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Patients Without Surrogates Pose Ethical Challenges at End of Life

Decision-maker often is unclear

Despite aggressive medical and surgical management, a patient who had been admitted to NYU Langone Medical Center in New York City with a cardiac arrest following an intracerebral hemorrhage suffered significant brain injury. The patient was unaccompanied.

"All efforts were made to attempt to seek a surrogate," says **Ariane Lewis**, MD, an assistant professor in the hospital's departments of neurology and neurosurgery. No one was identified.

"We were very disturbed that, because this patient had no surrogate to relay his wishes to us, we were legally obligated to continue organ support, despite the fact that he was in a vegetative state and we believed he would never be able to have a meaningful quality of life," says Lewis, who co-authored a paper on the case.[1]

The physicians were intrigued to learn that New York law regarding management of the case differed from the law in other states. "The law is not always clear-cut about how to handle these situations," says Lewis. It often is unclear who should make decisions on behalf of the patient — the physicians, an ethics committee, or an externally appointed, unaffiliated person.

> "MANAGEMENT OF 'UNBEFRIENDED' PATIENTS IS ALWAYS COMPLICATED, AS IS MANAGEMENT OF END-OF-LIFE ISSUES."

"Management of 'unbefriended' patients is always complicated, as is management of end-of-life issues," says Lewis. Cases that involve both scenarios are particularly complex. "Ethicists can help lawyers, physicians, and politicians to construct clearer policies

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for management of these situations," says Lewis.

Trevor M. Bibler, PhD, assistant professor of medicine at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, says, "Incapacitated, unrepresented patients pose a unique ethical challenge for a number of reasons."

End-of-life decisions typically are made through the process of shared decision-making. "This is meant to be a two-way street, where the feasible options for treatment are matched with the patient's values and treatment preferences," says Bibler.

If the patient has no one to speak on his or her behalf, clinicians have no way to know who the patient was, the kind of life he or she led, and what interventions he or she would accept or reject, given the patient's unique values. Thus, says Bibler, "any attempt to respect the patient's autonomy would be a shot in the dark."

Standards for Decision-making

According to an updated position statement from the American Geriatrics Society (AGS), the process of arriving at a treatment decision for an unbefriended older adult should include the following:

- capacity assessment;
- a search for potentially unidentified surrogate decision-makers, including non-traditional surrogates;
- a team-based effort to ascertain the unbefriended older adult's preferences by synthesizing all available evidence.[2]

"My initial motivation for writing the position statement was to improve my understanding of this highly vulnerable population, so I could provide them with the best possible care and advocate for them more effectively," says **Timothy Farrell**, MD, AGSF, one of the position statement's authors and associate professor of medicine in the division of geriatrics at University of Utah School of Medicine in Salt Lake City.

Farrell saw a need for physicians to become better acquainted with this population. "As I reviewed the literature, I noticed that the last AGS position statement on the topic needed to be updated to reflect new developments in providing the most appropriate care for this population," he says. These updates include the following:

- new data on the prevalence of the "unbefriended" population in ICUs and long-term care;
- recognition of variability among

EXECUTIVE SUMMARY

The issue of incapacitated patients lacking surrogates has received growing attention, resulting in a newly updated position statement and several case studies. Some ethical approaches include the following:

- relying on what an average and reasonable patient would have wanted in the same situation;
- minimizing foreseeable harm to the patient;
- considering not only the patient's physical needs, but also social interests and the need to retain dignity.

states with respect to their legal standards;

• a trend toward team consensus, rather than individual physician decision-making when action must be taken;

• recognition that "stranger" guardians are potentially problematic;

• promising new partnerships within communities to advocate for these uniquely vulnerable individuals.

One approach is to use a "best interests" standard to make decisions for unrepresented patients. "Decisions are based on what an average and reasonable patient would have wanted in the same situation," Bibler explains.

Using this approach, the team asks, "What action would an average patient want?" and acts accordingly. This doesn't necessarily reflect a particular patient's wishes. "Given the simple fact of preference diversity, there is always the possibility that a patient would prefer treatments outside the 'average,' or act 'irrationally,'" says Bibler.

Another possible standard for medical decision-making focuses on the physician's responsibility to minimize foreseeable harm. "Rather than attempting to prioritize autonomy through a reliance on best interests, this approach states that the best path is the path that minimizes possible bad outcomes that harm the patient," says Bibler.

The clinical team's question then becomes, "What action minimizes foreseeable harms?" "However, this 'minimizing harm' standard is not as clear-cut as it might appear at first blush," cautions Bibler.

Physical and psychological harms are visible and recognizable. "Intuition, professional guidance, and moral and legal norms tell us that unduly causing physical and psychological harm is a bad thing that should be avoided," says Bibler.

Other types of harm are more subjective. One example is performing CPR on a dying patient for the family's benefit, against the wishes of the patient. The patient will not directly experience either the pain of broken ribs or the psychological harm of having his or her wishes rejected.

"Other kinds of harm, such as harm to one's dignity or social standing, are less tangible than broken ribs and broken promises," adds Bibler. "What counts as a 'good' versus 'bad' decision can be hard to discern."

The time-sensitive nature of many decisions is another ethical challenge. "Since the patient is critically ill, this means that going through the process of establishing a guardian would take much longer than the patient may have," says Bibler.

There is a possibility that an appointed guardian will make decisions that preserve the "status quo" without considering the patient's overall welfare and dignity. "The patient's responsible physician then becomes responsible for making a kind of unilateral decision that goes against the default model of shared decision-making," says Bibler.

The finality of end-of-life decisions makes the situation even more ethically complex. "An unrepresented and incapacitated patient whose medical care includes less invasive, less consequential procedures is still a challenge, but less so," says Bibler.

Once the care team realizes that some kind of life-or-death decision must be made, "the ethicist has to unpack this," says Bibler. "The ethicist often finds a tendency to attempt to preserve bodily interests at the expense of other important interests."

In this scenario, ethicists can underscore the importance of considering the patient's social interests and retaining dignity. "Once these interests are accounted for, it will clarify what is at stake in continued treatment or withdrawing life-sustaining interventions," says Bibler.

Inaccurate Assumptions

The term "unbefriended" is commonly used in the medical and legal literature to describe adult patients without surrogates. Bibler objects to this term. "I see it as a needless and inaccurate neologism that assumes that the patient has no friends, and gives the impression that no one is invested in her care," he explains.

In contrast, the term "unrepresented" makes no value judgments about the patient's social-familial relationships. "Perhaps there is a better label than 'unrepresented,' but it isn't 'unbefriended,'" says Bibler.

Farrell agrees that it's important to remember that the term "unbefriended" doesn't mean that someone has no friends or close connections. Rather, it is a term used to refer to a person who lacks the capacity to provide informed consent to medical treatment, and faces added challenges because they have no documented care preferences and no identified surrogate.

"The new AGS guidance is, in part, an effort to ensure that all older adults take steps to document their wishes for medical treatment and identify surrogate decision-makers, if desired, to be better prepared for the future," says Farrell.

Hospital ethicists can identify at-risk patients and intervene appropriately. "One of the most important points we make in the position statement is that proactive

steps are needed to prevent men and women at risk for becoming 'unbefriended' from becoming unbefriended," says Farrell.

For instance, ethicists can search for surrogate decision-makers, including nontraditional ones. "When it becomes necessary to make medical decisions on behalf of an older adult who is unbefriended, the position statement may be a useful resource for hospital ethicists," says Farrell.

Completely Vulnerable

Massachusetts is one of only a few states without a formal public guardianship system. "There is a patchwork of agencies which help fund guardianships where possible. Otherwise, the courts rely on finding people, mainly attorneys, to serve as a guardian on a pro bono basis," explains **Casey Catlin**, MA, project coordinator for Boston VA Research Institute's Examining the Need for a Public Guardian in Massachusetts.

The researchers wanted to better understand how this system is functioning for adults who lack decision-making capacity, have no advance directives, and have no family or friends available to serve as a surrogate.[3] The use of guardianship was associated with procedural challenges and ethical concerns including delays in care, short-term gains for long-term costs, inabilities to meet a patient's values and preferences, and conflicts of interest.

Catlin says these findings, coupled with ongoing research, demonstrate the need for a public guardian's office to provide services for vulnerable individuals.

"I see public guardianship as an issue of social justice. People with the financial means to pay for a private guardian get better care," says Catlin. These individuals aren't left waiting during a search to find someone willing to take on a case pro bono. Paid guardians also are more likely to spend time and energy advocating for the patient.

"Another relevant ethical issue is respect for people's rights and dignity," says Catlin. Guardianship means the person gives up all legal rights as an individual, and is completely vulnerable to the guardian to whom the person entrusts his or her care. "Ideally, attempts will be made to restore or enhance capacity, and pursue less restrictive alternatives, before plenary guardianship is sought," says Catlin.

"I SEE PUBLIC GUARDIANSHIP AS AN ISSUE OF SOCIAL JUSTICE. PEOPLE WITH THE FINANCIAL MEANS TO PAY FOR A PRIVATE GUARDIAN GET BETTER CARE."

The researchers heard stories of caring and thoughtful guardians who treated their wards with respect and kindness. "Professional guardians are likely to know nothing about the ward prior to their appointment, so they must make an effort to understand the person's unique values, history, and preferences," says Catlin.

The researchers also heard of guardians who, overburdened and uncompensated, neglected to complete even basic duties like signing paperwork and returning phone calls. "It's essential for guardians to have proper training, education, and oversight," says Catlin. ■

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Unethical Marketing Practices for Stem Cell Treatments Continue

'Significant and growing' problem

Recently passed legislation allows Texas clinics to bypass FDA approval for investigational stem cell treatments for patients with certain severe chronic diseases or terminal illnesses. The law alarmed ethicists who have been monitoring these practices.

"Despite years of research on the topic, the marketing of unproven stem cell therapies remains a significant and growing health policy problem," says **Timothy Caulfield**, LLM, FRSC, FCAHS, research director at University of Alberta's Health Law Institute in Canada.

Caulfield co-authored a recent paper advocating a call to action to address the marketing of unproven stem cell treatments.[1] "The issue implicates tens of thousands of patients around the world. It hurts the legitimacy of good stem cell research," says Caulfield.

The paper's authors argue for a coordinated international response to regulate the situation. "Unless we develop a comprehensive strategy to deal with this issue, I think it is only going to get worse," Caulfield says.

Ethicists believe the marketing of unproven treatments hurts legitimate stem cell research. "Tremendously exciting work is being done all over the world," says Caulfield. "As the real therapies move closer to the clinic, it will become increasingly difficult to differentiate the real science from the bad."

A recent paper argues that biotech companies should screen consumers to ensure that products and services are being used appropriately, and should educate employees about unproven stem cell interventions.[2]

"Currently, the U.S. has experienced a massive growth in the unproven stem cell therapy industry," says **Zubin Master**, PhD, the paper's lead author and a consultant at the Mayo Clinic's Biomedical Ethics Research Program in Minneapolis.

Private clinics are selling unapproved, untested stem cell interventions directly to patients. "These have been shown to cause physical harms to patients. Also, many suffer financial hardship, and in some cases, emotional distress from a botched attempt," says Master.

Some companies recently announced plans to supply private clinics selling unapproved stem cell interventions with stem cell reagents. Master and colleagues wanted to find out how informed these companies were about the unproven stem cell intervention marketplace. "We embarked on a study to identify whether they have policies to screen clients who may engage in selling unproven stem cell interventions, and whether they offer any education to their employees about the unproven stem cell intervention marketplace," says Master. Some key findings include the following:

- About one-quarter of the companies surveyed were aware of the International Society for Stem Cell Research or International Society for Cellular Therapy position statements on unapproved stem cell interventions.
- About 20% of companies created policies to screen clients.
- Only 7% provided any education about unproven stem cell interventions to their employees.
- One respondent reported that clients sign contracts prior to the sale of the product, indicating that the end user will comply with the laws and policies in his or her country. If the client refuses to sign the contract, the company will not sell the product or offer the service.

"To curtail the direct-to-consumer sales of unproven stem cell therapies, everyone has to do their part," says Master.

The researchers argue that legitimate industry also has a role to play. "It's not just not the role of legislators and regulators to stop unethical business practices of providers," says Master. "Scientists and the scientific industry also play a pivotal role."

Douglas Sipp, another of the study's authors, says, "If the government decides to leave the market for stem cell-based treatments unsupervised, this is almost certain to harm individual patients in the field of stem cell research, and the healthcare system in general."

A number of high-profile incidents, including paralysis, blindness, and death, have been reported. "Evidence for the safety and efficacy of stem cells in human medicine is patchy and shallow in most cases," notes Sipp, a research specialist at the Riken Center for Developmental Biology in Kobe, Japan.

Patients who pursue treatments they later discover to be harmful or fraudulent may have little legal recourse due to indemnifications for providers.

"Ethicists, along with concerned scientists and physicians, have been arguing against these dangerous laws

for years — and will continue to do so, as long as they represent a threat to public health," says Sipp.

Leigh Turner, PhD, associate professor at the University of Minnesota's Center for Bioethics in Minneapolis, says of the Texas law, "In a way, what we have is a state carving out its own regulations that have the potential to undercut federal regulations." This mirrors "right to try" laws being passed in a growing number of states.

"It wouldn't be shocking if we see this in other states as well, with a lower regulatory bar in terms of bringing stem cell therapies to market," says Turner. One reason is that businesses that open and market clinics have considerable resources to actively lobby for such legislation.

The argument to policymakers was that people were going to offshore clinics for the interventions, so they should be made available in the state. "But the whole debate was premised on a false assumption. The reality is, there are already 70 to 100 clinics in Texas that market stem cell treatments," says Turner.

Turner says the real question is why clinics are marketing unproven treatments without adequate regulatory oversight: "State legislatures aren't dealing with the problem in any meaningful way."

In August 2017, the FDA announced it would strengthen regulatory oversight of clinics marketing stem cell treatments. The unanswered question, says Turner, is, "Are we going to see more enforcement action unfold, or is it going to be strong rhetoric without much action?"

As it stands now, clinics are making claims about therapies without credible scientific evidence. "All they have to do is put out a shingle on the internet and people know where to find them," says Turner.

At some point, questionable claims become outright fraud. "We shouldn't just be wringing our hands and standing there. People are at risk of having tens of thousands of dollars taken from them for nothing," says Turner.

Turner says action must be taken before additional serious complications occur. "If these clinics are allowed to proliferate in the absence of regulatory oversight, we should expect more people being harmed," he says. ■

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Can Intoxicated Patients Provide Informed Consent for Research?

It's not uncommon for ED patients to present with acute intoxication. This complicates not only their clinical care, but also the informed consent process.

A recent study set out to determine to what extent acute alcohol intoxication affects capacity to assent, consent, or refuse research participation.[1]

"We demonstrated that alcohol concentration is predictive of who may be appropriate to participate in the informed consent process," says **Marc L. Martel**, MD, the study's lead author and an emergency physician at Hennepin County Medical Center in Minneapolis. Some key findings include the following:

• Of 415 patients who completed the University of California, San Diego Brief Assessment of Capacity to Consent screening tool, only 16 answered all 10 questions correctly.

• Of the 16 patients deemed to possess the capacity, only eight could recall the consent process. "This raises a critical question: If a patient transiently has the capacity, can

consent be considered meaningful if the patient cannot recall the encounter?" asks Martel.

• Mean alcohol concentrations in the capacity group were lower than in those lacking capacity.

• Of the 287 patients who were interviewed upon sobriety at discharge, 182 patients did not recall completing the questionnaire.

The researchers were aware of the findings of a previous study in 2015.[2] That study supported the feasibility of using the same screening tool to assess the capacity of frequent ED users with severe alcohol use disorders to participate in research. Of 19 participants, 16 were deemed capable of providing informed consent. Capacity did not correlate with blood alcohol concentrations. "This finding was contrary to our clinical experience," says Martel.

Hennepin County Medical Center's ED has a separate area that is specifically designed and staffed to manage acutely intoxicated patients. "Although tolerance to the effects of ethanol is common in our frequent ED users, we were concerned by the data that would suggest these patients would be considered to have the capacity to consent to the higher standard required to consent to research," explains Martel.

Researchers enrolled patients who presented to the ED intoxicated and were undifferentiated. In contrast, the 2015 study's population consisted of individuals with severe alcohol use disorders. "In emergency research, it is unlikely that we will know the patient's substance use history," notes Martel. "Our findings can be generalized more so than the 2015 study."

This supports the concept that emergency research protocols involving time-sensitive treatments in intoxicated patients must be performed using an exception from informed consent (EFIC) under current guidelines, the researchers concluded.

"Although a reliable method to assess the capacity of acutely intoxicated patients would open doors to safely and ethically perform resuscitation or emergency research, the lack of a reliable method strongly suggests that more studies in these patients may need to be considered and qualify for EFIC," says Martel. ■

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Revised Common Rule Is Changing Informed Consent

Net result: A better informed consent process

The recently updated Federal Policy for the Protection of Human Subjects, also called the Common Rule, is changing informed consent practices in two important ways, says **Celia B. Fisher**, PhD, Marie Ward Doty University Chair in ethics and director of Fordham University's Center for Ethics Education in Bronx, NY. "Although both have the potential to increase the informational rights of participants, critical ethical questions remain," she says.

The following are the two relevant changes:

1. Investigators now are permitted to obtain broad consent from participants for future use of identifiable biospecimens by the original investigator or other investigators.

"This will increase the ability of scientists to combine large data sets to explore important medical questions," says Fisher. This may be done without the participant's knowledge or consent, as long as an IRB determines that the future studies are within the parameters of the broad consent.

"It is unclear whether hacking or the use of the identifiable information by government officials or others with access to the data will pose a social or economic risk to participants," adds Fisher.

It also is unclear whether the perspective of research participants will be taken into consideration as to how their data are later used. "This latter concern may be particularly problematic if identifiable data is used to inform policies that promote medical discrimination of already vulnerable groups," says Fisher. For example, there's the possibility that insurance companies will access data on individuals with pre-existing conditions.

2. Investigators now are required to give prospective participants a brief summary of "key points" that a reasonable person would want to know to make an informed choice.

"Done well, this can be an advantage over the current risk-averse legal language in informed consent materials," says Fisher. These often are difficult to understand, and lead to misconceptions and uninformed choices.

"However, one question that remains is: Who will decide what those key points are?" says Fisher. Investigators and IRB members might have very different ideas from participants about what constitutes important information.

Katrina A. Bramstedt, PhD, senior ethics officer at Philips Research and adjunct professor at Bond University School of Medicine in Queensland, Australia, says information must be presented in a way that that truly helps people make informed decisions, rather than simply words on paper.

Costs will be incurred due to the need to update procedures, study templates and checklists, and train IRB members on the new rules. "However, the net result should be a more effective consent process that better informs participants about research studies."

The posting of clinical trial consent forms on a public website raises issues of confidentiality and intellectual property for research teams. "New product development, as well as patents and technology transfers, are potential revenue streams, and intellectual property considerations are vital," says Bramstedt.

This is especially true for commercial entities that often partner with federal agencies such as the Veterans Administration during research projects, notes Bramstedt.

The ability to redact these consent forms before public posting is an ethical issue addressed in the revised Common Rule. "But the redaction process is still vague at this point in time, and not yet tested, as even the consent form posting website is still an unknown," says Bramstedt.

Overall, Bramstedt expects to see fewer hurdles, and faster approvals, for the secondary use of research data. The new rules guide researchers to writing better consent forms that prospectively account for future research and sharing of research data. "Data is the lifeblood of research," says Bramstedt. "The new regulations appear to make the path of use simpler for research teams." ■

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Study: Only About One-third of Adults Completed Advance Directives

Many barriers persist to completion of documents

Only about one-third (37%) of U.S. adults had completed any type of advance directive, found a recent review of studies.[1]

"Improving the quality of care that Americans receive near the end of their lives is a universally important and very personal matter," says **Katherine R. Courtright**, MD, MS, one of the study's authors and instructor of medicine in the division of pulmonary, allergy, and critical care, the Palliative and Advanced Illness Research (PAIR) Center, and the Fostering Improvement in End-of-Life Decision Science (FIELDS) program, all at University of Pennsylvania's Perelman School of Medicine.

Researchers analyzed 150 studies published from 2011-2016. They found that similar proportions of patients with chronic illnesses (38%) and healthy adults (33%) had completed advance directives.

There have been many educational, research, and policy efforts to improve the quality of end-of-life care by encouraging the completion of advance directives.

"Yet, we didn't have a great sense of the impact of these interventions," says Courtright.

The researchers weren't terribly surprised that few adults had completed an advanced directive. They did expect the number to be much higher for people with life-limiting and serious illnesses — which was not the case.

"These individuals are the ones ostensibly most likely to benefit from documenting their medical care preferences and/or a trusted surrogate decision-maker in the event they are irreversibly ill and unable to make their own medical decisions," says Courtright.

Low rates of advance directive completion persist, despite significant efforts to promote use. "This requires us to address the many barriers to completing these documents," says **Scott D. Halpern**, MD, PhD, another of the study's authors. Halpern is director of the PAIR Center and the FIELDS program, and an associate professor of medicine, epidemiology, and medical ethics and health policy at the Perelman School of Medicine.

One of the most notable barriers is the legal requirement to obtain signatures from multiple witnesses, and/or notary in order for advance directives to be considered valid.

"It can be argued that states have an ethical responsibility to change their existing laws that make it harder for seriously ill patients to complete advance directives," says Halpern. "These laws serve no demonstrated purpose that helps patients or caregivers."

Providers themselves often are ill-prepared to hold advance care planning discussions.

"Frankly, most people in healthcare are uncomfortable having these conversations. So, how can we expect our patients to have them?" asks **Lucia D. Wocial**, PhD, RN, a nurse ethicist at Fairbanks Center for Medical Ethics at Indiana University Health in Indianapolis.

It's unreasonable to put the burden on physicians to hold advance care planning conversations, argues Wocial: "If physicians are trying to have these discussions and the patient has never had a talk with their family, it's not going to go very well."

A 15-minute block of time, which is all physicians typically are allotted for patient visits, just isn't long enough for an in-depth advance care planning discussion.

"The healthcare system doesn't financially reward preventive care. And, in my mind, identifying people's preferences is a type of preventive care," says Wocial.

Providers can try two things in lieu of a lengthy discussion: Suggest to patients that they speak with family about their goals of care, and giving patients resources to help them do it. "Ten years ago, there was nothing — now, there's a long list of resources," says Wocial. Providers can say to a patient, for instance, "This is a really important thing and I want to have a discussion with you about it, but it makes more sense for you to have a conversation with your family. And if you're struggling with it, here are some resources that can help you."

Hospitals often designate social workers, chaplains, or others as the point person for advance planning discussions. "There are turf battles. But it's everybody's opportunity to have these conversations," says Wocial.

Regardless, advance care planning should be completed before an intractable conflict arises at the end of life, she says.

"If I, as an ethicist, am having this conversation with somebody, something has gone terribly wrong," says Wocial. "We've arrived at an impasse and somebody's called me in to help sort it all out."

Most hospitals offer classes on congestive heart failure and diabetes management free of charge to patients. "Why are we not offering classes, which could be led by nurses — not to complete the paperwork, but to help foster the discussion?" asks Wocial.

Upon admission to the hospital, patients typically are asked if they have an advance directive. "If yes, we check the box and put it in our files. If no, we ask them 'Do you want to talk to anybody?' I think that's the wrong approach," says Wocial.

She suggests instead asking the patient, "Who have you named to speak on your behalf if you can't speak for yourself? And if you haven't done that, we encourage you to."

"The emphasis should be less on the documents, and more on the discussion," says Wocial. ■

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'Ever-Expanding Options' Prolong Life, but Spark Conflicts

Upfront communication prevents disagreements

Surrogates may be struggling to let go of a loved one, may not understand clinical realities, or may have religious or cultural beliefs about withdrawal or withholding of life-sustaining medical interventions. Regardless of the reason, families sometimes want to "do everything" when the clinical team feels it's time to stop.

"This scenario is not infrequent, and may increase with the ever-expanding interventional options to keep people alive at the end of life," says **James Kirkpatrick**, MD, adjunct assistant professor in the department of bioethics and humanities at University of Washington Medical Center in Seattle.

Advance directives don't always prevent such conflicts. People can always disagree as to how they should be interpreted. In some cases, surrogates even directly contradict patients' stated wishes because they're hoping for a miracle.

"Many clinicians, particularly those from a secular medical world view that differs markedly from the belief systems of many patients and families, find these scenarios particularly vexing," says Kirkpatrick.

The clinical team likely lacks training in addressing such conflicts. Many struggle to identify the underlying ethical principles. "Many ethics consultants, on the other hand, have had some form of mediation training that ideally positions them to address these conflicts," says Kirkpatrick.

The earlier the intervention occurs, the better. "Involvement of ethics consultants at the initial points of conflict is preferable to late involvement," says Kirkpatrick.

Providers seek to provide the care patients and families want, with an emphasis on shared decision-making over paternalism. "In rare cases, though, we just can't say 'yes' to the request of a surrogate decision-maker," says **Tim Lahey**, MD MMSc, chair of the clinical ethics committee at Dartmouth-Hitchcock Medical Center in Lebanon, NH.

If the conflict persists even after extensive efforts at resolution, the clinical team tells the surrogate, "Our institution can no longer provide the requested type of care. But we are willing to assist with transfer of a patient to another institution that will, as long as one can be found with reasonable effort."

A therapy may be reasonable and requested by a surrogate with good intentions, yet clinicians feel it's causing excessive suffering. "The process of resolution is important here," says Lahey. "Often, disagreements can be resolved through information-sharing and consensus-building."

The team recently cared for a patient with sepsis and multiple organ dysfunction. The unanimous impression from all treating clinicians at the hospital was that death was inevitable. "Yet, his loving partner wanted us to continue intensive care, in part because prior clinicians had, in his impression, 'given up too early,'" says Lahey. When collaborative discussions didn't result in agreement in next steps in care, clinicians offered to help the partner find another hospital that would provide the level of care he felt was consistent with the patient's wishes. He could not. "This helped him come to grips with inevitability in a fashion that also allowed our providers not to feel they were mandated to provide care they felt would lead to undue suffering," says Lahey.

Right to Decline

Some states, including California and Texas, have laws granting hospitals and healthcare providers right to decline treatments that they regard as medically ineffective or medically inappropriate.

Early communication about prognosis can prevent some of these

requests in the first place. "One approach is to identify clinical criteria that are indicative of a poor outcome and communicate it upfront to the family," says **David Magnus**, PhD, Thomas A. Raffin professor of medicine and biomedical ethics, professor of pediatrics, and director of the Stanford (CA) Center for Biomedical Ethics.

A patient undergoing a bone marrow transplant who ends up in multisystem organ failure is a common example. "In our institution, we have well over 100 of those cases, and none of those patients have survived. If they go to the ICU, it's a one-way trip," says Magnus.

Clinicians explain this upfront to families of patients undergoing this procedure. They state that care will be aggressive up to a certain point, but if multisystem organ failure does occur, the patient won't go to the ICU because it won't be successful. "We work that out with them in advance, so they know it's coming," says Magnus.

Commonly, patients go to the ICU having had no conversation whatsoever about their goals of care. "I'm constantly amazed at seeing patients show up in the ICU with metastatic cancer, and the oncologist has not talked to them about the good chance they would die," says Magnus.

Many physicians' mindset is to focus solely on the possibility the patient will get better. Since the possibility of the patient's death is never addressed, conversations about patients' wishes don't occur.

"We tend to avoid that until the patient is much sicker and the family has misunderstood the possibilities," says Magnus. The family doesn't understand why the clinical team seems to suddenly be giving up, fostering mistrust. "There needs to be much more aggressive advance care planning, and it needs to happen much earlier in the process," he says.

If a patient underwent a Whipple procedure and is undergoing second-line chemotherapy, "people can't be that surprised when things are not going well — and yet, they are," says Magnus.

Determining which patients would benefit most from palliative care interventions is critical. These families then recognize that death is a realistic possibility. "If people see this coming, it won't make all conflicts go away completely. But it will certainly reduce the number of times where it comes out of the blue," says Magnus.

Scripting sometimes is helpful for clinicians who struggle to explain the clinical situation to families. "What's interesting is sometimes it turns out to be really easy," says Magnus. "I would say a huge percentage work out that way."

The clinical team perceives the family as insisting on prolonging the patient's life, but this isn't always as it seems. Some families assume the team keeps asking for their consent to continue because treatments are likely to work. When they learn otherwise, says Magnus, "even if the family really doesn't want to stop, most will acquiesce and start moving forward with the grieving process. A subset of cases are resistant and very unhappy."

In a recent case, a patient had clearly stated that he did not want life-sustaining treatment if a certain level of functioning was no longer achievable. "We were way past that point of what the patient would have found an acceptable quality of life. But the spouse just could not accept that," says Magnus. The spouse reported seeing clinical improvement that none of the neurologists or surgeons could see. In situations like this one, says Magnus, "If we send a patient to the ICU who is not going to benefit and has virtually no chance of getting out of the ICU, just to benefit the family, that is not a good use of an ICU bed." It means that a patient held in the ED waiting for an ICU bed, or for transfer to a higher-level institution, might die. "The conversation should have taken place on the floor, or even as an outpatient," says Magnus. "Too often, we allow these things to flow downstream." ■

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- Ethical considerations with unilateral DNR orders
- Ethics of genetically modified human embryos
- Realities of newly passed physician-assisted suicide law

MEDICAL ETHICS ADVISOR®

CME/CE QUESTIONS

1. **Which is true regarding patients who are incapacitated and lack surrogates, according to Timothy Farrell, MD, AGSF?**

   a. States' legal requirements are consistent for this population.
   b. Courts generally favor individual physicians making decisions on behalf of such patients, as opposed to externally appointed unaffiliated persons.
   c. There is a trend in the clinical environment toward team consensus rather than individual physician decision-making.
   d. Clinicians are legally obligated to prioritize patient autonomy over minimizing foreseeable harms.

2. **Which did a recent study find about acute alcohol intoxication and capacity to consent to research participation?**

   a. Alcohol concentration is predictive of who may be appropriate to participate in the informed consent process.
   b. All patients deemed to possess capacity were able to recall the consent process.
   c. Exception from informed consent under current guidelines is not appropriate for intoxicated patients.
   d. There is a reliable method to assess the capacity of acutely intoxicated patients.

3. **Which is true regarding marketing of unproven stem cell interventions?**

   a. Although untested stem cell interventions don't always benefit patients and can cause financial harm, they have not yet physically harmed patients.
   b. Companies supplying private clinics selling unapproved stem cell interventions are required to provide education on fraudulent marketing practices.
   c. The FDA has decreased regulatory oversight of clinics marketing stem cell treatments to eliminate barriers to care for vulnerable patients.
   d. Patients face both financial and safety risks if clinics are allowed to proliferate in the absence of regulatory oversight.

4. **Which is true regarding advance directives, according to a recent study?**

   a. Most U.S. adults have completed some type of advance directive.
   b. Similar proportions of patients with chronic illnesses and healthy adults have advance directives.
   c. Rates of advance directive completion have increased significantly in recent years due to widespread educational efforts.
   d. Advance directives no longer need to be signed by multiple witnesses or notarized.