particular period of time does not render him or her legally incompetent. The guardian could be a member of RQ's family but must be someone who, in the court's opinion, would act in his best interest. The hospital is entitled to follow the guardian's directions, just as it would the directions of a designated surrogate.

Alternative postdischarge placement. It is not true that RQ's only option is to go home. It may be possible to discharge him to a rehabilitation facility or to a long-term care facility. If RQ had lacked decision-making capacity, it might have been most appropriate to place him in a postacute care facility, since he probably would not be able to care for himself at home, even for brief periods of time. Since he does have decision-making capacity, such a placement would only be an option if he is amenable to it. If he is transferred to another facility, it would be wise to select a facility that can take ventilator patients in order to minimize any disruption to his life if, in the future, he becomes ventilator dependent again.

Physician orders for life-sustaining treatment (POLST). Many patients want to refuse aggressive, but ultimately futile, care. Inside the hospital this goal can be accomplished by either a **do-not-resuscitate** or a do-not-intubate order. These orders are typically not effective outside the hospital, so many states (currently 46)⁸ have implemented a provision for **POLST**. POLST is typically effective in directing first responders and emergency department personnel to follow the patient's wishes for refusing aggressive treatment. The implementation of a POLST order would be advantageous for RQ if he is insistent that he no longer wants aggressive care, even in a life-threatening situation. It also would provide evidence of his wishes in the event his estate decides to sue after his death.

Conclusion

In cases such as RQ's, the question is rarely, Can the patient go home? Discharge is a more complex and nuanced issue than that. As noted above, the discharge must be as safe as the hospital can reasonably make it. But how safe is safe enough? What is reasonable under the circumstances? Is there something that can be done to make it safer, while still respecting the patient's wishes? Each case may be unique because each patient is unique. There is no template for making these decisions, but there are a number of factors to consider.

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John C. West, JD, MA is the principal of West Consulting Services, LLC, which specializes in risk management and patient safety consulting. He holds a bachelor's degree from the University of Cincinnati, a law degree from Northern Kentucky University Salmon P. Chase College of Law, and a master's degree from Xavier University. He has also written a quarterly column for the *Journal of Healthcare Risk Management* since 1994.

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CASE AND COMMENTARY

Should a Good Risk Manager Worry About Cost and Price Transparency in Health Care?

Josh Charles Hyatt, DHSc, MHL, MBE(c) and Stephen L. Newman, MD, MBA

Abstract

Roles of hospital risk managers have grown over the last 30 years. Once largely focused on hospital liability risk management, risk managers today have a broader set of enterprise risk management responsibilities. The following commentary about a surprise billing case considers roles of risk managers in promoting cost and price transparency.

Case

JJ and KJ coparent EJ, their 16-year-old, who is recovering from being hospitalized for 8 days following a surgery. In the explanation of benefits they received from their insurer, a fraction of what the hospital charged was covered by the insurer, leaving JJ and KJ with a bill of about \$190 000 for their child's inpatient care. Shocked and dismayed, JJ and KJ called the insurer to complain. Investigation ensued and revealed substantial variation in what different organizations charge for comparable surgical care. Results of the investigation were published by a national print media company. One organization offered the procedure with an inpatient stay of 8 days and estimated that the cost to the patient's family would be about \$85 000. Another organization offered the procedure with 3 inpatient days for a total of about \$35 000 with an estimated cost to the patient's family of about \$25 000.

Members of the public began to ask, "Why is there such variation in what this procedure costs?" Recent responses to public concern about a lack of transparency in health care pricing and what's been called "no surprise billing" have prompted The White House to direct the US Department of Health and Human Services to develop rules requiring hospitals to publish prices "that reflect what people actually pay for services."¹

A risk manager, GG, at the hospital where EJ had surgery is relieved that the organization seems to have weathered negative public attention generated by EJ's case. GG has been wondering, however, how other organizations offer the procedure at lower costs: *Are they saving the money by cutting quality and thus increasing patients' risks of postsurgical complications that would probably be identified in an inpatient care setting? What should patients be told about this risk?* GG notes that EJ's hospital and the 2 organizations that offered the same surgery at lower cost performed approximately

the same number of procedures and suspects that pricing differences cannot be explained only in terms of volume or economies of scale.

GG also wonders, *Why is our organization's length of stay (LOS) so much longer than some others'? If we can reduce LOS, we should, because each day in hospital increases a patient's risk of contracting a nosocomial infection. I wonder what our patients are told about this.*

Aside from these questions facing the hospital, GG has broader concerns, too: *If organizations respond to public and government demand for pricing transparency, health care networks might respond by consolidating prices. This move would result in less cost variation across a market and less competition and could raise overall costs of care.* For example, GG recently read that the president and chief executive officer of America's Health Insurance Plans warned that price transparency rules requiring "publicly disclosing competitively negotiated, proprietary rates will reduce competition and push prices higher—not lower—for consumers, patients, and taxpayers."²

GG notes that markets tend to initially react negatively to concerns about increased prices: *When stocks of major hospital operators and insurers fall, shareholder value falls, reducing organizational access to capital or increasing the cost of capital. As a result, strategic planning for broadening market share or making capital improvements necessary to remain competitive could be placed on hold.* So, GG considers the scope of her responsibility to the organization's shareholders, too.

GG wonders what to do over the short- and long-term.

Commentary 1

by Josh Charles Hyatt, DHSc, MHL, MBE(c)

Cost transparency in health care allows individual patients to exercise choice by deciding what is in their best physical and financial interests. According to the US Census Bureau, in 2018 there were 27.5 million uninsured in the United States; Blacks (9.7%) and Hispanics (17.8%) are uninsured at a higher rate than non-Hispanic Whites (5.4%).³ Additionally, the number of underinsured people (whose out-of-pocket medical expenses are 5% to 10% of their annual income or who have deductibles that are more than 5% of their annual income⁴) grew to 44 million in 2018.⁴ These inequities are at the heart of social justice, inhibiting fairness and placing an undue burden on the most vulnerable (who have the highest risk of harm and least ability to afford it). Hospital risk managers (hereafter, risk managers) have a stake in preserving justice—viz, fairness and equity as they concern patient rights, consent, satisfaction, and harm reduction.

As a profession, health care risk management has not been at the vanguard of social justice issues. Hospital executives, leadership teams, and ethics committee representatives generally discuss and develop policy related to ethical and values-based concerns without the input of risk managers who are responsible to manage the aftermath when those decisions result in liability exposure. The scope of risk management has traditionally encompassed daily firefighting (ie, triaging and investigating events, managing sentinel events, engaging in institutional and clinician consultation) rather than ethically normative concerns (ie, what we ought to do). Similar to bioethics, risk management was born of necessity. Risk management questions and concerns are rarely straightforward clinical, regulatory, or legal issues; rather, these

inquiries, though not the traditional questions faced by an ethics committee, are multifaceted in nature, with values at their core and informed by ethical principles.

Justice advocacy expands the risk manager's role from managing loss, ensuring compliance, and overseeing billable services to augmenting risk mitigation (by taking steps to reduce the impact of liability) and addressing risk concerns from a morally courageous position (doing the right thing). The risk manager has a unique perspective on managing loss while being in a position to address broader elements of justice by reflecting on whose interests are predominant (patient, institution, profession, or society) and acting in a manner that seeks to balance the best interests of stakeholders. Reflecting both a moral and operational risk management imperative, this essay explores the issue of **cost transparency** as it relates to justice in health care.

Cost Transparency as a Moral Imperative

John Rawls suggests that a just society is a fair society, wherein all persons are equal, all have access to needed resources, and the least advantaged benefit.⁵ All health care professionals, including risk managers, embracing their obligation to work toward health care equality—currently a mere aspiration—is axiomatic to promoting a society in which fairness prevails.⁶ Ideally, access to needed services should be guaranteed and health care policies that emphasize equitable systems that benefit the vulnerable should be ubiquitous.⁷ Unfortunately, these conditions for distributive justice are not met in US health care. A record 25% of Americans reported in 2019 that they or a family member put off treatment for a serious medical condition in the past year because of cost, and, within this group, the income gap between top and bottom earners was 23%.⁸ One important step for the health care system to take is to cultivate transparency so that people are aware of the **costs of care** up front and can triage their options and plan their diagnostic testing and care with this information in mind, in consultation with their health care physician.

On November 15, 2019, the US Department of Health and Human Services, the US Department of Labor, and the US Department of the Treasury published the Transparency in Coverage Rule, which calls for health care price information to be accessible to the public to permit “easy comparison-shopping.”⁹ As of the writing of this essay, the rule has just completed the public comment phase. The principle argument against price transparency is that publishing fee schedules would affect hospitals' ability to negotiate lower contract rates with payers, resulting in a “floor” for prices that hospitals would be willing to accept.¹⁰ This argument appears to disregard the justice concerns of patient access and individual affordability.

As a result of this lack of transparency, the most vulnerable in our society are the most likely victims of predatory pricing via **price fixing**, a financial agreement between 2 parties (in this case, the payers and the institutions negotiating rates), and price discrimination, selling a product at different prices to different groups based on willingness to pay.¹¹ Price fixing and price discrimination primarily affect those who are uninsured or underinsured, are designed to exclude lower-priced managed care companies and Medicaid (the lifeline for vulnerable populations) from provider networks, and limit competition (driving up costs and limiting access to care). Ultimately, these agreements are socially unjust because they pose barriers to access and disenfranchise vulnerable populations.

Personal Liberty and Cost Transparency

Why is cost transparency a matter of personal liberty? Making autonomous, noncoerced, and informed health care decisions is the cornerstone of medical ethics and fundamental to health care policy and health law. Nevertheless, cost transparency and the impacts of care costs on the individual are not given adequate attention during informed consent deliberations and are more rarely discussed by risk managers as a tool for risk mitigation. People cannot thrive if they avoid seeking health care due to cost and a lack of control in the planning of their care. Health care policies at all levels (government, insurance company, and health care organization) should regard individuals, in Kant's terms,¹² as "an end" in themselves by ensuring cost transparency, thereby promoting patients' autonomy and collaboration with their clinicians.¹³

One area of health care in which price disclosure is commonplace, highly efficient, and upholds the individual's moral agency is dentistry. Dentists are often heavily constrained by insurance policies with varying levels of reimbursement and significant out-of-pocket expenses for the patient. Knowing that patients will have high expenses, dentists often provide patients with a summary of recommended procedures, triaged as to importance, and priced out for the patient's review.

Operational (Normative) Concerns

Billing. Surprise billing and billing for services that the patient believes are substandard generally lead to grievances, which are often the risk manager's first indications that a larger problem may exist (eg, quality of care concerns, patient injury, or interpersonal issues with the clinician or other staff). Risk managers walk a fine line between maintaining the institution's financial best interest and managing the patient's response to being blindsided by a surprise bill. Surprise billing has significant negative impacts on patient satisfaction (including by reducing patients' trust in the physician and institution); increases the risk of litigation and frivolous suits; consumes the time of the risk manager and staff; and increases conflict between clinicians, institutions, and patients. Effective transparency mitigates these concerns and time wasters.

Litigation risks. Patients who are harmed by or who are generally dissatisfied with care may not consider filing a lawsuit until they receive a bill for services they believe are substandard. This event might trigger distrust and rage in some people, leading to the first call to an attorney. Upstream actions, such as price transparency and discussing costs during informed consent deliberations, can avert litigation costs and the anxiety associated with them.

Safety risks. Patients with bills in collections for service they perceive as poor or for amounts they consider unreasonable can increase the risk of workplace harassment and violence. Workplace violence consists of both physical violence or threats and harassing or stalking behaviors. High concentrations of poverty and areas in which diminished economic opportunities exist are leading social and economic risk factors for type 2 (client-on-worker) workplace violence, per the Centers for Disease Control and Prevention classification.¹⁴ Workplace violence has become a national epidemic and a significant cause of employment and vocational dissatisfaction.¹⁵ For physicians and staff, violent behaviors consume time and energy, are morally distressing, and are potentially dangerous. Establishing clear billing expectations and having risk mitigation plans for when something unexpected occurs during treatment can decrease the risks of both litigation and workplace violence.

Limitations on Cost Transparency

I propose 2 specific reasons why risk managers may not see cost transparency as a social justice issue warranting their engagement. The first concerns the institutional burdens that it creates, and the second concerns the circumstances in which it is not feasible to get price consent prior to treatment.

Institutional burdens. Although transparency with patients regarding costs would preserve patients' autonomy and reduce their stress, it does present another unfunded burden with operational constrictions. Performing this function would involve either using clinical team members (ie, physicians, nurses, or other medical professionals), which would not be a good use of their time, or having nonclinical staff well trained in insurance complement the informed consent discussion provided by the physician, which, in adding a new administrative layer, would increase an already bloated system. However, cost transparency could potentially reduce administrative costs related to billing grievances, potential litigation, and safety risks.

Emergency services and competency. There will be times when transparency is not realistic or safe. The Emergency Medical Treatment and Labor Act (EMTALA) requires medical screening and emergent stabilization without consideration of ability to pay in emergency room settings,¹⁶ and there is a perceived ethical duty to rescue when a person's life is imminently threatened.¹⁷ However, the duty to treat does not alleviate the duty to be fair in pricing and explain existing costs when it is reasonable to do so.

Conclusion

It is incumbent upon the health care system to take the morally defensible position of ensuring fairness and equity for all stakeholders. Risk managers should advocate for transparency in pricing not only because ethics is an aspect of risk managers' daily work but also because transparency promotes personal liberty and fairness in society. Transparency is a means for the risk manager to advocate for patient autonomy and choice, encourage beneficent treatment and shared decision making, avoid harm from crippling debt and **unnecessary treatment or service**, and promote the general welfare. It also serves the secondary interests of improved patient satisfaction, increased patient trust in the institution and physician, improved patient relationships with clinicians, and reduced conflicts resulting from surprise billing.

Commentary 2: Peer-Reviewed Article

by Stephen L. Newman, MD

This case is familiar to clinicians, health care executives, payers, and many patients and their parents. The "balance after" is the amount a financially responsible party (EJ's family, in this case) owes after their insurance company pays its negotiated rate. For an 8-day, in-network hospitalization surgery, EJ's family owed \$190 000; some individuals have been known to receive a \$117 000 bill for surgical services provided at their local hospital, due to the assistant surgeon being out of network.¹⁸ This article explains why pricing variations occur and considers hospital risk managers' responsibilities to serve both patients and organizations.

Chargemaster Manipulation

Variations in hospital inpatient and outpatient pricing schedules are the result of chargemaster manipulations that have occurred since Medicare adopted, in 1983, the

Diagnosis Related Groups (DRGs) system for bundling payments for diagnosis-specific services.¹⁹ A **chargemaster** is a hospital-specific database of billable services and supplies used to itemize procedure-specific charges that are aggregated in bills sent to patients and insurers, although the amounts actually paid by patients and insurers are less. In response to increasing government regulation of payments through Medicare and Medicaid, hospitals inflate chargemaster prices to optimize reimbursement from these government programs. Such manipulations are also used in the commercial insurance sector, as insurers tend to adopt regulatory and payment practices first used in government payment systems. For example, a hospital that performs many orthopedic procedures but few cardiac procedures would disproportionately raise prices on orthopedic care items. Conversely, a hospital that performs many cardiac procedures but few orthopedic procedures would disproportionately raise prices on cardiac care items. Chargemaster manipulation explains why there is so much variation—and sometimes unexplained and ridiculously large variation—in prices of hospital inpatient and outpatient services among organizations that can be located in the same region.

Risk Managers' Responsibilities

Unsurprisingly, some hospital business practices are designed to optimize revenue, so let's turn now to hospital risk managers' duties in cases of surprise billing. A risk manager has a duty to serve his or her organization (shareholders, in this case), clinicians, external parties (for example, attorneys, payers, and regulators), and patients and their loved ones; the services a risk manager provides to each of these stakeholders might be different.

Responsibilities to patients. The American Society for Health Care Risk Management (ASHRM) lists several duties a hospital risk manager has to patients and families²⁰ that apply to the above case. First, a "health care risk manager has a responsibility to practice the profession with honesty, fairness, integrity, respect and good faith" and, second, "to help promote the overall quality of life, dignity, safety, and wellbeing of every individual needing healthcare services."²⁰ ASHRM also states that it is a risk manager's duty to "Communicate honestly and factually with patients and their families, as well as colleagues and others."²⁰

Of course, hospital risk managers do not typically interact with each patient in a hospital. However, in cases like this one, interaction is certainly appropriate and advisable, since a "balance after" bill of \$190 000 would very likely be an unpleasant surprise that could lead to litigation.²¹ Specifically, in this case, a risk manager, along with a patient financial services staff member, could have an adjunctive role in discussing surprise billing with EJ's parents; this role would include offering financial education and support and acting as a liaison to help EJ's parents interpret technical financial language.

Responsibility to an organization. A hospital's direct and indirect costs for delivering health care services performed by clinicians is confidential, but what a hospital charges payers and other financial guarantors is public. This distinction is important in the discussion of risk managers' roles and responsibilities, since risk managers are uniquely positioned to help organizations mitigate litigation risk that can be generated by surprise billing. Specifically, risk managers can advocate for up-front hospital inpatient and outpatient pricing transparency, such that financially responsible parties are informed about their copayment or coinsurance obligations before a hospital admission or before a health care service is rendered rather than after discharge, as occurred in EJ's case.

Distinguishing Financial Risk From Health Risk

The family's out-of-pocket financial responsibility is distinct from what a hospital charges, which is public information, and some have argued that, to motivate transparency, the coverage rates hospitals negotiate with insurers should also be public. Others have suggested that pricing transparency should be part of informed consent processes. Although risks and benefits are intended to be communicated during informed consent, financial risks differ importantly from health risks. Health risks should be conveyed and clarified by a clinician, and financial risk should be conveyed and clarified by a financial counselor, perhaps with a risk manager. If up-front disclosure of financial burden to patients and their families were adopted by an organization, a good risk manager could try to serve all constituents without compromising the protection of any constituent.

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Josh Charles Hyatt, DHSc, MHL, MBE(c) has more than 25 years of health care experience as a clinical risk manager, bioethicist, executive health care leader, and professor. He is currently employed at Coverys as a risk management systems manager and at Massachusetts College of Pharmacy and Health Sciences as an adjunct professor. His academic and professional interests include relationships between health law and medical ethics, moral distress, professionalism and its impact on patient safety, social media and its impact on the practice of health care, and LGBT health care.

Stephen L. Newman, MD, MBA is the executive chair and chief medical officer of CentraForce Health in Dallas, Texas. Previously, Newman served in several senior leadership positions at hospitals and health systems, including as vice-chairman and chief operating officer of Tenet Healthcare. He also served as an associate professor of

pediatrics and medicine at Wright State University School of Medicine and simultaneously as the chair of the Department of Gastroenterology and Nutritional Support at Children's Medical Center in Dayton, Ohio. In addition, he studied metabolic liver disease as a National Institutes of Health investigator, served on the board of directors at numerous institutions, and served as vice-chair of the Juvenile Diabetes Research Foundation.

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HEALTH LAW: PEER-REVIEWED ARTICLE

How Hospital Leaders and Risk Managers Can Nurture Ethics-Driven Lawyering

Norine A. McGrath, MD, Evan G. DeRenzo, PhD, John K. Kilcullen, MD, JD, MPH, and Jack Schwartz, JD

Abstract

How hospital lawyers assess legal risk in clinically and ethically complex cases can shape risk management operations, influence clinicians' morale, and affect the care patients receive. This article suggests that many disagreements, particularly those involving key ethical and legal questions arising from a patient's care, should launch a process that might include family meetings, early palliative care integration, and ethics consultation or committee review of clinical teams' and surrogates' reasons and perspectives. This article also explains why exploration of these perspectives can motivate fuller understanding of the sources of clinical and ethical disagreements and inform the approach to legal advice that hospital executives and risk managers should foster.

To claim one AMA PRA Category 1 Credit™ for the CME activity associated with this article, you must do the following: (1) read this article in its entirety, (2) answer at least 80 percent of the quiz questions correctly, and (3) complete an evaluation. The quiz, evaluation, and form for claiming AMA PRA Category 1 Credit™ are available through the [AMA Ed Hub™](#).

Legal Support for Ethics Processes

Suppose a patient on mechanical ventilation in an intensive care unit (ICU) is dying of widely metastatic cancer. The treating team believes that the patient's best interest would be served by compassionate extubation and comfort care. But suppose a surrogate is requesting, or perhaps demanding, that "everything be done" and that mechanical ventilation be continued.

This disagreement should be the beginning of a process, not the end of it. Through family meetings, early palliative care involvement, ethics consultation, and ethics committee review, a treating team's and surrogate's rationales can be fully understood and assessed against pertinent ethical norms and clinical realities. At some point in this process, however, a physician worried about the family's threat to get a lawyer if its demands are not met might call the hospital's legal counsel. What happens when clinical and ethical questions about a patient's best interests become focused instead on legal questions about risk mitigation?

This article addresses the impact of hospital-based legal counseling practices and how these practices shape risk management operations, influence clinician morale, and help resolve disputes about patient care. Legal counsel either can support ethics-driven approaches to conflict resolution or, if its view of risk assessment is too narrow, will likely frustrate an organization's ethics processes and procedures by taking ethically laden clinical decisions out of the purview of clinicians and the ethics committee. In this article, we call for lawyers giving advice in these conflict situations to be mindful of the hospital client's commitment to ethically sound clinical decision making and for senior executives, who speak for the client, to ensure that risk-related advice supports this commitment.

Critical Care Ethics

Every experienced clinician in emergency or critical care medicine is likely to have encountered troubling situations involving seriously ill patients unable to decide important issues directly. These situations include uncertainty about goals of care, given a lack of guidance from the patient; ambiguous provisions in an advance directive if such exists; disagreements among surrogate decision makers, including contention over who is entitled to speak for the patient; and disputes between surrogate decision makers and clinicians over the value of a life-extending intervention for a patient. These cases play out within both a legal and an ethical framework. Every state has some type of law that addresses **decision making for incapacitated patients**, although there is considerable heterogeneity.¹ Decision making for incapacitated patients invokes ethical principles, such as respect for autonomy and beneficence, as well as reflection on what counts as virtuous action under the circumstances.² Ever since the litigation over Karen Ann Quinlan's ventilator more than 40 years ago, the law and ethics of end-of-life care have been intertwined.³

These situations will likely be complex and emotional, often involving surrogate requests for the initiation or continuation of interventions when the clinicians believe that the patient is beyond rescue. Discordant perceptions have many causes.⁴ The surrogate might recount past situations in which other clinicians had said the patient was dying but then the patient recovered, so they no longer trust predictions of imminent death. Similarly, a surrogate may mistakenly believe that the patient's condition is virtually identical to that of another family member who recovered. Or the surrogate might believe the patient will recover based on signs of improvement that family members see when they interact with the patient but that the treating team never sees. Or perhaps a surrogate, such as a spouse in a decades-long marriage, is just so anxious at the thought of losing a life partner that emotion blocks the ability to process the information. Not infrequently, surrogates invoke the possibility of a miracle. Sometimes, out of fear of and frustration at the medical team's broaching of the idea of shifting to comfort measures only, a family member threatens to take everyone to court.

Legal Risk Advice

Addressing these situations effectively requires empathetic physicians who can listen to the surrogate's story, can **identify the ethical values at stake**, and are courageous enough to keep working through these complex dynamics with the family. This kind of process will only occur if the hospital's leadership has made it the ethical default for everyone in the hospital, including hospital counsel. Consider the introductory case of the dying ICU patient. The initial disagreement over the goals of care should be channeled into an ethics-oriented dispute resolution process that respects both the family's standing and the physicians' medical judgment. One robust template for this

process is discussed below. A danger, however, is that advice about legal risk might come so early and be so emphatic as to block the unfolding of this process.

It has long been recognized that a lawyer's participation in such emotionally fraught cases, particularly if they go to a hospital's ethics committee, risks directing the committee's attention to legal issues instead of ethical ones.⁵ A situation like the surrogate's disagreement with the ICU physicians involves several aspects of law: state laws that address decision making for incapacitated patients, which usually rank-order potential surrogates and standards for decision making, especially for decisions about life-sustaining treatments⁴; substantive and procedural law on hospital and clinician tort liability; and the licensing and regulatory regimes entailing standards, inspections, and grounds for professional discipline. Clinicians usually do not have an accurate and detailed understanding of the law.⁶ Hence, they must rely on the hospital lawyer's advice.

If the lawyer's advice to the attending physician or to the hospital ethics committee is blunt and unreflective—for instance, if it's that the surrogate has statutory authority to decide on treatment issues and that acquiescing to the surrogate's request would avoid the risk of a lawsuit—it is predictable that the treating team will retreat from advocating for the patient's best interest. Apart from the fear of liability, physicians dread the loss of time and other burdens they would face if they became enmeshed in legal proceedings.^{7,8} It is difficult to maintain an in-depth discussion of whether a treatment might be ethically inappropriate if clinicians focus instead on ominous legal advice. The experience of one bioethicist-lawyer is pertinent: "Once my audience thought I knew something about the law, the ethics discussion became completely short-circuited—everyone just wanted to know what the law required."⁹

If legal advice effectively forecloses discussion of the ethics of critical care, especially if such supplanting of ethics is seen as endorsed by the institution itself, clinicians' experience of moral distress is a likely outcome.¹⁰ Moral distress results when clinicians recognize the ethical dimensions of a situation and yet are prevented from acting on all the interests and values at stake.¹¹ Hospitals have a strong interest in reducing clinicians' moral distress, given its impact on quality practice, patient safety, and retention of skilled professionals.^{12,13}

A lawyer-driven outcome inconsistent with ethically sound medicine deserves its own term of reproach: *nomicogenic harm* (from *nomikos* (lawyer) and *genic* (arising from)). Excellence in hospital lawyering avoids nomicogenic harm. Hospital lawyers and risk managers can play a crucial role in maintaining ethics-based practice. Indeed, following an ethically sound process itself reduces risk of litigation, because it manifests the hospital's commitment to procedural fairness and avoidance of ad hoc decision making.

In the case of the cancer patient dying in the ICU, for example, the lawyer might advise that discontinuing mechanical ventilation in a patient with widely metastatic cancer in order to maximize comfort is well within standard of care; that the surrogate's authority is not unfettered and must be exercised within the legal standards of surrogate decision making, which parallel ethical criteria; and that, consequently, the overall litigation or regulatory risk of discontinuing mechanical ventilation is low. Legal advice of this kind reflects ethically attentive lawyering and preserves ethical discourse.

The 5-Society Statement Model

A **conflict resolution process** in which all ethically relevant considerations can be discussed and an ethically optimal decision reached is required for Joint Commission accreditation for hospitals.¹⁴ However, the Joint Commission requirement is quite general and does not elaborate on the details of the process. One ethically sound conflict-resolution process is a multisociety policy statement formally adopted in 2015 by 5 professional societies (the American Thoracic Society, the American Association for Critical Care Nurses, the American College of Chest Physicians, the European Society for Intensive Care Medicine, and the Society of Critical Care Medicine).¹⁵ The 5-society statement recommends specific steps that should be followed when clinicians are asked for treatments that they believe should not be administered. These are “treatments that have at least some chance of accomplishing the effect sought”—and hence are not physiologically futile—“but clinicians believe that competing ethical considerations justify not providing them.”¹⁵ Although the policy statement is broad enough to encompass situations in which the patient would have an extended life expectancy if the treatment were administered (eg, initiating dialysis in a patient in a persistent vegetative state), most cases will involve critical care patients in the last stage of life (eg, continuing mechanical ventilation in a patient with widely metastatic cancer).

The policy statement recognizes that many disputes in critical care medicine involve contested value judgments about what is appropriate treatment. The policy statement urges hospitals to implement proactive strategies to prevent discordant views from hardening into intractable conflicts, which might occur if a surrogate decision maker requests a treatment that is potentially inappropriate.¹⁵ Proactive communication consists of well-conducted family meetings focusing on the alignment of treatment options with the patient’s goals. The policy statement lays out an ethically sound, 7-step process for resolving seemingly intractable disagreements that can arise toward the end of a patient’s life.

The policy statement emphasizes early involvement of expert consultants (often palliative care, ethics, or both) who are particularly skilled in conflict resolution before conflicting positions become entrenched (Step 1).¹⁵ The policy statement envisions an advocacy role for physicians when a surrogate insists on treatments that the physicians believe would not benefit the patient. At family meetings, physicians should share their perspective and respectfully advocate for a better alternative. The physicians should attempt to explain to—and perhaps to convince—a surrogate that the patient is dying, that all that could have been done to change that inevitable outcome has been done, and that it is time to shift from attempting life-extending interventions to comfort measures only.

Should the disagreement over the appropriateness of a treatment persist after redoubled efforts to achieve a negotiated agreement, the policy statement lays out a sequence of conflict resolution steps: giving notice to the surrogate of the process to be initiated (Step 2); getting a second medical opinion (Step 3); having an interdisciplinary hospital committee review the case, with an opportunity for clinician and surrogate to explain their positions (Step 4); offering the surrogate assistance in arranging a transfer to another institution if the committee agrees that the requested treatment is inappropriate (Step 5); informing the surrogate of the option to seek review in court (Step 6); and, finally, assuming neither transfer nor a court order, withholding or withdrawing the inappropriate treatment (Step 7).¹⁵

This consensus-based policy statement reflects a commendable effort to outline a fair process for dispute resolution in critical care. Although we are unaware of data on the number of hospitals that have adopted these recommendations in policy or practice, we hope that an increasing number will do so. The recommended process cannot succeed, however, unless it functions within a supportive context.

Ethically Attentive Lawyering

Hospital leadership and hospital lawyers are rightly concerned about legal risk; the average cost of a closed claim originating in the intensive care unit, for example, is \$350 039.¹⁶ Ethically attentive legal advice, however, does not ignore risk but instead realistically appraises it. If, in the lawyer's reasoned judgment, an ethically permissible course entails a significant liability risk, the lawyer needs to explain the nature of the risk. Conversely, if under the circumstances the risk of litigation is low (albeit not zero) and the risk of liability even lower, the legal advisor should say that.

To be avoided is legal advice given with tunnel vision: identifying only one pathway deemed by the lawyer to minimize risk, without leaving room for alternatives or considering the impact of the advice on physicians' willingness to advocate for what they see as the best interest of their patients. The 5-society statement sets out a dispute-resolution process in which the ethical concerns of both surrogates and physicians can be heard. That process will not be invoked, however, if preemptive legal advice amounts to an imperative simply to yield to surrogate demands. Instead, legal advice needs to underscore the hospital's commitment both to supporting physicians who practice excellent patient-centered medicine and to a robust process, like the 5-society statement, for addressing ethical concerns.

In summary, the hospital's legal counsel should execute its functions with ethical perceptiveness. Lawyers should consciously give legal advice that leaves as much room for the work of ethics as possible. This is not a departure from good lawyering but an embodiment of it. Legal counseling should attend to the client's interests in a broad sense, including "moral" factors.¹⁷ Furthermore, hospital leadership should make clear that, given an institutional commitment to ethically sound medicine, this is the kind of lawyering it expects.

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Norine A. McGrath, MD is an emergency medicine physician who is the director of the John J. Lynch, MD Center for Ethics at MedStar Washington Hospital Center and an assistant professor at Georgetown University School of Medicine in Washington, DC.

Evan G. DeRenzo, PhD is the assistant director of the John J. Lynch, MD Center for Ethics at MedStar Washington Hospital Center in Washington, DC. She teaches, writes, and practices clinical ethics and publishes on clinical and clinical research ethics.

John K. Kilcullen, MD, JD, MPH is a former civil rights lawyer who works as a critical care physician at a tertiary hospital in the Washington, DC area.

Jack Schwartz, JD is an adjunct law professor at the University of Maryland Francis King Carey School of Law in Baltimore. He is a member of ethics committees at MedStar

Washington Hospital Center in Washington, DC, and Holy Cross Hospital in Silver Spring, Maryland.

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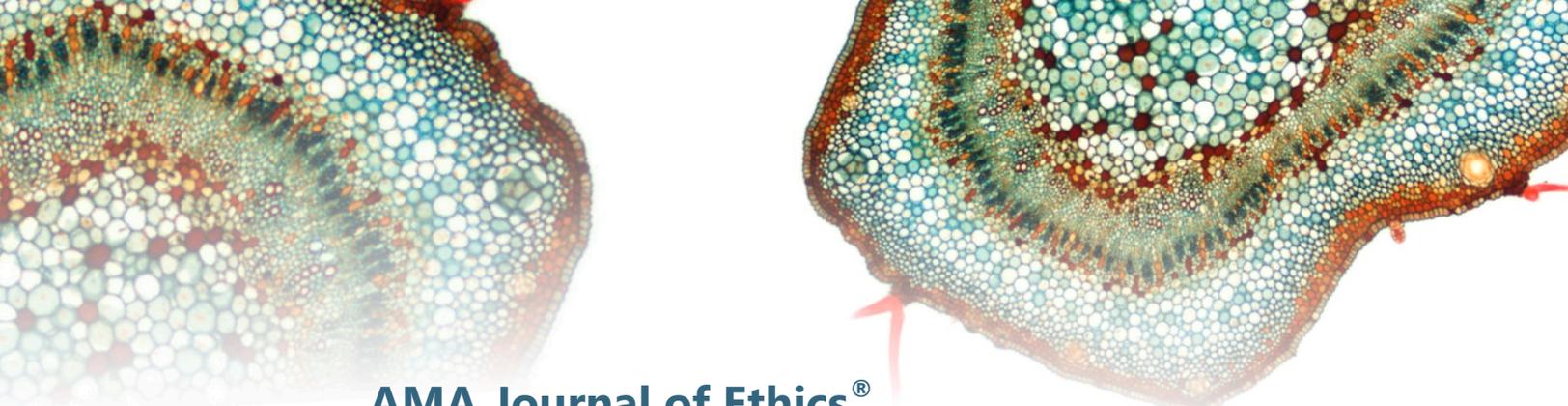
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AMA CODE SAYS

AMA Code of Medical Ethics' Opinions Related to Risk Management Ethics

Scott J. Schweikart, JD, MBE and Deborah M. Eng, MS, MA

Abstract

The *AMA Code of Medical Ethics* offers guidance on ethical issues pertaining to risks involving patient discharge, which provides an example of how the *Code* might pertain to issues in risk management. This article presents one example case regarding patient discharge and how the *Code* might be applied in such a scenario to help guide physicians in ethically discharging a patient while also managing associated risks.

Introduction

Risk management in health care “comprises the clinical and administrative systems, processes, and reports employed to detect, monitor, assess, mitigate, and prevent risks.”¹ Health care risk management functions to both reactively and proactively “safeguard patient safety” while also helping to protect health care organizations’ value.¹ The American Medical Association (AMA) *Code of Medical Ethics* does not speak specifically to the ethics of risk management; however, when the facts of a medical case involving risk management are considered, certain opinions of the *Code* become relevant and can provide guidance. One such example is a risk management case regarding patient discharge from a hospital. Here, the *Code* can guide physicians on how to address ethical issues that might arise when they plan a patient’s discharge. For example, discharge of patients with cognitive or physical disabilities often requires physicians to weigh ethical issues (eg, respect for patient autonomy, beneficence, nonmaleficence) against potential legal risks to the institution and to themselves.

Managing Risk During Discharge Planning

Case and Commentary 2 of this theme issue considers a 32-year-old man hospitalized with complications of end-stage multiple sclerosis who develops severe respiratory distress while in the intensive care unit. The patient repeatedly resists intubation through his body language, but his electronic health record (EHR) contains no advance directive. The pulmonologist believes the respiratory crisis is temporary and that remission is likely. She determines that the patient lacks decision-making capacity at this time and consults his parents. After obtaining their agreement, the medical team intubates the patient and begins mechanical ventilation. After 80 days, the patient’s condition stabilizes enough for him to be weaned from the ventilator. Soon afterward,

the patient covers his tracheostomy tube and states, “I don’t want any more machines and I don’t want any more treatment. I want to go home, and I want to be by myself.”

The patient’s mother and sister agree to add orders to the EHR to limit future life-sustaining treatment. However, the patient’s father insists on implementing all resuscitative measures if his condition worsens again. The pulmonologist explains that the son “has decision-making capacity now, and he understands the risks of going home, so it’s reasonable for us to explore discharge planning at this time.” However, the father becomes angry and threatens to sue the physician and the hospital if something happens to his son. The care team consults the hospital’s risk manager, who advises that “[e]ven with full assessment of his home environment, his deteriorating condition makes anywhere he’s alone unsafe. Allowing him to exercise his right to self-determination is just too risky for us in this case.” The risk manager recommends that the patient be discharged to a skilled nursing facility. Members of the medical team wonder what to do next.

Relevant *Code* Opinions

There are several *Code* opinions that offer relevant guidance in this case. First, and most directly relevant, is Opinion 1.1.8, “Physician Responsibilities for Safe Patient Discharge,” which states: “Physicians’ primary ethical obligation to promote the well-being of individual patients encompasses an obligation to collaborate in a discharge plan that is safe for the patient” and “physicians should resist any discharge requests that are likely to compromise a patient’s safety.”² In order to carry out this obligation to **safely discharge**, Opinion 1.1.8 states that physicians should:

- (1) Determine that the patient is medically stable and ready for discharge from the treating facility; and
- (2) Collaborate with those health care professionals and others who can facilitate a patient discharge to establish that a plan is in place for medically needed care that considers the patient’s particular needs and preferences.²

Applied to the case, the *Code* makes clear that the physician has a duty to ensure the patient’s safety when discharging and, in this case, that duty might require a plan that involves a safer option than home discharge—such as discharge to a skilled nursing facility—even though this option might be contrary to, and in tension with, the patient’s current wishes.

Also relevant are *Code* opinions regarding ascertaining and respecting a patient’s needs and preferences. Opinion 1.1.3, “Patient Rights,” states that “[a] patient who has decision-making capacity might accept or refuse any recommended medical intervention.”³ And Opinion 2.1.2, “Decisions for Adult Patients Who Lack Capacity,” advises that “[r]espect for patient autonomy is central to professional ethics and physicians should involve patients in health care decisions commensurate with the patient’s decision-making capacity” and that “[p]hysicians should engage patients whose capacity is impaired in decisions involving their own care to the greatest extent possible, including when the patient has previously designated a surrogate to make decisions on his or her behalf.”⁴ Applied to the case example, both opinions are key in that the patient had, at different points, **capacity and a lack of capacity**, and in both instances it is ethically important to understand and respect the desires of the patient—expressed either directly by the patient when he has capacity or by the patient’s surrogate when he lacks capacity—when making any medical decisions, such as about patient discharge.

Also relevant to patient autonomy regarding decisions about discharge is the *Code's* discussion of ethically and emotionally challenging decisions regarding **advance care planning**. Opinion 5.1, "Advance Care Planning," explains:

Planning in advance for decisions about care in the event of a life-threatening illness or injury gives individuals the opportunity to reflect on and express the values they want to have govern their care, to articulate the factors that are important to them for quality of life, and to make clear any preferences they have with respect to specific interventions.⁵

Opinion 5.1 makes clear that physicians should understand that "patients and families approach decision making in many different ways, informed by culture, faith traditions, and life experience, and should be sensitive to each patient's individual situations and preferences when broaching discussion of planning for care at the end of life."⁵ Advance care planning is acutely relevant to the case example, as the patient is at the end of life and planning the governance of his future care—including where and how he is discharged from the hospital—when it is critically important to uphold the patient's autonomy and self-determination; thoughtful planning must reflect the patient's goals. The *Code* recommends that physicians "encourage all patients" to consider "their values and perspectives on quality of life and articulate what goals they would have for care if they faced a life-threatening illness."⁵ In the current case, such a dialogue with the patient about his goals and values would help him better ascertain whether discharge to a skilled nursing facility truly reflects his values, thus upholding his autonomy.

Lastly, the *Code's* guidance on life-sustaining treatments has relevance for scenarios, as in the case example, in which patients resist discharge to a skilled nursing facility. Opinion 5.3, "Withholding or Withdrawing Life-Sustaining Treatment" reminds physicians that "a patient who has decision-making capacity appropriate to the decision at hand has the right to decline any medical intervention or ask that an intervention be stopped, even when that decision is expected to lead to his or her death and regardless of whether or not the individual is terminally ill," and that "[p]hysicians should elicit patient goals of care and preferences regarding life-sustaining interventions early in the course of care, including the patient's surrogate in that discussion whenever possible."⁶ In the case example, the patient, when he regains capacity, decides to decline life-sustaining treatment. If, after the physician has elicited the patient's goals and values and explained how nursing care might meet some of those goals, the patient still resists discharge to a skilled nursing facility, then the patient's decision to **decline life-sustaining treatment** must be ethically respected, although it is in tension with the wishes of his father and increases the safety risks involved with hospital discharge. The physician must find a balance—possibly with the help of an ethics committee—that at some level respects the patient's right to refuse life-sustaining treatment while also managing his discharge at an acceptable level of risk.

Conclusion

While the *Code* does not speak to risk management specifically, it certainly offers guidance regarding management of risk in the course of clinical care. In particular, the case example of patient discharge demonstrates the relevance of the *Code* to ethical issues of patient safety, patient autonomy (whether the patient has decision-making capacity), advance care planning, and the withholding or withdrawing of life-sustaining treatment. When physicians and hospital risk managers make decisions about discharging a patient, they must account not only for the risk assessment regarding discharge but also the ethical issues at hand. Tensions and disagreements—as in the case, where the patient wants to go home rather than to a skilled nursing facility—might

be inevitable. If disagreement persists over the risks and benefits of a particular treatment or discharge plan, physicians should consult the hospital ethics committee and other institutional resources,^{2,4} which might be able to offer additional perspectives relevant to patient-centered care. This input could help support physicians in making ethically justifiable decisions regarding discharge that lower the risks of patient harm to acceptable levels.

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Scott J. Schweikart, JD, MBE is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago, Illinois, where he is also the legal editor for the *AMA Journal of Ethics*. Previously, he worked as an attorney editor and reference attorney at Thomson Reuters and practiced law in Chicago. Mr Schweikart earned his MBE from the University of Pennsylvania, his JD from Case Western Reserve University, and his BA from Washington University in St Louis. He has research interests in health law, health policy, and bioethics.

Deborah M. Eng, MS, MA is a consultant medical writer and editor who currently writes regulatory documentation and scientific publications and served as a bioethics intern in the American Medical Association Ethics Group. She earned a master of science degree in biology and a master of arts degree in bioethics and health policy. Her recent interests include research ethics, ethical decision making, and the influence of social and psychological factors on moral behavior.

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STATE OF THE ART AND SCIENCE: PEER-REVIEWED ARTICLE

How Might Artificial Intelligence Applications Impact Risk Management?

John Banja, PhD

Abstract

Artificial intelligence (AI) applications have attracted considerable ethical attention for good reasons. Although AI models might advance human welfare in unprecedented ways, progress will not occur without substantial risks. This article considers 3 such risks: system malfunctions, privacy protections, and consent to data repurposing. To meet these challenges, traditional risk managers will likely need to collaborate intensively with computer scientists, bioinformaticists, information technologists, and data privacy and security experts. This essay will speculate on the degree to which these AI risks might be embraced or dismissed by risk management. In any event, it seems that integration of AI models into health care operations will almost certainly introduce, if not new forms of risk, then a dramatically heightened magnitude of risk that will have to be managed.

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AI Risks in Health Care

Artificial intelligence (AI) applications in health care have attracted enormous attention as well as immense public and private sector investment in the last few years.¹ The anticipation is that AI technologies will dramatically alter—perhaps overhaul—health care practices and delivery. At the very least, hospitals and clinics will likely begin importing numerous AI models, especially “deep learning” varieties that draw on aggregate data, over the next decade.²

A great deal of the ethics literature on AI has recently focused on the accuracy and fairness of algorithms, worries over privacy and confidentiality, “black box” decisional unexplainability, concerns over “big data” on which deep learning AI models depend, AI literacy, and the like.^{3,4} Although some of these risks, such as security breaches of medical records, have been around for some time, their materialization in AI applications will likely present large-scale **privacy and confidentiality risks**. AI models have already posed enormous challenges to hospitals and facilities by way of

cyberattacks on protected health information, and they will introduce new ethical obligations for providers who might wish to share patient data or sell it to others.⁵ Because AI models are themselves dependent on hardware, software, algorithmic development and accuracy, **implementation**, data sharing and storage, continuous upgrading, and the like, risk management will find itself confronted with a new panoply of liability risks. On the one hand, risk management can choose to address these new risks by developing mitigation strategies. On the other hand, because these AI risks present a novel landscape of risk that might be quite unfamiliar, risk management might choose to leave certain of those challenges to others. This essay will discuss this “approach-avoidance” possibility in connection with 3 categories of risk—system malfunctions, privacy breaches, and consent to data repurposing—and conclude with some speculations on how those decisions might play out.

System Malfunctions

Every human performance specialist knows that the introduction of a novel, powerful, and complex technology into an already complex and dynamic workspace presents a ripe opportunity for errors and system breakdowns.⁶ It is bad enough when computerized systems go down in health care facilities. AI-involved crashes or malfunctions might prove much worse. AI forecasters predict that clinicians will eventually come to rely heavily on AI applications, which, over time, will likely become thickly integrated with coding, billing, medical records, scheduling, contracting, medication ordering, and administrative functions.⁷ It is easy to imagine how a breakdown or virus affecting any one element of an AI chain could wreak havoc with the entire system.⁸ For example, if AI models ultimately come to schedule patients, interpret laboratory specimens or radiographs, generate a report to the referring entity, and send a bill to the insurer, then a malfunction at any point in this continuum could result in a high volume of errors and adverse events. One is reminded of the 2010 article by Dudzinski and colleagues that examined single-point failures—such as infection control lapses, malfunctioning disinfection technology, laboratory errors, and incompetent clinicians—that went on to affect thousands of patients.⁹ Within the past few years, one such single-point failure—weaknesses and vulnerabilities in data storage programs—enabled hackers access to health records, resulting in ransomware crimes and identity theft that affected millions of patients.¹⁰

Clinicians have only to reflect on their day-to-day experience with information technology and its frequent breakdowns—eg, disabled access to servers, computerized systems that freeze up, programs that are hard to navigate or easy to misuse, malware attacks—to appreciate how vulnerable workflow (and the liabilities that attach to it) could become to AI malfunctions. Moreover, none of these technologies and their related operations will remain static. Given the need for constant upgrading, the potential for new system failures is always present, frequently unpredictable, and sometimes impossible to prevent.

Privacy

While a recurrent problem for health care facilities has been their failure to protect massive data repositories from cyber predators, another risk-laden problem has involved hospitals and clinics simply **sharing their data** with other health care entities or uploading their data onto publicly accessible servers. Reports in the *Washington Post* and other media have described how Google partnerships for the purpose of training AI algorithms inadvertently resulted in some data with protected health information being uploaded in ways that exposed the data to anyone with basic search engine

capability.^{11,12} Data used for research purposes must be appropriately de-identified or scrubbed of various items that can identify the subjects.¹³ But, in certain instances, personnel have either failed to remove items that identified subjects—in one of the Google partnerships, by failing to notice x-ray images that showed patients' jewelry¹¹—or exposed patients' identities by failing to delete common identifiers like treatment dates or doctors' notes¹² or social security numbers or addresses.

The kind of big data use that is typical of AI exponentially heightens the risk of data exposure. In 2020, Zack Whittaker reported that hundreds of hospitals, medical offices, and imaging centers were found to have insecure storage systems that allowed “anyone with an internet connection and free-to-download software to access over 1 billion medical images of patients across the world.”¹⁴ In 2019, a diagnostic medical imaging services company paid \$300 million to the Office for Civil Rights to settle a data breach suit that exposed over 300 000 patients' protected health information.¹⁵ Certain US hospitals and imaging centers perpetrated some of the most notorious breaches, which can make patients, in Dirk Schrader's words, “perfect victims for medical insurance fraud.”¹⁴

Consent to Data Repurposing

Even if data are properly de-identified and protected from privacy intrusions, securing patients' informed consent for the use or reuse of their data can be ethically challenging. Typically, patients consent to their data being used upon admission, such as for their treatments and hospital operations like billing and insurance, or for public health (as well as public security or law enforcement) programs, as permitted under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).¹⁶ But beyond those uses—especially for **research purposes**—additional and explicit consent is required.¹³ Once patients consent to their deidentified data being used for purposes beyond those specified in the HIPAA regulations, however, HIPAA regulations no longer apply because HIPAA doesn't recognize deidentified patient information as protected.¹⁷ As such, health care facilities can use that data however they want, including sharing it or selling it to data brokers or companies in the private sector.^{13,18}

It is well recognized, however, that when deidentified data are coupled with other data streams, especially social media, it becomes easier to reidentify individuals and then classify them according to whatever an interested party's wishes are.¹⁹ For example, multiple data sets have been compiled that identify individuals who might be considerably harmed from identity exposure—eg, lists of rape victims or persons afflicted with genetic or neuropsychiatric illnesses, substance use disorders, or erectile dysfunction.²⁰ The moral question then becomes whether health care facilities should engage in sharing or selling data in light of these privacy concerns because, once a facility does so, it cannot control how that data will be subsequently repurposed unless there are explicit and agreed-upon use limitations.

A variation of this problem that affects risk management more directly involves sharing or selling data with personally identifying information without patient consent. At least 2 university health care systems have been sued for failing to inform patients that their records might be shared with or sold to the private sector when the shared data involved personally identifying information.¹² In 2013, the US Department of Health and Human Services filed a protective objection in Delaware bankruptcy court, arguing that health care facilities facing bankruptcy cannot sell their patient data for debt relief without explicit patient consent.²¹

Consequently, an interesting and evolving legal problem these cases present is how exacting must the language of patient consent be to allow a facility to use *even deidentified health data*? The federal government recently imposed a requirement for researchers participating in the 1000 Genomes Project to obtain informed consent for the use of deidentified data. Researchers would have to pledge that data would only be used for the approved research; there would be no attempt to (re)identify individual participants; and data obtained from National Institutes of Health data repositories would not be sold, nor would the data be shared with anyone other than authorized persons.²² Similarly, the California Consumer Privacy Act now requires businesses that collect consumer information to tell consumers how their data will be used and to inform them upon request with whom the data might be shared. Consumers also have the right to refuse to have their data sold.²³ Examples like these signal changing public attitudes toward the privacy of online data that will surely give health facilities pause. The question with which this essay will conclude is the extent to which risk management might find itself charged with managing developments like these.

A New Era

This discussion has largely focused on 2 varieties of risk from AI technologies: those attaching to data, especially big data, and those attaching to certain technologies immediately bearing on or functioning as patient care interventions. If we now ask which one is likely to have the greater impact on risk management operations, the answer would seem to be the latter. Although data repurposing and security might pose some liability considerations and therefore be of interest to risk managers, the discipline's attention historically has been focused more on the intersection of humans and their environments. Thus, because AI technologies are anticipated to increasingly replace the human element of that intersection, it seems inevitable that risk managers in clinical environments will increasingly find themselves contemplating strategies to mitigate the risks these new technologies pose.

There is certainly a positive, risk management side to these developments, as various diagnostic and prognostic AI models are being touted as at least—if not more—accurate than their human counterparts.²⁴ Furthermore, AI technologies do not suffer cognitive lapses from fatigue nor do they encumber employers with the costs of employee benefits. On the negative side, however, history has taught that the introduction of novel, powerful, and complex technologies always comes with risks that oftentimes are not appreciated until they materialize.

Anticipating the extent of that threat might pose the greatest challenge for risk managers because of the way AI technologies can precipitate large-scale disasters. As long as AI models remain relatively decoupled from one another and each one performs a discrete or narrow task—eg, does a first read of mammograms but nothing else—the risk of large-scale events is reduced.⁸ But as these models become “smarter” and begin “talking to one another”—a technological development that will likely be irresistible among AI developers—risk magnitude will exponentially increase.²⁵

If the importation of AI technologies for diagnosis or treatment is very rapid, risk managers could find themselves enrolling in crash courses that familiarize them with AI models and their vulnerabilities. It should not be surprising if some larger health systems have some of their risk managers specialize in AI applications to manage their attendant risks. In any event, risk management will not be able to expect “business as usual” in the coming decades for the simple reason that AI systems will dramatically

change the delivery of health care operations. Those changes will usher in a new era of and for risk management.

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John Banja, PhD is a professor and medical ethicist at Emory University in Atlanta, Georgia. He is the editor of *AJOB Neuroscience*, and his most recent book is *Patient Safety Ethics: How Vigilance, Mindfulness, Compliance, and Humility Can Make Healthcare Safer* (Johns Hopkins University Press, 2019).

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STATE OF THE ART AND SCIENCE: PEER-REVIEWED ARTICLE

How Should Risks Posed by Decision Support Be Managed?

Daniel Nystrom, MS

Abstract

Managing risk in cases that involve the use of clinical decision support tools is ethically complex. This article highlights some of these complexities and offers 3 considerations for risk managers to draw upon when assessing risk in cases using clinical decision support: (1) the type of decision support offered, (2) how well a decision support tool helps accomplish work that needs to be done, and (3) how well values embedded in a tool align with patients' and caregivers' professed values.

Decision Support

Clinical decision support systems are computerized systems designed to assist clinical decision making about an individual patient.¹ Although they offer a number of benefits to clinicians and patients, they have also been recognized as **introducing new risks** into clinical work.^{2,3} In this article, I describe 2 general types of clinical decision support systems—tools that augment human capabilities and tools that offload clinician work—and assess risks posed by each. I then offer 3 considerations to take into account when managing risks posed by using clinical decision support systems: (1) the type of decision support offered by the tool, (2) how well a tool's capabilities align with the work to be done, and (3) how well values embedded in a tool align with values held by patients, families, and caregivers subject to outcomes of a tool's use.^{4,5,6}

Two Types of Decision Support

Decision support systems generally belong in 1 of 2 categories: (1) tools that augment human capabilities and (2) tools that offload (primarily via automation) caregivers' tasks.^{4,5,6}

Capability-enhancing decision support is analogous to a microscope. The series of lenses in a microscope do not change a user's perception but enhance a user's "eye hardware" when applied on a small scale. Digital vital signs monitors, for example, create line plots that augment humans' abilities to recognize patterns in vital signs data. When properly designed, these tools often make it easier and safer for caregivers and others to maintain attention to their work, and their skill is enhanced by practice and training with the tool.^{6,7} When tools are designed poorly, however, users have difficulty forming an integrated picture of a situation, which has generated disastrous outcomes in some industries.⁸

Decision support systems that offload work complete or structure tasks, changing the actual work to be done. Self-driving vehicles or diagnostic systems (such as IBM's Watson program⁹), for example, use different forms of machine learning to recognize patterns in data, which, in health care, can inform clinical recommendations and obviate the need for a human to guide or direct task execution. As a result, a human's role shifts to monitoring and evaluating that system's output. In health care, these systems can **free up clinicians' time** so that, ideally, clinicians might focus more on human dimensions of providing care. But when humans are too far removed from or overly reliant on a system, patient care can suffer. For instance, because automated forms of clinical decision support mostly operate on information mined from a patient's electronic health record, limitations such as missing data, inadequate sample size, and classification errors can introduce bias into a system's outputs and thus into clinical recommendations that affect individual patients or entire populations of patients.¹⁰

Select the Right Tool

When considering a technological solution to a problem, the choice of tool should be made in light of the work context in which it will be used and not based solely on the tool's advertised features and functions. If work context is not considered when purchasing a new piece of technology, then the organization runs the risk of the tool not aligning with established workflows and processes, which can introduce new risks to patients and caregivers. One widely recognized failure to ensure appropriate alignment of a tool with the context in which it is used is the design of current **electronic health record systems**.³ Another example of a tool that relies heavily on its available features and functions—not its use in a particular context—is Google Glass, a wearable display mounted on eyeglass frames that facilitates users' hands-free internet access, photography, and videography.¹¹ Aside from technical glitches and privacy concerns, some wonder whether this device would help solve a problem in any workplace without further modification^{12,13} to specifically help accomplish work to be done, avoid errors, and, in health care, avoid being a source of harm to patients or workflow disruption to caregivers.

One way to determine whether and how well a decision support tool helps a caregiver's work is to rigorously test that tool by simulating conditions that closely mimic actual clinical situations in which that device would be used. Many simulations used by manufacturers to test decision support tools focus primarily on the development of use case scenarios that will portray their tool as effective in so-called ordinary occurrences in which it would be used. This approach to testing can generate unreasonable expectations about a device's promise, resulting in potentially dangerous mismatches between a device's intended uses and its actual capacity to help clinicians take care of patients. In contrast to developing use case scenarios that portray the device in a favorable light, simulation testing should be used to reveal when, how, and where a device could fail. In addition to more accurately situating clinicians' expectations about a device's limitations and capabilities, this approach can help risk managers shed light on potential hazards and misuses, develop contingency plans, and convey coveted (and not always easily procured) feedback to designers about patients' outcomes and caregivers' experiences of device implementation.¹⁴

Purpose and Value

From a humanitarian perspective, risk managers should consider the purpose (eg, cost savings, efficiency, accuracy) for which a decision support tool was developed and the corresponding values embedded in the tool. More specifically, risk managers should

determine if the purpose of and values informing the system align with those of the patients, families, and caregivers whose lives will be influenced by use of the tool. Given that current computerized systems are limited to processing of symbols (eg, words, numbers, categories), the values that drive decision support are those that correspond to priorities (eg, cost savings) that can be expressed as symbols and that can serve as a scaffold for decision support. Often, however, we tend to be driven by emotions, experiences, and intuitions of which we are not always aware and that do not align with values programmed into computerized systems because they cannot be translated into symbols recognized by a computer program.¹⁵

Consider, for example, route selection in a navigation aid, such as Google maps. The primary values that drive route recommendations in this tool include distance from a driver's location (point A) to a destination (point B) and the time it will take to travel from point A to point B. Currently, however, navigation applications do not account for less easily defined values that frequently guide human navigation behavior, such as scenery-based route preferences. Similar to gaps in values programmed into navigation aids and values held by motorists using them, health care is fraught with cases in which emotional values outweigh efficiencies or savings of "symbol-able" measurables, such as time or money.

Conclusion

Risk managers must consider values that drive engineered systems, note gaps between values expressed by decision support tools' designs and those expressed through the behaviors of those who use them, and avoid promoting overreliance on decision support tools. It is difficult to know exactly how decision support will be used to facilitate decision making within any given context or to anticipate emergence of behaviors that develop after a decision support system has been integrated into clinical settings. Managing risks introduced by a tool means understanding the type of decision support needed in a specific context, understanding the type of decision support offered by the tool, and recognizing how well the values embedded in the tool align with those of patients and caregivers.

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Daniel Nystrom, MS is a clinical risk manager at Intermountain Healthcare's Primary Children's Hospital in Salt Lake City, Utah. His previous work included applying cognitive engineering techniques to study medical diagnosis and improve the design of decision support. His research interests are in perception, decision making, and the application of human factors and cognitive engineering theories and principles to health care.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

A Call for Behavioral Emergency Response Teams in Inpatient Hospital Settings

Carmen Black Parker, MD, Amanda Calhoun, MD, MPH, Ambrose H. Wong, MD, MEd, Larry Davidson, PhD, and Charles Dike, MBChB, MPH

Abstract

Medical rapid response teams, now ubiquitous throughout hospitals, were designed to identify and proactively treat early warning signs of acute medical decompensation. Behavioral emergencies—including clinical psychiatric emergencies, coping/stress reactions, and iatrogenic injuries—are not responded to with the same vigor. At worst, behavioral crises are treated as unarmed security threats. Limited or inappropriate responses to such crises can lead to suboptimal outcomes on numerous levels, especially avoidable harm to patients and frontline clinicians. Widespread implementation of behavioral emergency response teams for patient-centered behavioral interventions has been impeded by a pervasive perception that these endeavors are medically unnecessary and optional. This article calls for a paradigm shift in responding to behavioral emergencies by arguing that security-driven risk management practices during behavioral emergencies are incompatible with fundamental medical and ethics principles.

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Responding to Emergencies

Medical rapid response teams (RRTs) were first promoted as standard of care within hospital medicine by the 100,000 Lives Campaign of 2004.¹ Although medical procedure codes already existed at that time for bedside cardiopulmonary resuscitation, RRTs advanced care of medical emergencies by placing a new emphasis on proactively identifying early warning signs of patient destabilization and delivering specialized, team-based treatment to avoid further decompensation. Hospitals around the country unified their efforts to innovate solutions for meeting and exceeding the project's goal of saving lives. What once was groundbreaking is now nearly ubiquitous in hospital medicine. Today, hospitals employ individualized medical intervention teams to mitigate risk during clinical crises such as cardiopulmonary arrests, strokes, surgical trauma,

obstetrical emergencies, and more. Behavioral emergencies, however, are less successfully addressed in the United States.

Behavioral emergency is an umbrella term describing symptoms of acute behavioral distress experienced by patients, including those on inpatient medical or surgical units. Behavioral emergencies comprise 3 distinct subtypes: clinical psychiatric emergencies, coping/stress reactions, and conflicts due to iatrogenic insults (see Table). *Clinical psychiatric emergencies* are fundamentally medical or pharmacological (ie, agitated delirium), developmental (ie, severe autism spectrum disorder), or neurobiological (ie, decompensated psychosis) in nature or are substance induced.^{2,3} Patients' *coping/stress reactions* describe their experiences of behavioral dysregulation after they receive bad news, such as a prognosis or diagnosis, or when they are feeling overwhelmed by the hospital course itself. *Conflicts due to iatrogenic insults* occur when patients experience emotional and behavioral distress after receiving poor clinical care due to **clinician bias** and stigma. Patient families might also experience coping/stress reactions and iatrogenic insults. In summary, although clinical psychiatric emergencies (related to the "disease process") are the most cited reason for behavioral emergencies,⁴ it is critical to note that there are numerous instances when patient distress is psychosocial and perhaps exacerbated by clinicians' own behaviors.^{4,5}

Table. Behavioral Emergencies and Their Subtypes

Behavioral Emergencies		
Clinical Psychiatric Emergencies	Coping and Stress Reactions	Iatrogenic Insults
<p>Clinical deficits in behavioral control +/- impairments in verbal expression</p> <ul style="list-style-type: none"> • Medical/Pharmacological: eg, adult with postoperative delirium • Developmental: eg, teenager with severe autism with behavioral dysregulation after painful procedure • Neurobiological: eg, adult with decompensated schizophrenia admitted for diverticulitis who becomes agitated due new bowel perforation but is unable to express why • Substance Induced: eg, adult with undetected alcohol withdrawal 	<p>Instances in which patients experience extreme psychological duress due to receiving bad news or due to the difficulty of the hospital and clinical course itself</p> <ul style="list-style-type: none"> • Example: A father becomes emotionally distraught and kicks a chair upon learning that his child will not survive a car accident 	<p>Patient emotional and behavioral distress that is a by-product of receiving poor clinical care and/or negative interpersonal encounters due to clinician-level stigma and bias</p> <ul style="list-style-type: none"> • Example: A female patient with a co-occurring psychiatric diagnosis and full decision-making capacity feels disrespected and begins yelling after clinicians repeatedly invalidate and argue against her wishes not to undergo a nonessential diagnostic procedure.

Widespread implementation of behavioral emergency response teams for patient-centered behavioral interventions has been impeded by a pervasive perception that

these endeavors are medically unnecessary and therefore optional and, at worst, can be treated as unarmed security threats. The objective of this article is to create awareness of the ethical pitfalls of the prevailing security-driven paradigm of behavioral emergencies. This article calls for a paradigm shift in the handling of behavioral emergencies, arguing that security-driven risk management practices during behavioral emergencies are incompatible with fundamental medical and ethics principles.

Current Management

The standardized emergency code suggestions of 21 state hospital associations fail to endorse a protocol for general behavioral emergencies that is distinct from security-only protocols.² Instead, behavioral emergencies in the United States are frequently equated with safety threats (see Figure). RRTs are called for medical emergencies, yet US clinicians are commonly trained to call a security code when confronted with behavioral crises. These security calls dispatch teams trained to suppress imminent violence rather than promote patient-centered treatment and support. This practice discriminates against people diagnosed with psychiatric disorders and begins a cascade of poor clinical, workplace safety, and financial outcomes.²

Figure. Shared Features of Clinical Behavioral and Unarmed Security Threats^a



^a A comprehensive intervention must function interchangeably under both domains.

Although behavioral emergencies are medical or patient-centered emergencies that might share features with unarmed security threats, it might be difficult for clinicians to immediately determine their cause. Security emergency codes do not alert trained clinicians to address acute medical needs and patient-centered concerns, and medical RRTs do not include trained personnel to address potential acute safety needs. A robust behavioral intervention must deliver both clinical oversight and patient advocacy while

seamlessly integrating security assistance to closely monitor for physical danger to staff members or patients.

Behavioral Emergency Response Teams

British Columbia has progressively implemented provincial-wide behavioral intervention teams since the 2000s.⁶ Some US hospitals have independently pioneered behavioral intervention teams, often called behavioral emergency response teams (BERTs).^{2,4,7} BERTs are a heterogeneous mixture of interdisciplinary, psychiatrically trained team members who deploy to behavioral emergencies across the hospital, similar to the way that medical RRTs respond to medical crises. But BERTs are by no means the only solution to the problem of providing more ethical interventions for behavioral emergencies. Many efficacious interventions have been described that improve responses to behavioral emergencies on medical and surgical inpatient units, the majority of which involve proactive psychiatric consultations.⁸ One drawback is that many of these interventions rely heavily on full-time psychiatry staff and dedicated psychiatric funding, which is not feasible in systems with minimal access to these types of resources. The flexible and collaborative care design of BERTs allows them to be universally implemented in any hospital regardless of geographic setting, psychiatric staffing, and psychiatric financial resources.

The following discussion of BERTs will focus on their most salient and fundamental features in order to better illustrate the inadequacies of security protocols. It is important to note, however, that an exhaustive overview of BERTs is beyond the scope of this article. Furthermore, focusing on the nuances of BERTs might paradoxically distract attention from the ethical obligations underlying their use. Here, we briefly summarize 2 recent literature reviews that extensively analyze and report promising data about BERTs' team composition, risk management strategy, and activation criteria, as well as financial considerations and clinical and workplace safety outcomes.^{2,7}

At a minimum, all BERTs include a primary, psychiatrically trained clinician and some form of secondary security assistance. The primary BERT clinician might be a psychiatrist, a mid-level practitioner, or a floor nurse, for example. Some primary BERT clinicians are fully employed within mental health while others are cross-trained general medical or surgical clinicians. Social workers, pastoral care workers, patient advocates, and psychologists might also join BERTs, depending on local staffing resources.

Like medical RRTs, BERTs emphasize identifying early warning signs. Early warning signs of behavioral distress are accorded behavioral urgency. When patient-clinician relationships become fraught, interdisciplinary BERT members are all trained to preserve patient-centeredness through de-escalation and problem solving while simultaneously reprioritizing proactive clinical investigation and treatment as indicated.^{2,7} Security staff are available but frequently are not involved or even seen by patients in these cases. Thus, a BERT is ideally activated before a patient demonstrates an outward act of internal distress akin to a behavioral emergency. Importantly, BERTs include reserve security staff who operate under the direction of the clinician and who might assist in a primary security response if needed. As primary teams witness BERTs de-escalate and favorably interact with patients, however, fewer BERT calls are required, as staff members become more skilled themselves in responding to behavioral crises.⁷

Ethics of Behavioral Emergency Responses

Using evidence-based practices for acute behavioral crises should not be a voluntary, optional undertaking. Just as the 100,000 Lives Campaign pushed proactive care

through RRTs, so must BERTs or clinically equivalent interventions become standard of care for acute behavioral emergencies. We argue that behavioral interventions for behavioral emergencies are ethically imperative based upon the 4 ethics principles of beneficence, autonomy, justice, and nonmaleficence.⁹

Beneficence vs neglect. Beneficence mandates treating patients in accordance with best available practices, but security interventions activated for clinical psychiatric emergencies fail to treat modifiable and potentially life-threatening medical diseases underlying patients' behavior. Neglect of patients' clinical needs more generally is evidenced by suboptimal morbidity and mortality outcomes of patients with co-occurring clinical psychiatric needs on inpatient medical and surgical units,² who primarily suffer from medical or surgical (as opposed to psychiatric) complications, such as procedural or medication errors, infections, skin breakdown, and acute renal failure.¹⁰ Security interventions also neglect the basic human rights of patients experiencing difficulty coping or iatrogenic insults from poor care. Instead of supporting patients and families during a vulnerable time, security enforcement negates and neglects the humanity of their experiences. Making BERTs an obligatory hospital service would support patient-centered, compassionate care.

BERTs advance practice and therefore represent best practice for acute behavioral dysregulation even when hospital psychiatric consultation-liaison services might be available. Clinicians often attempt to obtain an emergent psychiatry consult when they suspect a psychiatric component to a patient's distress. However, these efforts do not provide security backup and lack the fail-safe reliability, efficiency, and robustness of other medical emergency protocols like BERTs.^{2,7} Furthermore, the presence of a lone psychiatrist is insufficient to safeguard against the multifactorial inputs that contribute to poor medical and safety outcomes or iatrogenic discrimination.²

Beneficence also requires removing financial barriers to patient care. Currently, health systems are often disincentivized from considering distinct, nonsecurity interventions for behavioral emergencies due to poor insurance reimbursement for psychiatric care and a false perception that such interventions depend upon limited psychiatric financial resources.² BERTs, however, can be cost neutral.² Moreover, health systems that uphold beneficence by treating patients' behavioral emergencies as more than security threats create opportunities to recoup significant cost savings that would otherwise be lost to poor patient and provider outcomes.^{2,3,7,11}

Autonomy vs intentionality. Respect for patient autonomy requires clinicians to "consult people and obtain their agreement before we do things to them."⁹ Associating behavioral emergencies with security threats implies a level of intentionality to patients that does not exist for medical diseases. For example, a patient hospitalized for severe ulcerative colitis is understood to have frequent bloody bowel movements as a byproduct of medical illness, not because they desire it. Should this same patient develop steroid-induced psychosis with behavioral symptoms of agitation during treatment, the patient's behavioral distress is equally a byproduct of medical illness and equally undesired. Yet, patients who experience a clinical psychiatric emergency during their hospitalization receive security interventions with names like "code strong" that are prompted by plain language, such as a "show of force."³ One state goes as far as inserting the language of a "strike team" in security codes.¹² These codes promote aggression against patients' unintentional medical or psychiatric symptomology, thereby treating patients similarly to hospital intruders who pose intentional "safety threats" to others.

Respecting patients' autonomy means not only avoiding false assumptions that their behavior is intentional but also avoiding false assumptions that their behavior is merely a byproduct of mental illness. It is noteworthy that a psychiatric diagnosis does not automatically confer responsibility for behavioral crises upon patients. Although perhaps counterintuitive, incidents of coping/stress reactions and conflict due to iatrogenic insults collectively outnumber BERTs triggered by clinical psychiatric emergencies. Indeed, excluding clinical psychiatric emergencies, the top 5 of 6 root causes for one health system's BERTs were uncontrolled pain, inadequate nutrition, grief, loss of autonomy, and discharge concerns.⁴ These are mainly psychosocial needs that can be elucidated or modified by encouraging clinicians to engage in patient-centered dialogue. Indeed, communication, listening, and **respect for autonomy** are at the heart of patient-centered care. Furthermore, shared decision making reduces patient anxiety and enables care to better align with a patient's values.¹³

Clinicians undoubtedly strive for impartiality and equality. Yet, 35 studies found evidence of unconscious clinician bias—including racial, ethnic, gender, and age bias—and those that investigated relations involving unconscious clinician bias found that it was associated with lower quality of patient care.¹⁴ Take, for example, an African-American teen with a sickle cell crisis who is experiencing excruciating pain in an emergency department. The clinician, due to unconscious racial bias, assumes that the patient is intentionally drug seeking and fails to uphold patient-centered care by repeatedly ignoring the patient's request for analgesia. If the patient's pain goes untreated and the patient becomes exasperated, shouts, and throws a cup at a nurse, a call to security is prompted for "patient violence." Thus, the clinician's bias and resultant lack of patient-centeredness will have precipitated a behavioral emergency due to both a coping/stress reaction and an iatrogenic insult. Opportunities frequently arise for BERT members to demonstrate effective communication to primary teams and to provide corrective behavioral oversight. Respect for autonomy can be reestablished by providing role models, such as patient advocates and chaplains, by educating staff in behavioral de-escalation, and by debriefing clinicians on how to improve their future interactions with patients.^{2,4,7}

Justice vs scarcity. Justice is promoted by nondiscriminatory patient access to finite health care resources. Mismanaged behavioral emergencies unnecessarily consume additional resources needed for other patients. In addition, devastating clinician injuries from mismanaged behavioral emergencies can result in clinician burnout, staff shortages, overtime costs, and decreased safety,² as well as litigation costs for affected patients and clinicians. BERTs reduce hospital waste through improving patient and staff outcomes during behavioral emergencies, thereby liberating limited health care resources.^{2,7,11} However, treating patients with incidental behavioral emergencies cannot be confined to a psychiatric unit. Medical and psychiatric clinicians must mobilize for clinical psychiatric emergencies, just as patient advocates must mobilize for coping/stress reactions and conflicts due to iatrogenic insults.

Of course, all hospitals will at least call a medical RRT should they suspect a neurological crisis. Hospitals with greater access to stroke specialists, equipment, and funding might become certified as primary and comprehensive stroke centers to mark their ability to provide the highest level of stroke care.¹⁵ Like strokes, behavioral emergencies might one day be recognized as necessitating a tiered response. BERTs might represent a baseline level of intervention for all hospitals. The composition of BERTs already varies based upon locally available resources.^{2,4,6,7} Hospitals with

superior psychiatric resources might perhaps seek certification one day to become the equivalent of a primary or comprehensive stroke center.

Principles of justice and beneficence are upheld when hospitals instantiate clinical best practices in accordance with their resource limitations. Heterogeneity is welcomed in BERTs! Cross-training existing personnel allows the expansion of medical, psychiatric, and patient-centered expertise. For example, one institution significantly improved clinical outcomes and workplace safety by training security officers to become mental health technicians with distinctive, nonsecurity uniforms demarcating their specialization.¹¹

Nonmaleficence vs accountability. Nonmaleficence cautions clinicians to “first do no harm.” Coercive practices like security enforcement, involuntary chemical sedation, and nonconsensual physical restraints risk traumatizing patients and causing iatrogenic physical harm.¹⁶ For instance, prolonged immobilization from excessive restraints promotes skin breakdown and respiratory distress.²

Harm must be considered in a larger social context, as mistrust of police correlates with mistrust of health care institutions.¹⁷ Because patients with psychiatric diagnoses have a high prevalence of various childhood, medical, physical, sexual, racial, military combat, or police traumas,¹⁸ frontline **security presence can foster mistrust** and potentiate intensified behavioral dysregulation, with resultant iatrogenic physical or psychological injury. Security interventions absolve clinicians of accountability for potential additional psychological and physical trauma because they are justified as being for “the safety of others.” Superior, patient-centered workplace safety alternatives exist.

Conclusion

Security enforcement in behavioral emergencies promotes clinicians’ protection at the expense of patient care. A compassionate, patient-centered response to behavioral emergencies reprioritizes clinicians’ medical and ethical mission to provide care while also protecting clinicians from harm. To date, widespread implementation of BERTs in the United States has been impeded by perceptions that these teams are optional and expensive. This article has argued that, in order to adhere to the ethical tenets and traditions of medicine, we are ethically obligated to employ evidence-based, best practices when treating behavioral emergencies, which requires reframing behavioral emergencies as opportunities for clinical intervention and patient advocacy. Like the 100,000 Lives Campaign, unified efforts to innovate ethical interventions for behavioral emergencies can lead to solutions that respect the dignity of everyone who comes to us for care. First, however, ethical obligations must fuel motivation to innovate.

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Carmen Black Parker, MD is an assistant professor of psychiatry at the Yale University School of Medicine with a primary clinical appointment at the Connecticut Mental Health Center in New Haven, Connecticut. She is a proud African American physician with demonstrated research and advocacy interests in addressing unconscious bias within daily clinical practice and medical education. She is also a strong supporter of the equitable treatment of behavioral emergencies within general hospital medicine.

Amanda Calhoun, MD, MPH is a clinical fellow in the Albert J. Solnit Integrated Adult/Child Psychiatry Program at the Yale University School of Medicine in New Haven, Connecticut. Her research interests include patient-centered approaches to emergent behavioral care for children with autism spectrum disorder as well as improving global mental health outcomes in African/African diaspora and Indigenous children.

Ambrose H. Wong, MD, MEd is an assistant professor of emergency medicine at the Yale University School of Medicine in New Haven, Connecticut. His research focuses on workplace violence and improving practices in management of agitation events. He aims to use systems-based approaches and human factors methods to improve safety and care quality for mental health patients in the emergency department.

Larry Davidson, PhD is a professor of psychiatry at the Yale University School of Medicine in New Haven, Connecticut, where he also founded and directs the Yale Program for Recovery and Community Health. In addition, he serves as a senior policy advisor for the Connecticut Department of Mental Health and Addiction Services, the director of the Substance Abuse and Mental Health Services Administration-funded New England Mental Health Technology Transfer Center Network, and the editor-in-chief of the *American Journal of Psychiatric Rehabilitation*.

Charles Dike, MBChB, MPH is an associate professor of psychiatry at the Yale University School of Medicine in New Haven, Connecticut. He additionally serves as the medical director of the Connecticut Department of Mental Health and Addiction Services, the vice-chair of the Ethics Committee of the American Psychiatric Association, and the vice-president and former chair of the Ethics Committee of the American Academy of Psychiatry and the Law.

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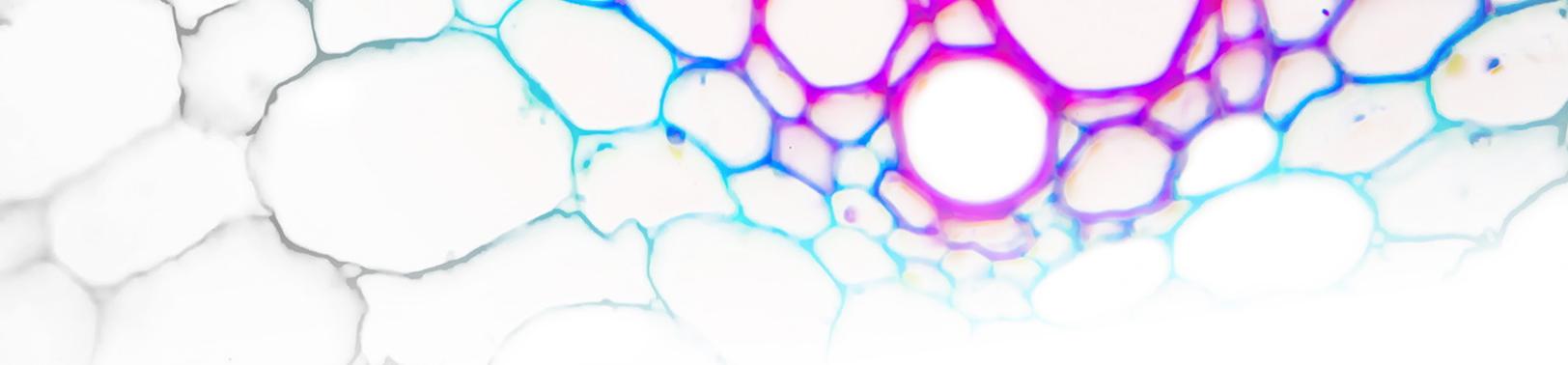
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What Is Ethically Informed Risk Management?

Alan J. Card, PhD, MPH, CPHQ, CPHRM

Abstract

Ethically informed risk management includes both the management of ethical risks and the ethical management of risks (professional ethics). This article aims to rekindle dormant discussion of professional ethics in health care risk management. It frames ethically informed risk management as a patient-centered and evidence-based practice, aligns its scope with that of biomedical ethics, and proposes specific ethical duties to guide risk management practice. It provides a starting point for more robust debate and the development of ethical standards for health care risk managers.

Introduction

There are 2 key avenues for applying ethical reasoning in health care risk management: the management of ethical risk and the ethical management of risk. The management of ethical risks (eg, related to advance directives, disclosure of accidental harm) has been the focus of significant attention in the risk management literature.^{1,2,3,4,5,6,7,8} The ethical management of risk (ie, professional ethics in risk management) has not been entirely ignored (see especially Kapp⁹) but has received far less attention and rarely appears to be a primary focus of ethical analysis.

The field of health care risk management has 3 foci, each of which has clear—and sometimes conflicting—ethical implications. It began as an insurance-focused response to the **malpractice** crisis of the 1970s and soon evolved to include legal and regulatory compliance. By the mid-1980s, its focus had expanded to include tackling clinical and patient safety risks through systems improvement.¹⁰ Outside the health care context, these 3 functions—risk finance, legal and regulatory compliance, and safety improvement—arose from very different traditions, each with its own ethos, praxis, and literature.^{11,12,13} Health care risk management encompasses the 3 in a single chimeric profession.¹⁴

Among risk managers, only attorneys have the benefit of a widely accepted code of ethics.¹⁵ Neither the strictures nor the freedoms (within those strictures) of legal ethics apply to the rest of the risk management community, however, and while the American Society for Healthcare Risk Management briefly promoted a code of ethics for all risk managers,¹⁶ it no longer does.

I will therefore focus on nonattorney risk managers. These professionals face significant moral dilemmas in the course of their work and would probably benefit from a code of professional ethics that speaks to their concerns in a relevant and principled way. In part, such a code would help provide clarity in sticky ethical situations, but, perhaps more consequentially, it would provide a potent defense against pressure (from administrators, clinicians, or even patients) to take unethical actions.^{17,18} If such a code of ethics were adopted, then—to paraphrase Latham¹⁸—when you hired a risk manager, you would get the code. It would serve as a *de facto* part of the employment contract, delineating the scope of action that risk managers would—and would not—take.¹⁸

It is not possible to construct a code of professional ethics from whole cloth in an article of this length, nor is it a task for a single author. I hope, however, to help begin a conversation about which ethical principles ought to guide an ethical code for health care risk management.

Purposes of Risk Management

On the face of it, risk managers pursue 2 different and sometimes conflicting goals: protecting patients and protecting the health care organization. Tracing the history of health care risk management, one could argue that the driving force behind the emergence of the profession was the need to protect health care organizations from legal liability.¹⁰ As usual, the truth is more complicated, and the rationale for a profession's birth does not necessarily paint a clear picture of its later life.¹⁸ Even accepting this premise, however, the need to protect health care organizations would still be just the starting point for analyzing the *ethical* basis of risk management practice. There are 2 key questions: What socially and ethically desirable purpose is served by protecting the organization? And what does this imply about the ethical duties of a risk manager? It is not enough to say, "My ethical duty is to perform the job I'm paid to do"; the ends served by that work must, themselves, be ethically sound (eg, managing risk for a violent criminal enterprise is unethical because of the organization's role in society).

What, then, is the socially and ethically desirable purpose that is served by protecting a health care organization? It is to serve the *mission* of health care: to improve the health (or at least the health trajectories) of patients.¹⁹ Health care organizations also do other things, of course; some are organized to make a profit, and all serve an important role as employers. But those facts are also true of ice cream shops. The special privileges of health care organizations, which allow them to tinker with the mechanics of life itself, are given to them by society because these organizations provide *care* to improve *health*.

Thus, to the extent that health care risk management exists to protect health care organizations, it does so in service of a mission to promote and protect patients' health. Risk managers accomplish this mission both directly (eg, through patient safety improvement) and indirectly, by protecting the organization's financial and operational ability to deliver on its mission (eg, loss prevention).²⁰ The patient-centered outlook derived from the health care mission should be a foundational principle of professional ethics for nonattorney risk managers.

Another purpose of risk managers as *risk managers* is to deliver excellence and effectiveness in the management of risk. Health care organizations pursue their mission primarily by delivering clinical care; they could as easily employ another clinician rather

than a risk manager. To justify that opportunity cost, risk managers must ensure that they deliver the greatest practicable value through their work. Achieving this goal calls for practice that is evidence-based²¹ and constantly advancing rather than benchmark-based and complacent in the status quo. It also calls for making the most of the unique and specialized skills that the risk management profession brings to the table: **systemic risk assessment** and participatory systems design. Risk managers should, to the best of their ability, spend their time actually *managing* risks rather than simply collecting, categorizing, and communicating those risks. By themselves, these activities do nothing to protect the health and safety of patients. It is only by informing the design, implementation, and sustainability of effective solutions that they have any impact on outcomes.

Ethically Informed Risk Management

Here, I propose specific principles that might inform professional ethics in health care risk management. They are not intended as the elucidation of any grand moral theory but rather as the starting point for developing a “practice model”²² for ethical, patient-centered practice in health care risk management and as a public profession of the standards to which that practice should be held.

I begin by applying to risk management the 4 principles of Beauchamp and Childress,²³ which play a prominent role in contemporary clinical ethics (see Table).^{24,25} Aligning the principles of risk management ethics with those most often referenced by clinicians creates a shared ethical vocabulary and helps establish the legitimacy of the broader suite of principles among patients and other stakeholders.

Table. The 4 Principles²³ Applied to Risk Management

Principle	Definition	Application in Risk Management
Beneficence	The obligation to provide benefits, prevent harm, and balance benefits against the risk of harm	Address not only physical and economic benefits or harms, but all other harms, including psychological harm and avoidable suffering. ^{26,27,28,29}
Nonmaleficence	The obligation to avoid actively causing harm (“first do no harm”), as opposed to the broader obligation to prevent harm from being caused	Apart from disclosure/apology and compensation programs, ^{27,30,31} current literature provides scant support for assessing how risk management practice can inflict (or avoid inflicting) harm.
Justice	An obligation to pursue the fair allocation of benefits, risks, and costs according to morally relevant criteria	<ul style="list-style-type: none"> Concerns about <i>distributive justice</i> underlie recognition of inequities in patient safety and quality of care^{32,33,34,35,36,37,38,39,40,41} and apportionment of blame when an adverse event occurs.^{42,43,44} Concerns about <i>procedural justice</i> have been addressed through the <i>just culture</i>^{45,46} approach, in which staff are not blamed for problems attributable to their work systems. Concerns about <i>restorative justice</i> underlie disclosure/apology and compensation programs.^{27,30,31}

Respect for Autonomy	A duty to (1) refrain from attempting to control and constrain the autonomous actions of others and (2) actively support autonomous decision making, especially by disclosing relevant information.	Risk management literature addresses support for clinicians and health care organizations in deciding how heavily to weigh patient autonomy in health care decision making. ^{3,5,9} For risk managers, respect for autonomy also pertains to interactions with the health care workforce, which has received far less attention.
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These 4 principles represent *prima facie* duties, which means they are binding obligations except when they conflict with one another—in which case, a balance must be struck between them (eg, balancing beneficence and autonomy in the case of a minor who requires a blood transfusion that is proscribed by the parents’ religion). Unfortunately, there is no checklist or algorithm to ensure the “right” balance is struck. If all ethical duties cannot be perfectly satisfied, the risk manager must attempt to find a solution that best satisfies⁴⁷ (*sufficiently* satisfies) those requirements in context.

Additional Principles

In the context of biomedical ethics, Beauchamp and Childress argue that the 4 principles (along with a few simple rules, such as truth telling) are a sufficient basis for moral reasoning.²³ Even within the systems-focused realm of health care risk management, one could probably use these principles to infer and justify each of the additional principles I will discuss below. In the context of supporting a practice model for risk management ethics, however, it is probably worth highlighting these more specific duties. The principles below are proposed as a supplementary set of *prima facie* obligations, with the aim of specifying key aspects of the 4 principles to better develop what Beauchamp would call the particular professional morality of health care risk management.⁴⁸

Patient-centered practice. As I argued earlier, the ethical duties of risk managers ultimately rest upon the foundation of the health care mission: to improve the health trajectories of patients. Everything else flows from this mission. Because risk managers’ scope of practice encompasses the systems level and not just dyadic interactions, **patient-centered practice** includes respect for the needs of patients in the aggregate (ie, the population of patients served by the organization’s mission) as well as the particular patients and families involved in any given situation. Similarly, because risk managers sit at the intersection of clinicians, administrators, patients, and families, they owe ethical duties to all of these stakeholders. The principle of patient-centered practice offers important guidance on how risk managers should uphold respect for autonomy, beneficence, justice, and nonmaleficence by explicitly privileging their ethical duties to patients.

Participatory design. Risk management is, at its heart, a design discipline. Its purpose is to design (or redesign) systems to reduce negative risk and leverage positive risk (ie, potential opportunities) in the service of the health care mission. Current practice focuses primarily on risk assessment (problem exploration), leaving risk control (the design of interventions to improve outcomes) as an afterthought. This oversight leads to predictable and—given the alternatives—frankly unethical failures of the risk management process, especially with regard to patient safety risks.^{49,50,51,52,53,54,55,56,57,58} Because health care organizations are complex adaptive systems characterized by what Plsek and Greenhalgh refer to as “individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that one agent’s

actions changes the context for other agents,”⁵⁹ the intervention design process can only hope to be safe and effective if it is informed by stakeholder participation (including that of patients⁶⁰ as well as staff).

In addition to ethical motivations related to outputs and outcomes, participatory design (or co-design or co-production) is also motivated by the ethical implications of design as a process (eg, procedural justice and respect for autonomy).^{61,62,63,64,65} As Robertson and Wagner state: “Perhaps the core principle of Participatory Design is that people have a basic right to make decisions about how they do their work and indeed any other activities where they might use [the products of design].”⁶⁵ In health care risk management, self-determination implies a need to include the voices of patients and families who have historically been excluded from the design process⁶⁰ and also to genuinely engage with staff in the design—not just the implementation—of interventions.

Competence, diligence, and evidence-based practice. Risk managers have an ethical obligation not only to do good, but also to do good well. Failures of competence and diligence have real impacts on the health care mission that, at a minimum, have implications for justice, beneficence, and nonmaleficence. Health care risk management practice has been built primarily on good intentions, expert opinion, and (often underexamined) consensus standards of practice rather than on evidence⁵⁸—a foundation for practice that is no longer seen as morally acceptable in other areas of health care.⁶⁶

To meet their obligations under this principle, risk managers must move toward a practice based on evidence and excellence. Examples of practice changes that might support this principle include adopting evidence-based approaches for risk control,^{50,51,57,58,67,68} adopting proactive disclosure and settlement, and reducing or deimplementing^{69,70} practices that have not proven effective, such as overuse of retrospective risk assessment at the expense of prospective risk assessment^{54,71,72,73,74} or excessive focus on categorizing and reporting risks in ways that do not inform action.^{75,76,77,78}

Respect for privacy. Respect for privacy is well-integrated into risk management practice—so much so that the code of silence can cause risk managers harm.²⁹ This principle remains worth mentioning, however, because it is important to public acceptance of risk management and because risk managers should be reminded to consider **risks to patient privacy** when new sources of risk (eg, emerging technologies)^{79,80,81} present themselves.

Equity. Equity is clearly implied by the principle of justice, but pervasive inequities in the distribution of patient safety risks, benefits of improvement initiatives,^{32,33,34,35,36,37,38,39,40,41} and the burden of blame in safety investigations (eg, preferentially blaming lower-status members of the clinical team)^{42,43,44} warrant the recognition of a stand-alone principle.

Honesty and transparency. Finally, risk managers should aim for the highest practicable level of honesty and transparency. Although a duty of honesty is likely to be noncontroversial, the loss-prevention aim of risk management might cause some to balk at a duty of transparency due to a belief that disclosing patient harm or ongoing risks (whether to patients or staff) might cause harm to the organization. Nevertheless, respect for autonomy (of both patients and health care workers) dictates that risk

managers enable informed decision making by being transparent about risks and actual harms. Fortunately, these 2 aims—honesty and transparency, on one hand, and loss prevention, on the other—are not necessarily at odds, as demonstrated by the industry’s experience with programs aimed at proactively **disclosing and apologizing** for adverse events and offering compensation to those affected.^{7,30,60,82,83,84}

Conclusion

The practice of health care risk management is a constant exercise in balancing ethical duties and their conflicts. Currently, risk managers face these dilemmas alone, without the support of an agreed-upon set of ethical principles, much less a formal code of ethics. This circumstance might make risk managers less effective in defending ethical decisions, which not only impairs their ability to support the health care mission but also can lead to a sense of futility and ethical failure.²⁹ This paper does not attempt to develop a formal code of ethics, but it does propose an ethical foundation for risk management practice and hopefully will rekindle the discussion of what constitutes ethically informed risk management.

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Alan J. Card, PhD, MPH, CPHQ, CPHRM is an assistant professor in the Department of Pediatrics at the University of California, San Diego School of Medicine. His research focuses on risk management, patient safety, quality improvement, and patient and health care worker well-being, with a particular focus on the frameworks, tools, and techniques that shape practice.

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ART OF MEDICINE

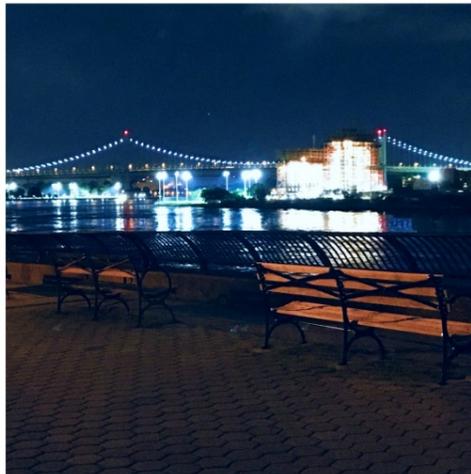
Bench Reflections on Healing and Patient Care

Julia H. Miao and Kathleen H. Miao

Abstract

Benches are a metaphor for a shared place of rest and reflection for patients and their loved ones as well as for physicians and other health care clinicians. *The Healing Bench* artwork thus represents the collective unity of communal decision making and reflections, as clinicians deliver compassionate patient care from bench to bedside.

Figure. *The Healing Bench*, 2020



Media

Photography and watercolor painting.

Caption

The metaphorical bench symbolizes a shared place of rest and reflection for patients and their loved ones as well as for physicians and other health care clinicians. In these thematic photographs and a watercolor painting, the motif of benches as spaces for viewing in diverse settings—where one can immerse oneself in nature or overlook a city’s skyline and harbor—draws attention to the **invitation to reflection** in any destination, wherever one is located.

This collaborative work of art additionally illuminates a shared moment between an elderly couple captured in loving embrace at a bench in the hospital’s garden, where they also embrace their last days together. It is in these shared areas of rest among nature that the limited time of patients and their loved ones stands still and where they share their last memories together. The bench is also where physicians and health care clinicians can rest and reflect upon the **shared decision-making space**, as they work with

their patients to provide optimal care. From enhancing quality of life to alleviating pain and suffering, reflections at the shared bench represent the resilient bond among physicians, patients, and their loved ones. *The Healing Bench* artwork thus represents the collective unity of communal decision making and reflections, as clinicians deliver compassionate patient care from bench to bedside.

Julia H. Miao is a medical student at the Renaissance School of Medicine at Stony Brook University in Stony Brook, New York. She is passionate about delivering excellence in patient care, research, teaching, and the intersection of humanities and sciences in medicine.

Kathleen H. Miao is a medical student at New York University School of Medicine in New York City. She is passionate about delivering excellence in patient care, research, teaching, and the intersection of humanities and sciences in medicine.

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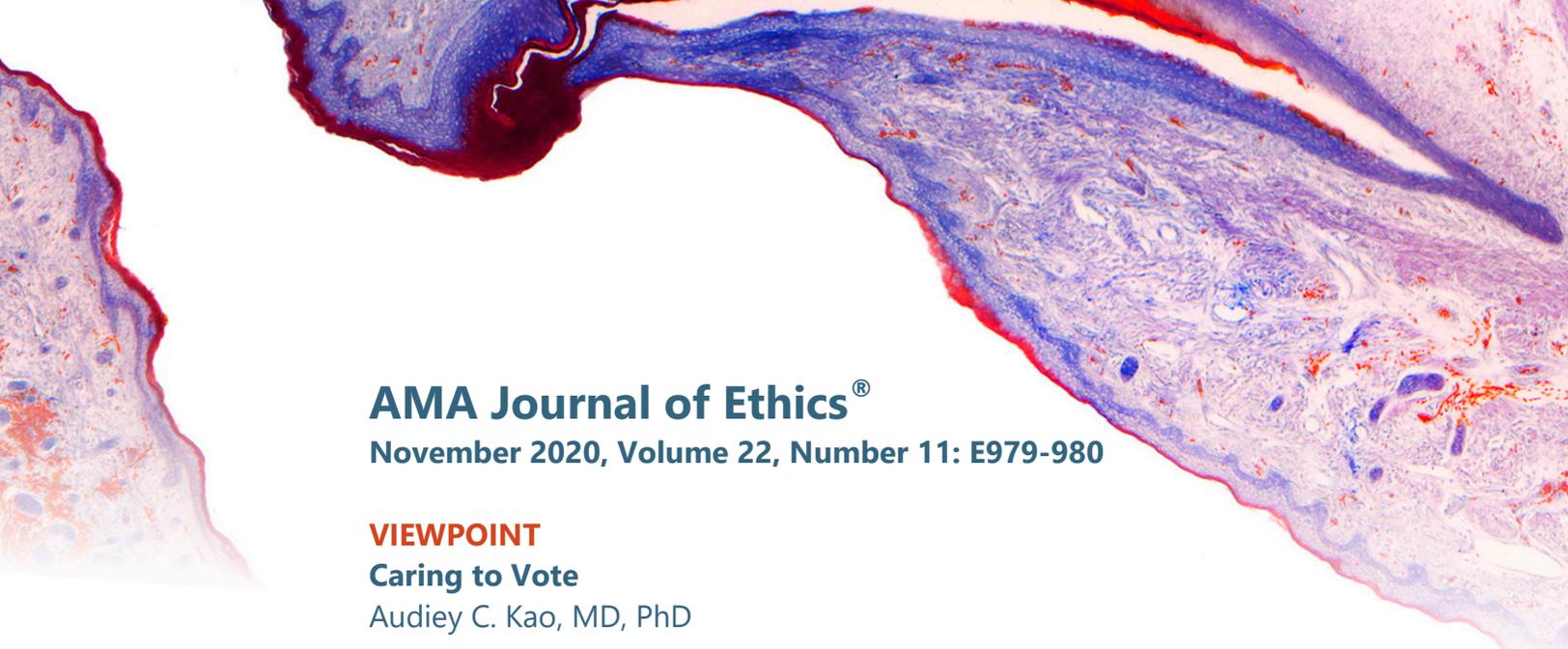
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VIEWPOINT

Caring to Vote

Audiey C. Kao, MD, PhD

Respect, compassion, and empathy are vital in any caring relationship.

Upholding the dignity of every individual is respect personified. Yet too much of this country's history has been marred by denying this basic human dignity. Racist, sexist, and other hateful ideologies that regard one group of people as superior to another have displaced, enslaved, and disenfranchised too many of us.^{1,2} Such ideologies expressed in personal actions and public policies continue to prevent everyone from realizing their full potential. For that, our country suffers mightily.

Concern for the suffering and distress of others is compassion personified. All of us are struggling to deal with the physical suffering and economic distress that have been wrought by the COVID-19 pandemic. This struggle is made that much more difficult when basic facts and critical evidence about the pandemic are discounted and disbelieved.^{3,4} If our country had tackled this public health threat as the emergency it was, more people would likely be alive today. It didn't have to be this way.

Placing oneself in another person's shoes is empathy personified. In a country that is polarized along so many different lines, the capacity to express empathy is sorely needed if our representative democracy is to survive, let alone thrive. Yet too many elected officials apparently lack the ability to empathize. Integrity-preserving compromise in the public square demands recognition of the position of one's rival or opponent.^{5,6} A house divided cannot stand.

The editor in chief and editorial board members of the *AMA Journal of Ethics* have been trained in caring disciplines and have committed our professional lives to promoting the health and welfare of the public. As we approach the end of an election year like no other, exercising our civic duty and voting for the common good are imperative.⁷ All of us are called upon to support candidates who personify respect, compassion, and empathy if we hope to realize a more fair and just future.

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