MEDICAL ETHICS ADVISOR®

YOUR PRACTICAL GUIDE TO ETHICS DECISION-MAKING

FEBRUARY 2021 Vol. 37, No. 2; p. 13-24

INSIDE

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Policy on Inappropriate Treatment Used in 25% of Ethics Consults

The family wants clinicians to do everything possible, but clinicians believe continued treatment would only result in extended suffering for a dying patient. Most hospitals have instituted policies to address these difficult cases.

"This is especially true among academic medical centers, where cases involving alleged inappropriate treatment are often transferred from community hospitals," says **Thaddeus Mason Pope**, JD, PhD, HEC-C, professor of law at Mitchell Hamline School of Law in St. Paul, MN.

Ethicists used a policy on inappropriate treatment in one-quarter of consults, according to an analysis of a volunteer ethics committee's work.[1] The hospital's conscientious practice policy was used in 42 of 178 consultations between 2013 and 2018. "This suggests that providers are looking for definitive tools, in addition to the ethics committee, to help resolve these difficult end-of-life cases," says **Bryan Kaps**, MD, MHS, the study's lead author. Many hospital policies reflect professional society policy statements.[2]

"Because most of those documents focus on consensus-building, so do most hospital policies," Pope explains.

> PROVIDERS ARE LOOKING FOR TOOLS TO RESOLVE DIFFCULT END-OF-LIFE CASES.

Most recommend seeking an outside second opinion involving a clinical ethics consultant, and convening a multidisciplinary committee to review the case.

"Only a subset of inappropriate treatment policies permit clinicians to withhold or withdraw treatment without surrogate consent," Pope notes.

Usually, this happens only after committee review and an opportunity to transfer to a facility willing to provide the disputed treatment.

"Policies on inappropriate treatment are not needed for conflicts over

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MEDICAL ETHICS ADVISOR®

***Medical Ethics Advisor®*, ISSN 0886-0653, is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Medical Ethics Advisor*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.**

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brain death, which are increasingly common," Pope says.

In those cases, both legal and ethical standards are clear. Clinicians and hospitals are not obligated to treat after a determination and declaration of death, other than affording a brief (often less than 24 hours) period of accommodation. Policies are most helpful when the patient is permanently unconscious (or otherwise catastrophically critically ill) with no chance of recovery or discharge from the ICU.

Clinicians find it helpful to be able to point to a policy if the family demands life-sustaining interventions in that situation. Some policies require the approval of the facility vice president of medical affairs or chief medical officer.

"Yet that official will sometimes not authorize withholding or withdrawal of treatment over family objections," Pope says.

Ethicists can help families and clinicians reach a consensus. "But even attending physicians decline to use inappropriate treatment policies in intractable disputes," Pope says.

There are no data on how many hospitals have created a policy on addressing requests for inappropriate treatment.

"There's also a big difference between having a policy on the books, and having a policy that providers are aware of and look to when making clinical decisions," says **Alison E. Turnbull**, DVM, MPH, PhD, an assistant professor in the division of pulmonary and critical care medicine at Johns Hopkins University.

Policies are invoked most frequently when clinicians do not want to initiate a form of life support (e.g., intubation, continuous veno-venous hemodialysis, or extracorporeal membrane oxygenation) that may prolong a patient's life but will not heal their underlying terminal condition or permit them to live outside the ICU ever again. Ideally, ethicists would have been involved in the case early to avoid conflict before it becomes intractable.

Often, though, ethicists' role is as part of the committee that is convened after the conflict resolution process has failed. At that point, a second medical opinion has been obtained already.

"That committee should convene promptly, review the case, and generate a written document that includes recommendations and rationale," Turnbull suggests. ■

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COMING IN FUTURE MONTHS

- Sharing ethics consultation notes with patients and families
- Some lawsuits allege advance directive was not followed
- Ethicists are comparing consult data with other institutions
- Preparing ICU nurses to handle ethical challenges

Ethics Consultants Want More Training for First Jobs

Graduates of a clinical ethics fellowship would have liked better preparation for their first job in some areas, according to a recent survey.[1]

"The idea for this study arose when a couple of the authors were sitting in a meeting talking about whether clinical bioethics fellowship programs should be accredited," says **Douglas S. Diekema**, MD, MPH, one of the study's authors.

The group disagreed on what accreditation should include, largely because of how different their programs were from one another. "We really didn't have a good idea of how diverse the various programs were, and whether they were meeting the needs of their graduates," says Diekema, an attending physician and director of education for the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Hospital.

Diekema and colleagues surveyed 45 graduating fellows. For some programs, ethical theory was not a focus because the authors assumed fellows already underwent that training. Other fellowships did an excellent job teaching applied ethics, but general theory was not covered much. "I was surprised at just how little standardization and similarity there is from one program to another," Diekema observes.

Medical residency programs differ in small ways, but are fairly consistent from one institution to the next. "By and large, they follow the same basic template in terms of learning experiences," Diekema notes. "That did not seem to be the case in clinical bioethics training programs."

Clinical bioethics training programs serve a wide variety of individuals, some with clinical backgrounds, others with PhDs. "Most graduates indicated that their basic training in ethics was adequate," Diekema says. Still, many wanted more training in quality improvement skills, including some exposure to quality improvement methodology. They also wanted to learn how to negotiate for resources and how to communicate with hospital leadership.

Yale New Haven (CT) Hospital's ethics committee surveyed 22 of its members recently about their top priorities. Most (78%) said creating a packet of key ethics readings was a top priority, and 56% named ethics training as a top priority. "We've been particularly focused on education in ethics theory and clinical ethics best practices, including frameworks for approaching common consult questions," says **Benjamin Tolchin**, MD, MS, co-chair of the adult ethics committee at Yale New Haven Hospital and assistant professor of neurology at the Yale School of Medicine.

The overarching goal is to ensure consistent, high-quality practices are used by all of the health system's ethics consultants. "We have also been working with the healthcare system administration much more closely during the pandemic," Tolchin reports.

Ethicists have developed and implemented system policies, including crisis standards of care triage. "This has definitely been a learning experience for us as we've become involved in organizational ethics," Tolchin says.

Ethicists had to achieve consensus with a much broader range of stakeholders than they normally do during traditional clinical ethics consults. Building on these new relationships, ethicists began collaborating with health disparity researchers. "We wanted to assess the outcomes of new hospital policies — in particular, to ensure that they do not propagate or exacerbate racial or socioeconomic health disparities," Tolchin explains. The ethics committee made these other changes to improve member training:

• Members are encouraged to obtain the American Society for Bioethics and Humanities Healthcare Ethics Consultant-Certification (HEC-C). Two committee co-chairs recently completed the exam, and a third member is preparing. The goal is for at least one ethicist participating in every consultation to earn the HEC-C.

"The idea is for this team leader to mentor junior team members, and to ensure that consultations meet national guidelines and best practices," Tolchin says.

• Ethicists participate in short, focused sessions based on topics from previous cases. Recent topics included standards for surrogate decision-making, medical care for underrepresented patients, and accommodating religious faiths and the hope for miracles among patients and families.

• The committee started engaging in ethics case simulations. "We intend to simulate very standard 'bread-and-butter' clinical ethics cases," Tolchin says.

One example is a family meeting during which some (but not all) adult children of an intubated patient ask for life-prolonging care the clinical team believes to be extremely unlikely to benefit the patient. "The goal here

is not to introduce complex ethical topics, but to give newer committee members a chance to practice basic clinical ethics and communication skills," Tolchin says.

Training of individuals performing clinical ethics consults depends in large part on available resources. Consult services that can hire full- or part-time clinical ethicists likely will employ individuals formally trained in bioethics.

"These individuals are going to have at least a masters-level education; often, a degree in bioethics or a field related to bioethics; and will have engaged in coursework, practica, or fellowships that directly relate to the knowledge and skills needed for consults," says **Erica K. Salter**, PhD, HEC-C, associate professor and PhD program director of healthcare ethics at Saint Louis (MO) University.

Graduate-level training in bioethics ideally includes common clinical ethics topics and the steps of an ethics consult, mediation, and communication. Clinical ethics practica and fellowships offer the chance to observe and participate in actual ethics consults. "A majority of ethics consult services do not have a significant budget," Salter notes.

Most are staffed by volunteer members, likely without any formal training in how to handle consults. "Most training of these individuals will, by necessity, be on-the-job training," Salter explains.

Many committees offer short workshops or training sessions to cover the basic steps of how to complete a consult, what to document, and how to follow up, or an apprenticeship model, with new consultants shadowing experienced consultants.

"Some institutions will have the budget to send new consultants to conferences, workshops, or certificate programs for additional intensive training," Salter says. Two other areas are overlooked frequently:

• **The skills of effective literature review.** Ethicists need the ability to find and apply the most recent and relevant scholarly literature to analyze cases and justify recommendations. "These skills are typically a strength of formal ethics education, and a weakness of on-the-job ethics training," Salter says.

• **Mediation skills, which emphasize the importance of conflict resolution and interpersonal communication.** "So much of an effective consult depends on relationship-building and good communication," Salter observes. "We often forget that these skills can be learned and practiced."

Ethicists and skilled communicators engage in simulated mediations, playing the roles of clinicians or family members. The session ends with a debriefing during which the mediator's choices and tactics are discussed. "Trainees practice the skills of bioethics mediation, and view dilemmas from various perspectives and moral positions," Salter adds. ■

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Consultants Need Preparation for Common Ethics Challenges

The American Society for Bioethics and Humanities' Core Competencies for Healthcare Ethics Consultation was meant to address persistent concerns about training clinical ethics consultants.[1] "But there is still work to do to standardize training programs across the country," says **Seema K. Shah**, JD, founder's board professor of medical ethics in the department of pediatrics at Northwestern University.

Shah says shadowing experienced ethics consultants and participating in debriefings after consults with other members of the ethics team are top priorities for ethics training.

Training to adequately prepare someone to perform ethics consults "depends on how the consults are run," says **Rosamond Rhodes**, PhD, director of bioethics education at Icahn School of Medicine at Mount Sinai in New York City. Where a team of people are consulting together, at least one person should have undergone significant training and experience in medical ethics, "but the other members of the team can have their medical experience as a basis," Rhodes says.

If an individual is consulting alone, that person will need significant and focused training in ethics. "A degree in philosophy is not sufficient. A certificate program or week-long course in bioethics is not sufficient," Rhodes stresses. "Just being able to recite the four principles of bioethics is certainly inadequate."

Rhodes is associate director of Clarkson University's bioethics

program. There, in addition to theoretical courses, clinical ethics trainees complete two semester-long courses in case analysis and learn a methodology for approaching clinical ethics dilemmas. Trainees learn to elicit factual information about the case, and how to go about analyzing the ethical issues.

"What we use for teaching is a structured methodology for how to go through a clinical ethics consultation," Rhodes says.

First, trainees must know how to identify the ethics question that is at issue. "That is really hard for a lot of people," Rhodes acknowledges. "The clinical ethics question should involve the word 'should.' Because we are talking about ethics, it's not how many or when; it's 'What should we do?'"

Ethics consults are called because two different values are in conflict, and clinicians are looking for direction on what to do. "You need to be able to use the factual information to support reasons for going one way or another," Rhodes says.

That involves an in-depth conversation, typically 30 minutes to an hour. "Like anything else, the more you do it, the better you get," Rhodes says.

To prepare trainees to handle actual ethics consults, the program provides a week of intensive training focused on about 20 real cases. Several involve role-playing, with actors playing the part of patients, family members, and clinicians. "I believe this level of intensive, skill-based training is unique to our program," Rhodes offers.

Classmates observe one another. Experts in ethics and communication skills critique what they see. "Even though we have increased the case analysis training as much as the schedule allows, our trainees always want more and more experience," Rhodes says. These are some of the case scenarios used to prepare trainees:

• **Decisional capacity.** The ethicist does not have legal authority to assess someone's capacity, but has to recognize the need to involve someone who does. "You might need to get the psychiatrist on staff to make a determination, either globally or for a specific decision," Rhodes observes.

Depending on state law, any licensed physician or several clinicians who have interacted with the patient might be able to make the determination on capacity. "A patient may be somewhat impaired, but still have the capacity to make the specific decision that's in front of them," Rhodes notes. "Sometimes, it's the surrogate who lacks capacity."

• **No capacity, no surrogates.** With "unbefriended" patients, "you need a good idea of their prognosis and condition, and the legal constraints on the kind of decisions you can make on their behalf," Rhodes says.

• **Surrogate requests the clinical team believes are inappropriate.** The ethicist has to evaluate the surrogate's concern for the patient. "You don't have to think that the patient's life is the only thing that matters, but you do have to have a reasonable concern for the patient's well-being," Rhodes explains.

The central concern for ethicists is whether the surrogate's decision is reasonable. A decision to not give pain medication to a terminally ill patient who clearly is suffering greatly is not reasonable.

"We are not accepting that decision. It is inhumane," Rhodes says.

• **Refusal of treatment.** The ethicist needs to be able to assess when clinicians are entitled to impose treatment over the patient's objection, and when they are not. "It takes a lot of understanding of what you're entitled to force on somebody," Rhodes notes.

Refusals can range from something relatively inconsequential to a condition that is highly treatable but will otherwise result in death. An extreme example would be a patient with strangulated hernia who will die without surgery, but most likely will see a full recovery with surgery. The ethical question is: Is the team justified in imposing treatment over the patient's objection because the patient will otherwise die?

"You have to have the authority to explain to the team why what the patient is saying is not a good enough reason. You need a lot of background information to be able to do that. It's rather a daunting task," Rhodes admits.

Some patients refuse dialysis, even though it would allow them to continue living many years. In other consults, the ethics question is whether it is OK to impose artificial feeding, or what to do if patients want to leave the hospital against medical advice.

"The consult should involve people with the needed expertise, and a lot of social work intervention, to arrange a safe discharge," Rhodes says.

In all these "refusal" cases, the ethicist must consider: How great is the benefit? How likely is the benefit with treatment? How great is the harm without treatment? How likely is the harm? "You have to be able to synthesize all this with your reasons, and explain it to the team that wants your input," Rhodes says.

• **Multiple surrogates with different opinions.** Rhodes says it is useful to ask a small group to meet with all the surrogates. At first, ethicists talk about the patient, rather

than the decision at hand. Next, ethicists ask each surrogate if the patient ever talked about medical decision-making.

"This can take hours. But usually by the end of the conversations, there is a resolution without anybody pushing things," Rhodes says.

• A conflict between the surrogate and the clinical team. Some surrogates really care about the patient and want something that is in the patient's interest, but the doctor thinks something else is appropriate. "Sometimes, you might have to adjudicate between the doctor and the surrogate," Rhodes says.

The clinician's core beliefs may need to be challenged. Clinicians might think they would never want to live in the same condition as their patient, and that they would find it unacceptable and deplorable. The patient cannot communicate, and the family wants life to continue.

"This is a place where the decision isn't made by the clinician's values and goals, but by societal limits on what's acceptable," Rhodes explains.

• Futility and withdrawal of life-sustaining interventions (e.g., turning off pacemakers). The ethical question might be framed in terms of prolonging life, or in terms of ending life. The ethicist might have to convey to the clinical team that in this particular case, it is simply not their call.

"Ethicists may need to say, 'This is a legitimate place for the family to make a decision,' and talk about how far we have to go to accommodate the family," Rhodes suggests. Even after intensive training, it is questionable that trainees truly have learned enough to handle all the conversations and judgments involved in varied and complex cases. "We try hard in our program. To me, it doesn't feel like it's enough, but it's probably as far as we can go in training," Rhodes adds. ■

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Palliative Care Encounters Ethical Conflicts: Consistent Communication Is Key

Palliative care specialists encounter a wide range of ethical challenges in their day-to-day practice, such as navigating institutional policies, interprofessional conflicts, and resource allocation, according to a review of 13 studies from nine countries.[1]

"My hope is that our research will help provide a robust evidence base from which others can design ethical resources for palliative care practitioners," says **Guy Schofield**, MD, the study's lead author and a clinical research fellow at the Centre for Ethics in Medicine at Bristol Medical School in the United Kingdom.

The study's findings show the range of ethical challenges palliative care practitioners face is "far broader than people might first think," Schofield adds.

Palliative care specialists often become involved in difficult goals-of-care decisions with families of hospitalized patients who are incapacitated with a poor prognosis, says **David Y. Hwang**, MD, FAAN(Neurology), FCCM, FNCS, an associate professor in the division of neurocritical care and emergency neurology at the Yale School of Medicine.

At Yale New Haven Hospital, if a clinical team experiences conflict with a family over a request for potentially inappropriate care at the end of life, and is calling the ethics team for consultation, the palliative care consult team also becomes involved. In a typical case, the clinical team believes it would be in an intubated, brain-injured patient's best interest to switch to comfort measures, but the family is insistent on continuing aggressive care. "It is helpful for all teams involved in caring for a patient to huddle before family meetings and ensure that all are on the same page," Hwang offers.

It can be difficult to coordinate schedules for all busy team members. Someone from the primary team has to contact all the involved parties, including the family. That person has to sort out when everyone can meet. "But it is invaluable in making sure that communication is consistent among all parties," Hwang adds.

In the neurological ICU, "goals of care" conflicts arise occasionally. "We have had situations where miscommunication among all teams — not just palliative care and ethics, but the primary team as well — has inadvertently happened," Hwang laments. This makes maintaining trust with the family difficult. In one recent

case, an attending who was caring for a patient with a poor prognosis was under the impression the ethics team had recommended hospital protocol be initiated to withdraw care against a family's request. A second attending (who took over for the first attending) communicated that recommendation to the family.

The second attending later learned that, in fact, the ethics team had not yet rendered a final, formal opinion. This miscommunication complicated subsequent discussions with the family. "The effort that is paid in trying to ensure all clinical teams are on the same page is well worth it," Hwang stresses.

"There is a good deal of cross-pollination that occurs between the disciplines of palliative care and clinical ethics," says **Richard Sams**, MD, an associate professor in the department of family medicine and the Center for Bioethics & Health Policy at Augusta (GA) University.

Palliative care providers are members of ethics committees and oversee clinical ethics programs. "Common ethical dilemmas occur at the fringes of life, both at the beginning and near the end," Sams notes.

Non-beneficial treatments, advance directives, surrogate decision-makers, and requests for physician-assisted suicide are examples of ethical issues that also involve palliative care. "Where palliative care services are not available, there are many more ethics consults due to the moral distress of the treating team caused by non-beneficial treatments," Sams observes. A robust palliative care program identifies goals of care and adequately addresses suffering. This results in fewer ethics consults.

"Clinical ethicists can support palliative care services by providing an additional voice to especially complicated clinical-ethical cases," Sams adds. ■

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Ethical Concerns if Clinical Trial Results Go Unreported

Many clinical trial results are never published or publicly reported, raising ethical concerns about transparency of the findings.

A 2020 court ruling addressed this long-standing issue by requiring clinical trial sponsors to report missing data for trials conducted between 2007 and 2017 to ClinicalTrials.gov, a public database.[1] "The failure to report trial results is the betrayal of the participants and a skewing of the evidence that the public can see," says **Harlan Krumholz**, MD, director of the Center for Outcomes Research and Evaluation at Yale. When results are not reported, "it undoes the implicit pact between researcher and study participant," Krumholz adds.

Study participants believe investigators are conducting their research to promote the public good and scientific advancement. But leaving trial data unpublished creates its own kind of bias, possibly harming the public. "This has the potential of leading people to incorrect conclusions about the evidence. In this case, evidence has been created, but hidden from public view," Krumholz explains.

Patients who participate in clinical trials often do so out of a spirit of altruism. Participants are looking to "pay it forward" so future patients can benefit from new knowledge. "When trials go unpublished, it disenfranchises these patients," says **Erick Turner**, MD, associate professor of psychiatry at OHSU School of Medicine in Portland, OR.

If critical evidence remains unpublished that could leave the false impression a drug is efficacious and safe, which is misleading to clinicians and patients. Notably, the 2020 court ruling addresses only the issue of reporting in the ClinicalTrials.gov database. The court did not address reporting in medical journal articles, where drug companies are free to publish or not as they see fit.

"Of those that are published, they are free to put 'lipstick on a pig' and make a negative trial look positive," Turner says. Since, in contrast, ClinicalTrials.gov requires all trial results to be published, it provides a "useful reality check on what appears in journal articles," Turner adds.

Patients are more likely to use ineffective or harmful treatments if clinical trial data are selectively reported. "When the answer to a question is known, but the answer is hidden from public view, researchers will enroll patients in experiments that don't need to be done," says **Evan Mayo-Wilson**, MPA, DPhil, an

associate professor in the department of epidemiology and biostatistics at Indiana University School of Public Health-Bloomington. That wastes time and money — and it also is unethical, because it exposes patients to avoidable harm. "Many organizations are reporting trial results because it's the right thing to do," Mayo-Wilson observes. "This ruling is an important step forward, and I hope manufacturers and universities will comply."

To date, the FDA has not exercised its authority to issue civil monetary penalties to manufacturers and other organizations that fail to report trials of regulated products. The National Institutes of Health also can withhold funding from grantees that do not report trial results, including universities and academic medical centers. "This ruling is a reminder that penalties for noncompliance are long overdue," Mayo-Wilson says.

Public awareness of this issue seems to be growing. "Across disciplines, scientists are facing essentially the same problem; that is, scientists test a lot of hypotheses and disproportionately report those tests with positive results," Mayo-Wilson explains. This happens whether the hypothesis is about the effect of a drug, the association between eating red meat and cancer, or the effect of body language on self-confidence. Because scientists do not report all tests with "negative" results, it appears as though their hypotheses are true more often than is the case. "We need to replace our current norms and incentives with ones that foster transparent and open science," Mayo-Wilson says. ■

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Evolving Ethics of 'Right to Try' Unproven Drugs

Ethical concerns persist regarding seriously ill patients who want the chance to try unproven, unapproved drugs.

"'Right to try' refers to the ethical intuition that persons should be free to access pharmaceuticals, just as they should be free to refuse medical interventions of all kinds," says **Michael Brodrick**, PhD, a philosopher at the Institute for Humane Studies at George Mason University in Fairfax, VA. "The freedom to choose an intervention is just the reciprocal of the freedom to refuse it. The right to refuse medical treatment arguably includes the right to access pharmaceuticals."

However, the right to refuse treatment is firmly established in U.S. law. In contrast, an array of laws and regulations prohibit persons from accessing pharmaceuticals. "Those laws and regulations, therefore, raise ethical concerns," Brodrick notes. On the other hand, legislation purporting to create a legal right to access pharmaceuticals whose safety and efficacy has not been established raises other ethical concerns. A proposed rule would require companies to report serious adverse effects annually under the 2018 Right to Try Act.[1]

However, there is no enforcement mechanism for reporting the serious adverse events, and there is no guarantee manufacturers will be compliant, says **Lisa Kearns**, MS, MA, a senior research associate in the division of medical ethics at NYU School of Medicine and a member of its Working Group on Compassionate Use and Pre-approval Access.

Although FDA approval is not needed under the right to try requirements, the treating physician still has to secure approval from the drug manufacturer. "The manufacturer won't be excited about doing that, for several reasons," says **Gail Van Norman**, MD, adjunct professor in the University of Washington Medicine's department of bioethics and humanities. First, the drug manufacturer has to complete certain studies to receive market approval. "Typically, they start with healthy people as opposed to seriously ill people who are more likely to have adverse outcomes," Van Norman observes. "There are also concerns about liability if there are unexpected serious outcomes."[2]

One ethical concern is that most people overestimate the odds researchers will determine an experimental drug is safe and effective. "When a drug is in its early investigational phase, the odds that it will ever be approved are very small, about one in 10," Van Norman says.[3]

Manufacturers could unintentionally exploit or mislead vulnerable people desperate for cures. "It can be easy to overplay the potential efficacy of your drug," Van Norman says. "There's an element of bias and wishful thinking."

Individuals looking for cures do not automatically become incompetent to make risky decisions on their own behalf. "People taking on personal risks in their own self-interest is a balancing act, ethically. It is very situational-dependent," Van Norman explains.

Individual rights to try an unproven drug must be balanced with the public good. "Enough people seeking right to try could potentially deplete supplies of the drug meant for

studies," Norman offers. Also, if an adverse event occurs in a patient who took the drug outside a clinical trial, it could lead to negative repercussions for eventual drug availability. "Investors funding that trial might get nervous and stop supporting that drug in development," Kearns explains.

Right to try also could divert patients away from participating in clinical trials. "That could slow the careful vetting process that must be completed before a new drug can be approved for sale," Brodrick says.

The Right to Try Act was "unnecessary in the first place," according to Kearns. Terminally or seriously ill patients have had the ability to access investigational drugs via the FDA Expanded Access (EA) pathway for decades.[4] "The Right to Try Act, in a sense, amended the FDA program by eliminating crucial patient safeguards," Kearns argues.

FDA's experienced, expert reviewers are best positioned to know whether an investigational drug could cause harm to patients because they can access confidential information about the drug (and similar drugs in development) that no one else can. "Right to try also eliminates institutional review board oversight of both the treatment protocol and — so important — informed consent," Kearns says.

Although right to try does require informed consent, it does not specify what consent must include. In contrast, the FDA EA pathway mandates that consent align with Code of Federal Regulations requirements.

Additionally, while right to try prohibits charging more than direct costs for investigational products, it provides no enforcement mechanism for this. In contrast, the FDA program requires documentation of charges to ensure drug manufacturers are not profiting from providing preapproval access.

"Without an oversight body monitoring charging, right to try leaves the door wide open to unscrupulous actors. Patients could be charged anything at all," Kearns warns.

Truly informed consent is difficult to achieve for terminally ill patients seeking access to drugs that have only completed the first phase of clinical trials. Little data on safety (and almost none on efficacy) are available. "According to some experts, consent forms should, among other things, state that the drug is experimental and has not been approved by the FDA," Brodrick says.[5]

Safety and efficacy information, if available, and any potential risks and benefits should be disclosed. Alternative options, including palliative care, should be mentioned. Patients who might be eligible for clinical trials should be informed of them. "Finally, consent forms should disclose the cost of the drug and any financial risks to the patient," Brodrick adds.

Right to try "intentionally errs on the side of removing potential access barriers while allowing patients to assume greater risk of being harmed by unapproved drugs," Brodrick explains. However, state laws that do not conflict with federal law could provide for third-party oversight of right to try requests.

Drug companies and medical institutions also are adding oversight requirements to the right to try pathway. "Given the coexistence of these two pathways and the different ethical tradeoffs they present, medical institutions and drug companies will have to decide which pathway they should require, or whether they should offer both options," Brodrick says. ■

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Community-Led Research Bolstered by Access to Big Data

Segments of the population with the lowest health status are unlikely to be able to take advantage of the benefits of big data, says **Megan Doerr**, MS, LGC, principal scientist at Seattle-based Sage Bionetworks.

Doerr and colleagues researched this closer.[1] "We were thinking about efforts in citizen science and patient-led science, and the research needs of ethnically diverse communities," Doerr says.

How should one use big data to move beyond community

engagement to the point where research actually was community-led? The researchers interviewed 16 community leaders about their opinions on about big data, with varying levels of research participation. Some had already participated in robust collaborations with traditional research institutions.

"Some had struck out on their own, leading citizen science investigations, and others were just getting their feet wet in the research ecosystem," Doerr reports.

Some were suspicious of big data, labeling it elitist and exploitative, expressing frustration that they could not get access to its supposed benefits. A few talked about feeling like they had to entice researchers to study issues of concern to their communities. "Others said they had tried, and were done with that, and just wanted to be able to ask and answer their own questions," Doerr notes.

Accesses to big data creates new possibilities in terms of the citizen science movement. "It is reimagining who gets to do what in science," Doerr observes. For instance, communities could identify questions that need answers, and hire a data scientist to analyze publicly available data. Environmental and water pollution data could be analyzed on how it correlates to disease incidence in a particular community.

The next step is to determine the logistics of how to empower communities with the tools they need to ask and answer their own research questions. The focus is on engaging communities that have been historically excluded from research. Developing a research ethics framework is an important step. "We hope to extend our work to support community leaders collectively developing their own system of ethics review for their research endeavors," Doerr says, noting this need is highlighted by the proliferation of unregulated health research with wearable devices.[2]

When communities lead their own research, they will be able to contextualize their findings. "This is the opposite of helicopter science, where people are dropping into a community and coming up with answers for them to implement," Doerr explains. The overarching focus is democratizing big data. Researchers and community leaders both need to give input on barriers to, and facilitators of, the use of big data at the community level. "There needs to be a cohesive bridge between the traditional research establishment and community-led science," Doerr suggests. ■

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Video Facilitates Informed Consent for ICU Procedures

Audiovisual modules may improve knowledge and comprehension of ICU procedures, according to the results of a study of critically ill surgical patients and their legally authorized representatives.[1]

"This study was motivated by our observation that there are substantial barriers to obtaining informed consent for commonly performed ICU procedures," says **Tyler J. Loftus**, MD, the study's lead author and an assistant professor of acute care surgery at the University of Florida.

Time constraints limit clinicians' ability to provide a full, detailed description of each procedure. "Verbal descriptions of complex medical and procedural concepts can be difficult for patients to understand without the use of audiovisual aids," Loftus laments.

The audiovisual module described eight commonly performed ICU procedures. Most (75%) indicated the video was easy to understand, and 70% believed it improved their understanding of ICU procedures. "Bundled audiovisual ICU consent should not replace human interaction, which remains necessary to build trust and rapport with the patient and their caregiver," Loftus cautions. Decision-making capacity often is in question in the ICU. "Sometimes, it can be difficult to gauge whether someone has decision-making capacity, especially when someone might be experiencing hypoactive delirium," says **Kathleen Akgün**, MD, MS, BS, director of the MICU at VA Connecticut Healthcare System.

If patients are on mechanical ventilators, or experiencing medication-induced sedation, clinicians need to obtain consent from surrogates instead. There also is the inherent difficulty of putting complex ICU procedures in simple

terms anyone can understand. "We are also susceptible to cognitive biases, such as anchoring bias, where we focus on our first impressions of a patient's diagnosis and best next steps for treatment," Akgün says.

Akgün suggests ethicists offer round-the-clock coverage to support clinicians in obtaining consent for time-sensitive decisions.

Ethicists also could evaluate competence of informed consent practices on an ongoing basis. Providers might tend to overemphasize ongoing disease-targeted treatment, and not give as much emphasis to high-quality end-of-life care. For example, for the third time in five weeks, a patient presents with septic shock from advanced gastrointestinal cancer that is eroding into their intestines.

In that case, ICU providers may talk about decisions regarding central venous catheter placement for blood pressure support using vasopressors and antibiotic administration, without mentioning the alternative: focusing on comfort and allowing a natural death. "These concerns are potentially heightened with less bedside presence of surrogate decision-makers, as we have seen in the setting of the COVID-19 pandemic," Akgün observes. ■

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Quality of Life Important to ICU Patients, But Clinicians Lack Data

There is an ongoing focus on the need to deliver high-quality patient and family-centered care in a variety of clinical settings.

"But exactly what that meant, particularly in the ICU, was unclear," says **Catherine Auriemma**, MD, a fellow in the division of pulmonary and critical care medicine at the Hospital of the University of Pennsylvania.

Commonly used metrics to evaluate the quality of ICU care are length of stay, infection and mortality rates, and ventilator-free days.

"While these metrics are important, we didn't know if they would tell the whole story of how patients and family would define a good outcome," Auriemma recalls.

To learn more, researchers from Penn Medicine's Palliative and Advanced Illness Research Center interviewed 19 ICU survivors and 30 family members in 2012 and 2013.[1]

"Survival alone wasn't uniformly the most important outcome," says Auriemma, the study's lead author. "Function and quality of life were sometimes more important." About one-quarter of participants said survival was the most important outcome. However, most participants deemed some outcomes worse than death, such as severe physical disability, dependence on machines, constant severe pain, and inability to communicate.

Survival is the most commonly used outcome measure in clinical trials of ICU patients, according to Auriemma.

"Our findings underscore the need for researchers and clinicians to develop more nuanced outcome measures that incorporate function and quality of life," she says.

The study's findings on what is most important to patients and family raises the question on whether clinicians are ethically obligated to share information about function and quality of life outcomes.

"The answer is unclear," Auriemma observes. "Prognostication of functional outcomes is far from perfect, and quality of life is highly subjective."

Patients and family care about function and quality of life, yet clinicians' ability to give accurate predictions and recommendations is limited. One reason is long-term functional outcome is individualized.

"Some people can adapt tremendously. People may think things are going to be a lot worse than they are when they experience a loss of function," Auriemma explains.

Individuals often cannot accurately predict how a future functional state might affect them. Many might tolerate future levels of disability far better than they would have anticipated.

"While this complicates the use of expected functional and quality of life outcomes in real-time decision-making, it stresses how we must start keeping track of these outcomes in order to improve our ability to predict them and provide patients and families with information they clearly want," Auriemma says. ■

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CME/CE INSTRUCTIONS

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CME/CE QUESTIONS

1. **Which is true regarding policies on inappropriate treatment?**
   a. Academic medical centers are no longer allowed to accept transfers from community hospitals if inappropriate treatment is involved.
   b. Inappropriate treatment policies generally permit clinicians to withdraw treatment without surrogate consent.
   c. Policies are most helpful when the ICU patient is permanently unconscious (or otherwise catastrophically critically ill) with no chance of recovery or discharge.
   d. Policies are especially necessary if there are conflicts over brain death, since both legal and ethical standards are unclear in those cases.

2. **Which did the authors of a recent study find regarding training of clinical ethics consultants?**
   a. Trainees believed strongly that clinical bioethics fellowship programs should not be accredited.
   b. Graduates expressed a desire for more training in quality improvement and communicating with hospital leaders.
   c. Clinical bioethics fellowship programs were far more homogenous than researchers expected.
   d. The programs provided more training in general ethical theory than in applied ethics.

3. **Which is true if the results of clinical trials are not reported?**
   a. There is no real direct harm to the public, since none of the evidence in public view is inaccurate.
   b. Study participants are harmed because non-publication violates an implicit understanding that the research will promote the public good.
   c. Patients are less likely to use harmful treatments if clinical trials are selectively reported.
   d. Researchers are less likely to enroll patients in experiments that do not need to be conducted.

4. **Which is true regarding the right to try unproven drugs?**
   a. There is no enforcement mechanism for reporting the serious adverse events, and no guarantee that manufacturers will be compliant.
   b. Some drug manufacturers are overreporting serious adverse effects to comply with overly burdensome requirements.
   c. Treating physicians no longer need approval from manufacturers to offer patients unapproved drugs.
   d. Evidence shows people significantly underestimate the odds an experimental drug will be declared safe and effective.