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YOUR PRACTICAL GUIDE TO ETHICS DECISION-MAKING

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Updated Guidance on Health Equity Movement

There are many new recommendations to help hospitals achieve health equity after the American Medical Association issued a report on racial justice and health equity. In it, the authors recommended healthcare leaders take steps to ensure "just representation of Black, Indigenous, and Latinx people in medical school admissions as well as medical school and hospital leadership ranks."[1]

Diversity, equity, inclusion, and belonging, along with racial, ethnic, and gender inequities also are addressed in updated guidance from the American Heart Association and American College of Cardiology.[2]

"Boards of directors should make expectations clear to senior management, and should hold executives accountable for achieving specific results," says **William J. Oetgen**, MD, MBA, FACC, a clinical professor of medicine at Georgetown University and report co-author.

A third report, from the National Academy of Medicine (NAM), explores how nurses can alleviate health disparities and promote health equity.[3] Many are unaware of how nurses affect health equity, according to **Maureen Bisognano**, MS, president emerita and senior fellow at the Institute for Healthcare Improvement. "Nurses are well-positioned to create fair and just opportunities for everyone to live their healthiest life," says Bisognano, report co-author.

Education and leadership development are needed to support nurses in this endeavor. "Promoting diversity, equity, and inclusion, both in nursing education and in the workforce, is critical," Bisognano says. The NAM report authors suggested two necessary changes for nursing schools:

• **Nursing curricula should include data on health disparities.** In most nursing schools, professors teach social determinants of health and related subjects in stand-alone courses. Bisognano argues this approach will not help nurses address the problem meaningfully. Instead, she suggests integrating the content throughout curricula, supplemented with community-based experiential opportunities.

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• Schools should address financial barriers that can prevent people of color, those with low incomes, or first-generation students from pursuing careers or advanced degrees in nursing. Bisognano says administrators should commit to recruiting, hiring, and advancing diverse professionals while eliminating policies that perpetuate discrimination.

For example, Bisognano notes that, historically, nursing curricula leaned heavily toward contributions of only white and women nurses. She believes this unbalanced focus sends a message to students about what faculty consider important. "Moving forward, curricula need to include a critical examination of the history of racism within nursing, and an acknowledgment and celebration of the contribution of nurses of color," Bisognano and colleagues wrote.[3]

To succeed, such efforts must be led by a broad group of individuals from all levels within an institution, according to the NAM report authors. "Racism in institutional practices can be so ingrained that it is difficult for those with power to recognize," they wrote.[3]

Nurses might be reluctant to disclose a mental illness or disability, or to request a need for accommodations. "There has been a call for both healthcare organizations and nursing schools to see beyond disability as a disqualifier for nursing practice, and instead value professionals with disabilities who can offer unique and different perspectives," Bisognano and colleagues wrote.[3]

Sometimes, nurse leaders from underrepresented groups are asked to participate in diversity and inclusion initiatives without compensation. "Employers need to provide adequate space, support, and payment for this work, which can be emotionally taxing," Bisognano says.

The overarching goal, says Bisognano, is for hospitals to be "embedding equity and antiracism into every aspect of nursing, not treating them as separate from everyday activities and responsibilities." ■

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COMING IN FUTURE MONTHS

- Ethical concerns on hospitals' inconsistent code status options
- How small community hospitals are meeting ethics needs
- Update on efforts to simplify informed consent processes
- Ethical controversy over artificial intelligence in healthcare

Revised Ethics Recommendations on Cardiology Care Reflect 2021 Priorities

Although the tenets of medical ethics remain unchanged, "the specific challenging circumstances evolve," says **William J. Oetgen**, MD, MBA, FACC, of recently reformed recommendations from the American Heart Association (AHA) and American College of Cardiology (ACC).[1]

Administrators should "determine which recommendations are most relevant to their organizations, and proactively partner with their boards of directors to address those," says Oetgen, noting the 2021 AHA/ACC report is directed at clinicians of all types. "The document recognizes that modern cardiovascular care is frequently provided in a team setting," says Oetgen, report co-author.

The motivation for the AHA/ACC's Consensus Conference on Professionalism and Ethics came in late 2019. "Leadership realized that 16 years had passed since there had been a statement on professionalism and ethics from the two organizations," says Oetgen, clinical professor of medicine at Georgetown. Previous conferences concentrated on specific ethics issues:

- 1989: Ethics of physician-owned organizations, distributive justice in the allocation of scarce resources, and professionalism in the care of AIDS patients.
- 1997: End-of-life and futility issues, and the ethics of cardiovascular genetics.
- 2004: Human subjects research codes of conduct, and physician self-referrals.

All three conferences, plus the 2021 gathering, focused on relationships with industry and conflicts of interest. "In the ensuing two decades, new issues have arisen, which required thought and attention," Oetgen notes.

In 2021, new insights on diversity, equity, inclusion, and belonging are a major focus. "The tenet of justice demands that clinicians, hospitals, and healthcare systems give strong consideration to how they can ameliorate the effects of the social determinants of health for patients whose circumstances result in healthcare disparities," Oetgen says.

Elsewhere in the 2021 AHA/ACC report, Oetgen and colleagues wrote about clinician well-being. "This is a topic of urgency, and is deserving of board-level attention," Oetgen says.

The authors reported a more sophisticated understanding of the problem is needed. "Boards should expect that hospital- or systemwide efforts go well beyond clinician-resilience training," Oetgen explains. Some factors negatively affecting clinicians are, in fact, systemic issues. Physicians struggle with insufficient clerical support for clinicians, burdensome electronic health record requirements, and unreasonable clinical workloads. Dysfunctional clinical team dynamics are another underlying factor. "Boards should expect their organizations to deal promptly, fairly, and compassionately with disruptive clinician behavior, which can have severely negative implications for both patient safety and clinician well-being," Oetgen cautions.

Finally, the AHA/ACC report authors touched on the ethics of evolving healthcare delivery systems. "All ethical tenets are under challenge in the increasingly common circumstance where clinicians are the paid employees of hospitals and systems," Oetgen says. ■

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Billing, Disparities Now Part of Hospital Surveys

The 2021 Leapfrog Hospital Survey now includes two sets of questions regarding ethical billing and disparities in care.[1]

"Patient safety begins with a respect for the dignity of every patient. Part of respecting dignity is to treat people with compassion and fairness in billing for care. Part of that is treating people equitably," says **Leah Binder**, president and CEO of The Leapfrog Group.

From a health equity standpoint, hospitals are asked if they stratify their data to monitor potential inequities in the delivery of care; and if so, what they do if those issues are observed. "When we set standards for safety and quality, those standards apply to all patients, regardless of race, ethnicity, sociodemographic status, disability, LGBTQ status, language, or other factors known to disrupt quality," Binder explains.

The Leapfrog Group wants to see hospitals ensuring bias is not undermining the quality of care delivered to particular patients. From

a billing standpoint, fear of costs prevents some from seeking needed care. Unfair, unethical billing processes exacerbate stress and compromise decision-making. "We recommend ethicists work with CFOs and others on the 'business' side of hospitals," Binder says. Ethicists can do this in a few ways:

• Help finance leaders align their practices with ethical standards for patient respect and quality of care. Ethicists can look at whether hospitals alert patients to out-of-network services at in-network hospitals before the service, if the price the patient will need to pay is available in advance, if the hospital provides an itemized bill that patients can understand, and if the hospital does all it can to ensure options for charity care and discounts are clear.

"Ethicists should monitor collections practices like suing patients to assure they meet standards for ethical business practices," Binder offers.

• Review patient complaints to identify underlying ethical issues. A patient might receive a bill he or she does not understand or believe contains an error. "Or, a patient might get a bill for care that was needed because of a medication error, and the patient doesn't want to pay the extra costs," Binder says.

• Work with hospital boards when billing and equity policies are undergoing updates. "The business of healthcare is bound to the same ethical standards as the clinical side," Binder emphasizes. ■

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Some Consults Specifically Address Moral Distress

Since 2006, staff at Charlottesville, VA-based UVA Health have been able to request a consult specifically for moral distress.[1] "We have learned so much in the last 10 or 20 years about what moral distress is, and why it's important to recognize and intervene," says **Beth Epstein**, PhD, RN, HEC-C, FAAN, associate professor and interim director of academic programs at UVA School of Nursing and UVA Center for Health Humanities & Ethics.

To date, ethicists have conducted 115 consults. To obtain data on the usefulness of the Moral Distress Consultation Service, Epstein and colleagues recently analyzed 21 consults and interviewed the participants.[2] "We hoped that our study would give others some ideas about addressing moral distress, and perhaps even [about] developing a similar service," Epstein says.

Only a small decrease in moral distress was found after consults. This finding was unexpected and somewhat disappointing. "But when we looked carefully at the quantitative and qualitative data, there were two reasons why we didn't see a big change," Epstein reports.

First, moral distress levels for some consult attendees were fairly low at presentation. "After spending an hour discussing the case, they realized how truly morally distressing the situation actually was, and left with higher levels of moral distress," Epstein says.

Others entered the consult with already-high levels of moral distress. After realizing colleagues shared similar concerns, and identifying some coping tactics, these participants reported lower levels of moral distress.

Second, at the end of the consult, the morally distressing situation remained ongoing. "The group has identified some actions to resolve the situation, but they haven't acted yet," Epstein notes.

Overall, participants found the consult service to be valuable as a way to figure out how to resolve difficult cases as a team. Participants also believed it was a demonstration that the organization values them. "We frequently get feedback from those who've attended consults that this is the case," Epstein says. "The consult service is a good mechanism for empowering clinicians to speak and act." One participant mentioned "no retribution or fear of other people thinking poorly of you."

The consult service seemed to affect the ICU more than non-ICU settings. "There could be several reasons for this," Epstein says.

One possibility is the causes of moral distress differ, depending on the setting. In the ICU, the issue often is prolonged aggressive treatment the clinical team believes is not in the patient's best interests. "The team can work on strategies that address that specific instance," Epstein offers.

In non-ICU settings, the issues tend to more broadly involve unit and system factors. Some of those consults focused on managing patients with aggressive behavioral issues. Trying to improve the way such cases are managed cannot happen without involvement from outside areas: security, behavioral medicine, or psychiatry. This adds complexity to the process. "When clinicians are already time-constrained,

fixing the problem can seem too big a task," Epstein observes.

Addressing moral distress is different than addressing ethical challenges, according to Epstein. She says awareness of these differences is important. Ethical challenges involve specifying the justifiable paths that could be taken, and a process to decide which is the "best right path." Moral distress challenges involve violations of professional obligations and constraints that inhibit healthcare providers from taking the right action.

During moral distress consults, ethical issues might arise. For instance, some consults involve a fully capable patient with metastatic cancer who requested no further treatment and wants to go home with hospice care. The patient's adult children demand she continue treatment, refuse to take her home, and threaten to call a lawyer if the team does not comply with their demands.

In this situation, the team may coax the patient to continue treatment, and the patient unenthusiastically complies. "She has tried to speak up for herself, but has not been heard," Epstein says. "During this consult, the ethical issue of respecting a patient's wishes arises." For this issue, an ethics consult would be appropriate.

Ethicists who want to pursue this at their own organizations can consult with the recently formed Moral Distress Consultation Collaborative. This is a group of 10 ethicists at six organizations who practice some form of moral distress consultation. "The goal is to conduct research and develop educational materials and competencies for clinical ethicists interested in addressing moral distress at their institutions," Epstein says. ■

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Ethics Tries to Keep Up with Quickly Evolving Stem Cell Research

Recently updated guidelines from the International Society for Stem Cell Research address many controversial, rapidly evolving areas.[1]

The 2021 guidelines offer specific recommendations for embryo research, stem cell embryo models, organoids, chimeras, germline genome editing, and mitochondrial replacement techniques. Public support for controversial research is an overarching goal. "If controversial areas of scientific biomedical research are not trusted by the public, then the benefits of this research are diminished," says **Amander Clark**, PhD, guidelines co-author and chair of the UCLA Department of Molecular, Cell, and Developmental Biology.

Ultimately, science aims to serve societal interests. "The ethical duty of beneficence extends beyond the purview of the physician. It also includes biomedical researchers hoping to make a positive impact on future developments in biomedicine," says **Insoo Hyun**, PhD, guidelines co-author and faculty member at the Harvard Medical School Center for Bioethics.

For preclinical research, clinical trials, and approval processes, it is important there are "no loopholes or gray areas or gaps. This is something that governments need to confront and address," says **Leigh Turner**, PhD, guidelines co-author and an associate professor at the University of Minnesota Center for Bioethics.

Stem cell research requires careful oversight to find out if it is safe and efficacious. "The burden is on researchers to generate that evidence, rather than just assume it," Turner says.

The 2021 guidelines include a new category: research that is not permitted now, but might be one day. "The 14-day rule is a good example of this," Clark offers. For jurisdictions that permit research with human embryos, the international consensus is embryos should not be cultured for longer than 14 days from the point of fertilization or formation of the primitive streak, whichever occurs first. This is known as the 14-day rule.

"In most jurisdictions, even those that are permissive to embryo culture rules, a scientific and ethical oversight process monitors experiments to ensure that the 14-day rule is observed," Clark says.

However, the formation of the primitive streak and the patterning of the embryo, which occur on and after the 14th day, are critical for embryo survival as well as healthy embryo and fetal development during pregnancy. "Therefore, studying these events using embryos cultured in vitro under appropriate regulatory oversight could help scientists understand and, therefore, develop treatments for devastating childhood disorders that begin before birth," Clark says.

Examples could include neural tube defects, heart defects, or neurological disorders.

The gestation and subsequent live birth of animal host embryos containing human stem cells (i.e., nonhuman chimeric embryos) is another example of research no one is actively pursuing, but might one day go forward. "Such research must be aimed at an important scientific question that is of clinical relevance for understanding human disease, and it must be carried out using the least complex animal embryo species," Hyun says.

Frequent examination of the chimeric embryo's developmental progress must be conducted along the way at defined points so there are no surprises when the chimeric animal is born. "This ensures that the human contribution is localized to the specific tissue type of clinical interest," Hyun explains.

The guidance also addresses the ongoing issue of businesses marketing stem cell products. These continue to proliferate across the United States. One can find these products in every state, with hot spots including Texas, Florida, and California.[2] This has been the case for years. "What's changed is the recognition of the extent that this is a serious problem for patient safety and public health," Turner says.[3,4]

To better regulate stem cell clinics, the FDA sent warning letters to hundreds of businesses, warning that they may be in violation of federal law, and sought permanent injunctions against several organizations.[5,6] "But while the FDA was taking action against some businesses, many more saw a commercial opportunity and set up shop," Turner notes.

Today, the FDA is confronted with a vastly bigger marketplace, with finite resources. "There's a limit to the number of businesses that can be dragged into court," Turner observes. "Some might decide to play the odds — and, in the meantime, can make a pile of money." ■

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Fewer Family Meetings in ICU Are Reason for Dissatisfaction

Supporting families faced with making critical decisions for incapacitated loved ones is a core ethical duty for ICU clinicians. "Yet little is known about family characteristics that predict their dissatisfaction with support during decision-making," says **David Y. Hwang**, MD, FAAN, FCCM, FNCS, an associate professor of neurology at Yale.

To learn more, Hwang and colleagues surveyed 355 family members at two academic medical centers.[1] Patients stayed an average 8.6 days. Families who decided to keep a patient as full code, without any treatment limitations, tended to be less satisfied. About half indicated they were dissatisfied with the amount of support available when difficult decisions needed to be made.

The researchers studied several factors to see which predicted dissatisfaction. Race, level of education, and prior ICU experience were not predictive of dissatisfaction. The only significant predictor of dissatisfaction with decision-making support was a family member reporting three or fewer family meetings during the ICU hospitalization. "If ethicists are involved in designing protocols and methods for improving decision-making support in ICUs, focusing on initiatives that increase families' perceptions of number of family meetings with the clinical team may be a worthwhile core strategy," Hwang says. ■

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Chaplains Report Receiving No Ethics Education

Chaplains often serve on ethics committees, as ethics consultants, and as institutional review board members. Yet there are no standardized ethics curricula in Clinical Pastoral Education (CPE) programs. "Chaplains' training in ethics varies a great deal," says the Rev. **David Fleenor**, STM, BCC, ACPE, director of education at the Center for Spirituality and Health at the Mount Sinai Icahn School of Medicine in New York City.

In reviewing the curriculum for the CPE residency program, Fleenor noted an insufficient focus on ethics. Three of the 31 competencies for board certification focus on ethics. Based on personal communications with committee leaders for chaplaincy certifying bodies, says Fleenor, "two of those three are frequently failed by board-certification candidates."

To prepare CPE residency graduates to become board-certified chaplains, "we needed to improve this area of the curriculum," Fleenor says. He contacted the Mount Sinai bioethics program "to learn what they taught and to whom."

An ethicist agreed to provide education to residents and also help develop appropriate curricula. Formerly, an ACPE-certified educator taught a 60-minute didactic on the basics of bioethics. "This only skimmed the surface," Fleenor says.

Once the ethicist agreed to teach in the CPE residency, 12 one-hour sessions were added. These cover important issues like confidentiality, justice, respect for autonomy, and assessing decisional capacity. "Our CPE residents now receive much more comprehensive coverage of ethics," Fleenor reports.

To find out more about how other programs teach ethics, Fleenor and colleagues recently surveyed 84 CPE residency program directors about their ethics curricula.[1] Seventy-three percent of programs included a required ethics component in their curriculum, 10% were in the process of developing one, and 18% included none. Among the programs that did include an ethics component, the amount of training varied widely.

"Some programs offer as little as occasional discussion of ethical situations that occur in spiritual care cases. Others offer formal ethics courses that run for 12 to 16 weeks," Fleenor says.

Fleenor suggests ethicists provide training to chaplains and spiritual care trainees and/or partner with ACPE-certified educators to teach CPE residents together. "While chaplains generally need to learn the same bioethics information as other healthcare professionals, they also have discipline-specific learning needs," Fleenor notes.

A few years ago, **M. Jeanne Wirpsa**, MA, BCC, HEC-C, created an ethics curriculum tailored to the unique role of the healthcare chaplain on the interprofessional care team. "The goal of the modules is not to prepare chaplains to become professional healthcare ethicists, though many of them will be tapped to lead ethics committees and conduct ethics consultations," says Wirpsa, a clinical ethicist and research chaplain at Northwestern Memorial Hospital in Chicago.

Rather, the hope is chaplains can contribute meaningfully to ethical care. "Chaplains are experts in communication; values-clarification; cultural awareness; and the impact of religious beliefs, emotions, family dynamics, and cultural practices on medical decision-making," Wirpsa says.

Chaplains often do not see the connection between this expertise and medical ethics. "When you look at the competencies and professional virtues outlined by the American Society for Bioethics and Humanities for ethics leaders and consultants, there is notable overlap with chaplaincy identity and training," Wirpsa says. The ability to consider competing perspectives is one example.

"Training in counseling and narrative approaches to medicine prepares chaplains to discern values, deeply held beliefs, and goals embedded in patient and family stories," Wirpsa explains.

At Northwestern Memorial, ethicists frequently partner with chaplains in complex cases where religious beliefs feature predominantly in an ethical conflict. Recently, a family stated

that "hope for a miracle" was their primary reason for continuing aggressive ICU care. A chaplain stepped in to acknowledge the family's religious beliefs and emotions, including grief and guilt.

"With time, the family member became ready to accept the patient's preference not to be kept alive on mechanical ventilation, even as she hoped God would perform a miracle when life support was discontinued," Wirpsa recalls.

Some families perceive their religious beliefs are at risk of violation during the delivery of healthcare. Chaplains offer respect and appreciation for what is at stake in these cases. "Chaplains serve as 'translators' between the medical team and patients and families," Wirpsa notes.

Solid ethics education adds to chaplains' foundational knowledge of religious traditions. For example, chaplains benefit from understanding that traditional Jewish ethics focuses on duties and relationships rather than individual rights. In some cases, this means the rabbi is the primary decision-maker authorized to apply relevant Jewish law to the specifics of the patient's situation. "Chaplains can intervene to ensure this alternative approach to decision-making is implemented," says Wirpsa.

As part of a study published in 2019, Wirpsa and colleagues surveyed 463 chaplains on their role of chaplains in medical decision-making.[2] "We discovered that chaplains need to have a 'seat at the table' to fully contribute," Wirpsa reports.

For example, chaplains should be included in family meetings and goals of care conversations. "It goes without saying that every ethics committee should include the unique lens of the healthcare chaplain," Wirpsa says.

When chaplains are tapped to lead ethics programs or ethics consultation services, they might need more training than they received during their residencies. Chaplains can take advantage of programs offering bioethics degrees or certification in healthcare ethics consultation. "A proliferation of online courses makes gaining this additional layer of skill and knowledge relatively accessible," Wirpsa adds. ■

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The Unique Characteristics of Surgical Consults

Ethics consults called by surgical specialties differ somewhat from consults called by other hospital specialties.[1]

During the research period of her residency at Weill Cornell Medicine in New York City, **Nicole Meredyth**, MD, decided to pursue a clinical ethics fellowship. Surgeons called ethics consults less often than other hospital areas. "It seemed like surgeons tried to work through difficult decision-making on their own, instead of consulting our ethics consultation team," Meredyth says.

Meredyth and colleagues set out to determine if this was the case. If so, why? "We believed this information would be relevant not only to surgeons, but also to ethics consultants," says **Inmaculada de Melo-Martin**, PhD, MS, the study co-author and professor of medical ethics at Weill Cornell Medical College.

Knowing the unique factors involved could help ethicists identify where surgeons most need their help. Researchers analyzed 548 consults (135 in surgical areas, 413 in nonsurgical areas) called between 2013 and 2018 at NYP Weill Cornell Medical Center. Most surgical consults were called for ICUs, as opposed to the floor or step-down (lower-acuity) units.

Surgical patients were less likely to have a DNR order in place (22.2%) than nonsurgical patients (37.5%). "Surgical patients have to be full code, typically, to undergo an operation, which is likely why these patients were less likely to have a DNR in place on their charts," Meredyth says.

Issues relating to withholding or withdrawing life-sustaining treatment came up more often in surgical consults than other hospital areas. "This is a common topic for ethics consultations in general," Meredyth says. However, an analysis of the ethics notes revealed some interesting nuances. Many surgical consults were called when patients or surrogates requested to withdraw life-sustaining treatment in the postoperative period. "Surgeons thought that such a request was premature, because there was still significant prognostic uncertainty both in terms of survival and quality of life," Meredyth reports.

For ethicists, these findings confirmed that different specialties face unique ethical issues. "It reminds ethics consultants that it is important to understand the context of the

ethics consultation and the culture of the specialty from which the consult arises," Meredyth says. ■

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Intensity of Treatment Is Common Issue in Consults for Solid Organ Transplant

Ethical questions on organ transplantation have focused mainly on resource allocation — access to transplantation and prioritization of donor organs. A recent analysis revealed few consults were called for questions about appropriate resource allocation.[1]

"The actual experience with ethics consultation in this population can reveal unanticipated complexities in organ allocation decisions and the care of transplant candidates and recipients," the authors wrote.

To learn more about reasons for ethics consults involving transplants, researchers analyzed all adult ethics consultations from 2007-2017 at Massachusetts General. Taken together (candidates and recipients), nurses and physicians requested consults with equal frequency. However, nurses called ethics consults for transplant recipients far more often than physicians (80% vs. 20% of cases).

"In their bedside role, clinical nurses may be more attuned to patient suffering and the burdens imposed by ongoing or escalating interventions," the authors wrote.

Nurses also spot communication breakdowns because of conversations with different medical services that happen throughout the day.

"There are particular complexities to transplant recipients that make them more susceptible to this type of breakdown," says **Andrew Courtwright**, MD, PhD, the study's lead author and an assistant professor of clinical medicine at University of Pennsylvania's Perelman School of Medicine.

Cases entail multiple providers, regulatory considerations about one-year survival, and high-intensity treatments. Of 880 ethics consults, 60 involved solid organ transplant (39 for candidates and 21 for recipients).

UNIT-BASED CONVERSATIONS ON ETHICAL ISSUES IN TRANSPLANT PATIENTS CAN HELP PREVENT CONFLICTS.

The most common issue differed, depending on whether the patient was a candidate or recipient.

For transplant candidates, the most common issue was conflict over treatment intensity once the patient was determined not to be a candidate for transplantation. For transplant recipients, the most common issue was a disagreement between surrogates and providers over intensity of treatment.

These usually are cases in which surrogates (or patients themselves) do not want to continue life-sustaining treatment after transplant because of ongoing burdens or quality of life. The transplant team wants to continue because they believe a good outcome is still possible.

"Our study has several implications for clinicians and bioethicists," Courtwright says.

The findings underscore the need for better communication — specifically, the expectations around the care of transplant candidates and recipients. For example, patients should talk about goals of care if it turns out transplant is not possible. "Only a third of patients undergoing transplant evaluation in our cohort had advance care planning documents," Courtwright reports.

Clear criteria regarding inactivation — when the patient is no longer a transplant candidate — also are needed, as well as specific benchmarks for reactivation.

"While flexibility is important in evolving clinical scenarios, shifting goals and a perceived lack of transparency may increase moral distress," Courtwright and colleagues wrote.

Unit-based conversations on specific ethical issues in transplant patients can help prevent conflicts and "may provide a forum for giving voice to ethical concerns before formal ethical consultation is needed," the authors added. ■

REFERENCE

1. Courtwright AM, Erler KS, Bandini JI, et al. Ethics consultation for adult solid organ transplantation candidates and recipients: A single centre experience. *J Bioeth Inq*. 2021. https://bit.ly/3g7InN7

Ethical Obstacles When Securing Informed Consent for ICU Research

Usually, there is plenty of time for patients or families to decide if they want to be involved in a clinical trial, and there is adequate time for a thorough informed consent process. "It's a bit different in the ICU," says **Trevor Lane**, MD, pulmonologist and critical care fellow at the University of Colorado.

A family member suddenly goes on a ventilator, and the family is immediately asked, "Do you want CPR if the patient goes into cardiac arrest?"

"Then, hours later, they are asked about participation in a research study," Lane says. "People have information overload."

What makes it even more challenging is patients often are unconscious and lack decision-making capacity. Therefore, the decision on whether to enroll falls to the patient's surrogate decision-maker. "The whole process of how informed consent is undertaken in the ICU is very variable," Lane observes.

Lane and colleagues interviewed surrogates of critically ill patients on ventilators about participation in hypothetical research studies.[1] "The motivation is to create the most optimal, ethical informed consent situation," Lane explains.

In this study, 21 out of 34 surrogates approached agreed to participate. If someone declined to participate, busy research coordinators quickly moved to someone else. "Our study highlights the need to capture more data on why people decline consent," Lane offers. "This would be tremendously helpful."

The study's findings suggest trust is a major factor in decision-making. One surrogate put it this way: "We've gone to this hospital for a long time, and if you think it's a good idea, we're on board."

Others said they decided to participate based on the fact the inpatient team thought it was OK for the researchers to approach the family (the treating physician gave permission for the research team to approach the patient or family).

Some surrogates talked about trusting the research would in some way help their loved ones. This revealed a common misconception: If the patient participated, he or she will get better care.

"Of course, we hope that the research we do will result in that. The reality is that often times it doesn't," Lane laments. To clear this up, researchers explained it is possible the patient will be randomized to the control group or receive a placebo.

Other surrogates based their decision on the severity of the patient's condition. "ICU patients are quite sick, and some are near death. The family may think, 'if there's a Hail Mary out there, I want to try it.' Or, they might not want to take any additional risk because things are already so dicey," Lane says.

Still others wanted to learn about the researchers before deciding. "One surrogate talked about not wanting to be just a number," Lane recalls.

Sadly, time does not permit this. Participation decisions usually need to be made in one or two days. "Many ICU studies need data from the first day or two of the ICU stay, when patients are first put on ventilators or sepsis patients are first given fluids or antibiotics," Lane explains.

Many participants expressed a strong sense of altruism. One surrogate talked about how she benefited from research as a pediatric cancer patient, and would not be alive today if it was not for others consenting to research. "We heard from different people that 'If it's not very high risk, then it makes sense for me to give back,'" Lane says.

The goal is not to just increase consent rates. "It's to ensure that this is truly an ethical process, and that surrogates can make the best decision with substituted judgment for the patient," Lane says.

Surrogate decision-makers are not always immediately available to

give consent. Some just do not feel comfortable making the decision to enroll their loved one in clinical research. "Because trial interventions must be started quickly in some cases, decision-making can be further complicated by considerable time pressure," says **William B. Feldman**, MD, DPhil, MPH, member of the ethics committee at Brigham and Women's Hospital in Boston.

Clinical trial investigators must ensure patients and surrogates have ample time to ask questions and understand the proposed research. "Respecting individual autonomy in these acute settings requires both skill and commitment by clinical trial investigators," Feldman says.

If the potential patient/subject is incapacitated, investigators "need to recognize this subject requires special protections by virtue of their inability to express their autonomous decisions to participate and/or voluntarily withdraw from a study," says **Julie M. Aultman**, PhD, director of the medical ethics and humanities program at Northeast Ohio Medical University in Rootstown.

Considering the vulnerability of this population, Aultman recommends these practices for investigators and institutional review boards:

• The risks and benefits of the study should be weighed carefully, determining whether risks to potential subjects are ethically justified and whether benefits are therapeutically beneficial to subjects.

• If a study might produce direct, therapeutic benefits, and the patient/subject can consent, he or she should be fully informed about possibly losing capacity at some point to ask questions or voluntarily withdraw. "Then, in such cases, the subject ought to decide whether to permit investigators to continue the therapeutic study while they are incapacitated," Aultman says.

• If the subject wishes to participate when he or she becomes incapacitated, there should be a process by which investigators use a waiver of consent or involve a proxy or surrogate decision-maker.

• If a subject never had capacity to consent at the start of a study, but the study involves interventions that provide direct benefits with minimal risks or risks that are reasonable in relation to the anticipated benefits, then a waiver of consent (for emergency, urgent, or time-critical situations) and/or a designated proxy should be involved.

• If there is a designated proxy or surrogate decision-maker, that individual should be fully informed at the start of the study and participate in the consent process.

• It should be noted that next of kin or a surrogate decision-maker may not be able to provide informed consent due to emotional or psychological distress associated with a loved one staying in the ICU.

"Some are simply not readily and physically available," Aultman notes. "Thus, investigators should be mindful that a study might not be able to continue for these reasons."

• Investigators should ensure the proxy is acting on behalf of the patient/subject, using substituted judgment or the best interest standard.

"The surrogate should not be making decisions based on their own values and interests," Aultman underscores. ■

REFERENCE

1. Lane T, Brereton E, Nowels C, et al. Surrogate informed consent: A qualitative analysis of surrogate decision-makers' perspectives. *Ann Am Thorac Soc* 2021; Feb 2. doi: 10.1513/AnnalsATS.202007-851OC. [Online ahead of print].

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Upon completion of this educational activity, participants should be able to:

1. Discuss new developments in regulation and healthcare system approaches to bioethical issues applicable to specific healthcare systems;
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CME/CE QUESTIONS

1. **Which is true regarding surgical ethics consults?**

   a. Surgical areas call ethics consults more often than nonsurgical areas.
   b. Surgical patients were more likely to have a DNR order than nonsurgical patients.
   c. Conflicts over withholding life-sustaining treatment came up less often in surgical areas than nonsurgical areas.
   d. Conflicts over requests to withdraw treatment in the postoperative period were common.

2. **Which did the authors of a study find regarding organ transplant-related ethics consults?**

   a. Almost all consults for transplant recipients were requested by physicians.
   b. Most ethics consults involved prioritization of donor organs.
   c. For transplant recipients, the most common issue was disagreement over treatment intensity.
   d. Early discussions with patients on goals of care (if it turns out that transplant is not possible) increased subsequent conflicts.

3. **Which is true regarding updated guidelines for stem cell research?**

   a. The consensus is embryos can be cultured for longer than 14 days from the point of fertilization without oversight.
   b. No one is actively pursuing research on nonhuman chimeric embryos.
   c. Use of embryos cultured in vitro is no longer permitted, even with appropriate regulatory oversight.
   d. The FDA has sought permanent injunctions against all businesses marketing unproven stem cell products in the United States.

4. **Which factor was linked to family dissatisfaction with ICU decision-making?**

   a. The patient's race
   b. Surrogates with a higher level of education
   c. Three or fewer family meetings during the ICU hospitalization
   d. A prior ICU admission in the previous year

5. **Which is true regarding chaplains' ethics training?**

   a. None of the competencies for board certification focus on ethics.
   b. The amount of ethics training varies widely in CPE residency programs.
   c. All CPE residency programs include a required ethics component.
   d. At least 12 hour-long sessions of ethics education are required for board certification.