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INSIDE

RELIAS MEDIA

Hospital Leaders Asking Questions About 'Value' of Clinical Ethics to Organization

Administrators expect to see evidence that a clinical ethical program is worth supporting with financial resources. Yet many ethicists are unprepared for this kind of conversation, one that requires data for an effective response.

"Document as much as possible the benefit of ethics resources to clinicians, patients and families, and administrators," advises **William Nelson**, PhD, MDiv, director of the Geisel Ethics and Human Values program at Dartmouth. Here are some common questions from hospital leaders:

• **What are the role and function of the ethics committees?** A yearly detailed report on the committee's activities should be provided to institutional leaders, according to Nelson. The report should include the number and types of ethics consults; all ethics education provided to staff, community, and committee members; and institutional policies that the committee reviewed or drafted.

• **Are ethics committee members knowledgeable and skilled? Have they received formal training?** Ethics leaders can respond by talking about formal training programs in healthcare ethics, as well as the American Society for Bioethics and Humanities' Healthcare Ethics Consultant-Certified program.

• **Is the ethics committee assisting the organization in fulfilling its stated mission and values?** Effective responses include any available data verifying the effectiveness of ethics consultations, Nelson offers. Results of post-consult assessments, feedback from focus groups, and suggestions for improvement from clinical leaders are some examples.

"Existing tools, such as staff and patient satisfaction surveys, can be used to evaluate ethical alignment or the lack of it," Nelson adds.

Ethicists also can note how their work prevents costs by proactively addressing moral distress and conflicts, thus preventing burnout and litigation. "It's good to describe how the ethics program has moved beyond just a reactive approach, and instead, is using a preventive approach," Nelson observes.

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Most ethical conflicts are recurring, such as disagreements on medical futility. Post-consult reviews can determine if system changes are needed to prevent future conflicts, Nelson suggests. It also is relevant to talk to administrators about meeting their own ethical obligations based on the American College of Healthcare Executives' Code of Ethics.

"The ethics committee's activities can assist the leaders in fulfilling various aspect of the required expectations," Nelson explains.

Many hospital administrators asking about the "value" of ethics are thinking in terms of cost savings; in other words, monetary value.

"This kind of value does not necessarily map onto the kind of value that should be the focus of ethics interventions," says **Jane Jankowski**, DPS, interim director of the Cleveland Clinic Center for Bioethics. The authors of a recent paper advocated for a narrative approach to demonstrating value.[1]

However, ethicists must account for how their work contributes to the ethical delivery of healthcare. "The clinical ethics service should explicitly connect its work to the mission of the institution," says Jankowski, one of the paper's authors.

Administrators may be surprised at the scope of the ethicist's work, and the multiple ethical challenges in a single case.

"We are a weird bird in the hospital in that we do not produce RVUs [relative value units] or have clearly defined metrics set by regulatory bodies," says **Laura Guidry-Grimes**, PhD, another of the paper's authors and an assistant professor of medical humanities and a clinical ethicist at the University of Arkansas for Medical Sciences in Little Rock.

Hospital leaders understand data (e.g., length of stay, consult volume, or patient satisfaction scores). "While ethics consultation may have some indirect impact on these measures, they should not be the primary aim of our work," Guidry-Grimes offers.

Discussions with hospital leaders can be difficult because of a lack of understanding of what ethics does. "Some ethicists have even reported being asked to find ways to be revenue-generating," Guidry-Grimes reports.

Many healthcare positions do not bill patients or generate revenue, but are nonetheless part of assuring safe and high-quality healthcare, Jankowski notes. "Ethicists, just like everyone else in healthcare, are expected to uphold responsible stewardship of fiscal resources," she notes.

Many other hospital departments can talk about how ethics contributes to patient-centered care.

"Clinical ethics services might find amazing allies in unexpected places," Guidry-Grimes says. Social workers, case managers, palliative care providers, psychiatrists, patient advocacy or patient experience offices, pastoral care, and legal counsel all are potential ethics advocates.

To make allies out of administrators, ethics should find ways to meet the needs of specific patient populations, Guidry-Grimes suggests. For example, the institution might be committed to growing its outreach to underserved patient populations in urban or rural areas. "An ethics team could offer to provide education on health literacy barriers in the informed consent process," Guidry-Grimes says.

The process of resolving an ethical conflict cannot be quantified in dollars. "It may not necessarily be captured in metrics. However, narratives are quite powerful," says **Hannah I. Lipman**, MD, MS, director of bioethics at Hackensack (NJ) University Medical Center. Bioethicists can demonstrate value by telling compelling stories about how a particular issue

was addressed. "Ideally, the narrative shows how bioethics bring a variety of stakeholders together," Lipman offers.

At Hackensack, bioethicists routinely provide ethics education on cases during ICU rounds. Recently, a resident identified an ethical issue in one of her cases, and consulted ethics. There was a conflict among surrogate decision-makers who disagreed with an order not to attempt resuscitation.

"During the consultation, the bioethicist identified additional opportunities for education," Lipman recalls. These included conflict resolution techniques, the hierarchy of surrogates when the family dynamics are complicated, and good communication practices for conversations about do-not-resuscitate orders. "This shows how the various activities of bioethics are interconnected," Lipman notes.

The resident knew to consult bioethics because she had learned from the bioethicist on rounds. Then, the bioethicist ensured the lessons learned from an individual case were addressed on a systems level.

This kind of story brings home the "value" of ethics to hospital administrators.

"We should be in the habit of sharing these narratives, and be ready to unpack in detail the specific contributions we made," Lipman says. ■

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Ethical Response Needed if Surrogate Disregards Patients' Wishes

The role of surrogate decision-makers is to make decisions consistent with the patient's previously expressed wishes, written documents, and values. "But that is not what usually happens," says **Cheyn Onarecker**, MD, MA, chair of the healthcare ethics council at Trinity International University's The Center for Bioethics & Human Dignity in Deerfield, IL.

Lack of communication between the patient and the surrogate and/or between the surrogate and the medical team is the biggest obstacle, according to Onarecker. There are a few common examples:

• Often, the person who becomes the surrogate does not know the patient well enough to make an informed decision, and there is no advance directive. "Nonetheless, the surrogate must try to make a decision that is in the best interests of the patient," Onarecker observes.

• Surrogates feel solely responsible for deciding on life or death for the patient. "It is very difficult for the surrogate to make a decision to stop life-sustaining treatment," Onarecker notes.

This can cause surrogates to make a choice that appears contrary to the wishes of the patient. "We contribute to this, sometimes, by asking questions incorrectly," Onarecker admits. If surrogates are asked a general question such as, "What would this patient want?," the answer is usually going to be something like, "To do everything they can to get well."

"The better question, many times, is 'Given that your mother will not recover the ability to interact with her family or care for herself, what would she want us to do?'" Onarecker offers.

• Surrogates become confused when multiple clinicians bombard them with technical information. "The hospitalist team changes every week — and sometimes more often than that," Onarecker says.

Surrogates do not know who is making medical decisions for the patient. To the medical team, it looks like the surrogate is stubbornly refusing to make what seems like an obvious decision. "To the surrogate, though, multiple physicians are giving out different opinions on what should be done," Onarecker notes. Surrogates establish a rapport with a particular hospitalist, only to find a different physician in charge the next day. Designating one physician to handle the back-and-forth of information from the medical team to the surrogate is helpful.

• It may be unclear to everyone what option is really in the patient's best interest. "There are many situations when there does not seem to be one best solution," Onarecker says.

The medical team is unsure about the prognosis; many specialists are offering various treatment options. "How is the surrogate supposed to know what is best when the medical team doesn't even know?" Onarecker asks.

Surrogates in this situation need all the support they can receive from the medical team, including palliative care, hospice, or chaplains. "As medical professionals, we are involved with life-and-death situations all the time," Onarecker says. "But surrogates don't do this for a living."

Before losing decision-making capacity, patients may decide to forgo life-sustaining treatment. "But later, the surrogate insists upon such treatment," says **Robert N. Swidler**, vice president of legal services at St.

Peter's Health Partners. Swidler and a colleague created an informational pamphlet for these cases called "When a Patient's Prior Decision to Forgo Treatment Conflicts with a Family's Current Insistence that Treatment be Provided." Specific to New York state law, the pamphlet helps in these ways:

• **It shows the surrogates they are not the first ones who misunderstood their role.** "It demonstrates that the situation is not unique, and that we have planned for it," Swidler explains.

• **It explains the surrogates' role is to advocate for the patient's wishes, not to impose their own view.** "This can lessen the emotional burden on the surrogate," Swidler offers. That is because much of the stress surrogates experience stems from the burden of making a decision. "They just need to recognize that a decision has already been made," Swidler adds.

• **It reduces tension between the surrogate and the clinical team.** Putting something in writing for guidance makes it clear clinicians are not pushing their personal values onto the situation. "Rather, they are informing the surrogate about the ethical principles the hospital follows in all cases," Swidler offers.

• **It is an educational tool for staff.** Some surrogates are adamantly opposed to the patient's prior decision. "The pamphlet will help reduce the number and duration of disputes," Swidler says. "But it won't eliminate them." Sometimes, the situation resolves on its own, as the patient passes away despite treatment efforts. Otherwise, says Swidler, there are three options:

• Obey the surrogate, do not write the do-not-resuscitate (DNR) order, and resuscitate the patient in the event of cardiac arrest;

• Obey the surrogate for the moment, but seek a court order authorizing the DNR order;

• Obey the patient, write the DNR order, and let the surrogate challenge it in court if he or she is so inclined. "The specific facts of the case may tilt the matter more toward one or another of these options," Swidler adds. ■

Researchers Identify Ethical Concerns With Pragmatic Trials

Pragmatic trials raise some new ethical issues that need greater attention, according to the authors of a recent study.[1]

"Existing ethics guidance is not well-suited to pragmatic trials," says **Stuart Nicholls**, PhD, the study's lead author and a senior clinical research associate at Ottawa Hospital Research Institute in Ontario, Canada.

Pragmatic trials aim to evaluate interventions under real-world conditions. "The current empirical ethics literature does not reflect the full range of stakeholder perspectives," Nicholls says. Previous studies focused on a narrow range of topics, such as when written consent approaches may be modified.[2-6] "We aimed to explore more broadly what ethical challenges may arise in the design and conduct of pragmatic trials," Nicholls explains.

Nicholls and colleagues interviewed 45 stakeholders, including ethicists, clinical investigators, methodologists, and patients. Participants reported ethical concerns about how "minimal" risk is determined, when it is appropriate to alter traditional informed consent practices, and how to distinguish between quality improvement and research.

They also expressed concern about determining what protections are owed to the broader populations the trial affects and the diversity of participants. During interviews, Nicholls and colleagues heard feedback regarding justice and equity. "This is particularly important, given the potentially heterogeneous populations within pragmatic trials," Nicholls notes.

There is a general feeling that more pragmatic trials are needed, says **Spencer Phillips Hey**, PhD, another of the study's authors and a faculty member at the Harvard Medical School Center for Bioethics. Mainly, the creators of clinical trials enroll people who are most likely to benefit from what is studied. "A drug that looks really promising in an idealized trial might not actually work so well in clinical practice," Hey observes.

Pragmatic trials give a better idea of how an intervention's going to work in the real world. Including groups that are excluded often from research is another potential benefit. "Getting more people, particularly historically underrepresented groups of people, involved in research is an encouraging feature of some pragmatic trials," Hey offers.

One unresolved ethical issue is how researchers are going to protect the interests of these broader participant groups. "We have not really come to a clear consensus on how to handle this move toward pragmatism while still appropriately protecting the rights of the participants," Hey laments.

Traditional informed consent is not always going to be possible in these studies. This means investigators have to find other ways to protect

participants. "We still have to think about how to best show respect and safeguard their interests, even if we are not getting consents," Hey suggests. Exactly when it is ethically permissible to waive consent in the first place is debatable, too. "This is probably the biggest area of controversy," Hey notes.

One condition in the Office for Human Research Protections regulations for waiver of informed consent notes securing traditional consent is "impracticable." Some people might interpret this to mean if there is not enough money to obtain informed consent from everyone, that means consent is impracticable, and a waiver is needed. "But cost alone is not a sufficient justification," Hey cautions.

For some pragmatic trials, traditional informed consent remains ethically necessary. "There seems to be a push from some investigators [who say] that just because a trial is pragmatic, it's taken as justification to not get consent. That is very much putting the cart before the horse," Hey explains. Whether consent is needed depends on multiple ethical considerations, such as whether the individual's welfare is adversely affected. If it turns out informed consent is needed after all, researchers have to either find a way to do it, or perhaps conduct a smaller study than they planned. In other cases, the study design has to be re-evaluated. "You may have to tweak the questions a bit, and then it's ethically acceptable to get a waiver," Hey suggests. There are various types of pragmatic trials, each with its own ethical considerations depending on the study design. "Pragmatic trials mean different things to different people," Hey observes.

One study might use electronic health record data to prospectively follow patient outcomes. Another randomizes huge numbers of patients at dozens of hospitals with no opportunity for the patients to opt out. "Both of those things can be pragmatic trials. But the ethical consequences that flow from those study design choices can be different," Hey explains.

As it stands, investigators often struggle to find guidance on the particular ethical questions their study raises. "My worry is that it's not practical to have to go to the literature and comb through dozens of studies to find out what you need to do," Hey shares. There is no searchable online resource for investigators to plug in the parameters of their intended trial and find answers to relevant ethical questions. "That would be really compelling and valuable," Hey says. "That's the guidance and support that's missing right now." ■

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Payment for Physician Referrals: Difficult for Hospital Leaders to Maintain 'Clean Hands'

For years, federal laws (and some state laws) have prohibited hospitals from paying physicians for referrals. Yet some hospitals continue unethical and illegal practices, possibly due to a perception of low risk.[1,2]

"The mentality is something like 'The odds of getting caught are small, we will not be prosecuted, so it is worth the gamble,'" says **Tom Ealey**, professor of business administration at Alma (MI) College. The changing relationship between physicians and hospitals is another contributing factor. Employed physicians now outnumber self-employed physicians, according to a recent American Medical Association study on physician practice arrangements.[3] Another factor is many hospitals are struggling financially. "In many areas, the competition between hospitals and systems is really brutal. That is not an excuse, but it is certainly a cause," Ealey notes.

To survive in competitive markets, hospitals need a certain amount of market share. "High-quality physicians bring market share, and large paychecks bring high-quality physicians," Ealey explains. The problem is that

some paychecks are disproportionately large and clearly not justified by the revenue brought in by the physician. Thus, says Ealey, "the compensation appears to be bribes for filling beds and ordering ancillaries."

Ethical concerns enter the picture if physicians put their own interests above patients'. "Some patients are steered toward services in order to fulfill an unethical and/or illegal business arrangement — or, worse, subjected to unnecessary services simply to generate revenue," Ealey says.

Kickbacks are only possible if insurers overpay physicians or hospitals for some procedures or types of admissions, says **Mark V. Pauly**, PhD, professor of healthcare management, business economics, and public policy at the Wharton School of the University of Pennsylvania. "It is better to remove the incentive for high-profit referrals than to shame those who yield to temptation," Pauly offers.

This can happen by payers not overpaying and hospitals not accepting overpayment — or, if they do, to fully disclose how that revenue is shared with physicians. "If they fully disclose, I would not regard that as clearly unethical," Pauly suggests.

In reality, this rarely, if ever, happens. "I don't think hospitals or networks ever share physician compensation information with patients, and I doubt they share it with insurers," Ealey says. There is little transparency about these financial matters in the hospital sector, says Ealey, "other than mandated reports, which do not tell us much at a detail level."

The problem is better handled on the payer side, Pauly says. For instance, insurance plans could offer network membership only to physicians and hospitals that do not engage in low-value referrals. For hospital leaders, there is little reason to take action. "Unless it affects their revenues from admissions or other services for which they are the referral partner, they have a hard time having clean hands," Pauly says.

Influences over referrals, if handled well, can support informed choices and higher-value referral practices, argues **Matthew DeCamp**, MD, PhD, associate professor in the Center for Bioethics and Humanities at University of Colorado Anschutz Medical Campus.[4]

"The primary ethics concern, of course, is whether any method of influencing referrals, whether financial or nonfinancial, inappropriately affects what is best for the patient or their choices," DeCamp says.

There also are justice-related concerns if referral practices put certain groups of patients at a disadvantage, DeCamp adds. For example, rural patients may be referred to urban centers that require unaffordable long-distance travel.

Some institutions are trying to shape referral practices to achieve better coordinated, higher-value care. "At the institutional level, a real need exists to ensure that these well-intentioned efforts actually function as intended," DeCamp says. When referral programs are evaluated, costs and medical outcomes may be all that is considered. "It is paramount that hospital leaders understand the real-world experiences of patients and frontline clinicians when they decide whether referral programs are successful or not," DeCamp says. ■

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Ethics Guidance for Surgeons on Humanitarian Missions

During a humanitarian mission as a resident in 2008, **Matthew D. Tadlock**, MD, saw a patient with a massive ventral incisional hernia. Previously, the patient had sustained a gunshot wound to the abdomen, which required an exploratory laparotomy.

"To fix his hernia would have likely resulted in more harm than good for the patient," says Tadlock, now a trauma surgery specialty advisor to the U.S. surgeon general . The clinical team tried to explain this, but the man still begged for them to fix his hernia. "We gave him false hope by visiting his country, and it was quickly dashed after a brief clinic visit," Tadlock says.

"We caused harm to this patient, despite our team's best intentions."

Ethical practices for informed consent, truth-telling, error disclosure, triage, and the involvement of the trainee all are somewhat different in the humanitarian surgery environment than in the hospital setting, Tadlock notes. "When evaluating patients for a potential surgery, sometimes the best answer a surgeon can give is 'No.' Nothing really prepared me for this," Tadlock says.

At various meetings and venues over the years, Tadlock found some surgeons measured their impact during humanitarian missions strictly in terms of case numbers. "Some surgeons really focused on their inherent gain, not on the people they were helping, without any thought to the sustainability of their actions," Tadlock recalls. Often, surgeons made comments such as, "We went to this country and performed X number of operations."

"This really hit home for me," Tadlock says. "Some type of premission ethical curriculum preparing residents and novice humanitarian surgeons was needed." To see what existed, Tadlock and colleagues conducted a literature review of 49 papers.[1] "There was a lot of guidance for specific surgical specialties. But we wanted to catalogue it, put it together in one place, and make it easily accessible," Tadlock reports. Three main areas of controversy were identified:

- Providing surgical care to patients with a dismal prognosis, such as major congenital defects or severe trauma;
- The role of residents during humanitarian missions;
- The role of surgical innovation.

"An innovative use of standard surgical principles may be required to successfully care for your patient," Tadlock notes.

For elective operations, the benefits must outweigh the risks, and humanitarian surgeons must have a reasonable chance to make the patient better. "However, in the emergency and disaster relief setting, there may be a role for surgical innovation," Tadlock adds.

The researchers developed a Humanitarian Ethics Curriculum, and administered the course to 18 residents about to embark on a humanitarian mission. "Like anything in life, you will be better at something if you prepare for it. Dealing with ethical dilemmas in the global health and humanitarian setting is no different," Tadlock says. Later, the residents were asked to describe an ethical dilemma they encountered on the mission. Sixty-one percent of these involved surgical patients. The ethics guidance gives surgeons a resource to review the core bioethical principles of medicine and surgery as these apply to the humanitarian and global health context. It is not just patients who will benefit; surgeons will, too. "They will have the framework to keep their moral bearings when dealing with challenging ethical dilemmas," Tadlock says. ■

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Ethics Recommendations Span Years for Some Patients

When someone requests an ethics consult, the patient's social and clinical history is important to know. So is the history of ethicists' involvement. "It is not uncommon for our consult service to be called multiple times over a number of years to assist with a care question that resurfaces," says **Christine Gorka**, PhD, director of the Clinical Ethics Center at Passavant Area Hospital in Springfield, IL. There are certain instances when ethics becomes involved repeatedly:

- Ongoing questions about a patient's decision-making capacity;
- Family-related dynamics that complicate decision-making, repeatedly, for the same patient;
- Social or financial issues that need to be addressed whenever a patient presents for care;
- Goals of care might need to be reconsidered considering a patient's current clinical status.

Ethicists were consulted four times over a four-year period on capacity, decisions about goals, and discharge planning for a patient with a chronic illness related to a life-long disability. The man was wheelchair-bound and dependent on others for his daily needs. Initially, clinicians perceived him as someone who could not live outside an institutional setting.

"He was remarkable in the fact that he had maintained his independence for most of his life and fought fiercely to continue doing so," says **Barbara Hinze**, PhD, one of Passavant Area Hospital's clinical ethicists.

During previous consults, ethicists documented the man had support available 24 hours a day, the same as he would have received in a care facility. This allowed clinicians to honor

the man's preference to be discharged home until it was no longer feasible. Family dynamics complicated the case further. There were frequent disagreements on who was the appropriate decision-maker. "Ethics clarified a path for decision-making during times of his incapacity," Hinze reports.

In another case, a series of ethics consults spanned many years for a patient with long-standing cognitive barriers. Clinicians requested the first consult with a question about decision-making capacity. "We were not called for another 18 years, when questions around matters of decision-making appeared again," Hinze says. The last few consults primarily focused on goals of care at the end of the patient's life.

Ethicists previously noted the patient fared better with written materials than verbal descriptions. They also charted the patient identified an out-of-state family member as someone who should be involved in important discussions. All that documentation resulted in more patient-centered care at the end of the patient's life. "We were better able to share his values, goals for treatment, and communication needs," Hinze reports.

Passavant Area Hospital's ethics service set a high bar for documentation. The first step was to create a database dating back to the first consult in 1987. "We expect to enter our 10,000th consult in 2020," Gorka shares.

Since each consult is documented, there is a reliable record to which everyone can refer. "Having kept detailed records provides us a longitudinal picture of ethics involvement, and how various issues were resolved," Gorka notes, adding such a system prevents needless rework. "One ethicist can pick up where another left off without 'reinventing the wheel.'"

The benefits of thorough ethics documentation over a period of years goes beyond an individual patient's care. "It has also allowed us to ask ethics-related research questions and contribute to the literature," Gorka says. Ethicists used their database to analyze how the number of consults had increased over two decades.[1] They also analyzed how gender and race factor into the timing of ethics consultation requests.[2] "Building a culture where ethics recommendations are expected in the medical record firmly establishes the practice," Gorka offers.

Ethicists receive occasional after-hours calls from clinicians, and share some advice informally. These late-night conversations went undocumented — until the ICU director called to request ethics chart its recommendations on the next work day. "I realized then that our culture had equivalent expectations for ethics consults as they did for clinical consults," Gorka says. ■

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Tips for Device Reps and Clinicians Searching for Ethics Advice

The Advanced Medical Technology Association (AdvaMed) code of ethics for interactions with healthcare professionals has been revised for 2020.[1] "The updates reflect the evolving legal standards, business models, and best practices seen over the last decade," says **Nancy Travis**, AdvaMed's vice president of international compliance and governance. Device reps giving technical support in the clinical setting is a key area of focus. "One of the ways that medical technology companies can serve the interests of patients is through beneficial collaborations with healthcare professionals," Travis says. Collaborative relationships help develop new medical technologies, and ensure they are used safely and effectively, according to Travis. The code of ethics clarifies socially responsible conduct related to these interactions. "This ensures healthcare decisions are always in patients' best interests," Travis says.

Device reps' training and credentialing is "a great concern," says **Lisa Spruce**, RN, director of evidence-based perioperative practice at the Association of periOperative Registered Nurses (AORN). This group recently released an education and credentialing tool, RepDirect, that incorporates AdvaMed's code of ethics.[2] "This assures perioperative nurses that healthcare industry representatives have undergone training and have demonstrated competency and ethical practices," Spruce says. What are the specific ethical concerns regarding the relationship between clinicians and device reps?

• Some clinicians rely too heavily on the expertise of reps during surgical procedures. Some reps (and even clinicians) may not have received adequate training to speak as experts on the subject.

• **Device reps may be performing functions outside their scope of responsibility.** "Credentialing processes for personnel who will have patient contact are different than for industry representatives," Spruce explains.

Many organizations have instituted policies that prohibit device reps from opening sterile supplies, as this task carries infection risk to the patient. There also could be a conflict of interest if reps are opening their own company's supplies or implants. "Clinicians and reps must work together to avoid crossovers that are outside their respective roles, training, and education," Spruce stresses.

• **Clinicians may lack training on commercial bias and marketing efforts.** "Clinicians are ethically bound to act in the best interest of the patient and are licensed to do so, whereas reps are representing the manufacturer," Spruce observes.

• **Patients often lack knowledge of the rep's presence during surgery and/or their role.** Patients should be fully informed of these things, according to Spruce. Clinicians should obtain informed consent (to the extent possible). "In some cases, it is unfeasible or unsafe for patients to refuse the presence of an industry rep," Spruce acknowledges.

The rep's presence might be necessary to ensure a surgical device is used safely. Regardless, says Spruce, "facilities should have policies that clearly delineate the role of the rep when they are in the clinical space."

The obvious ethical concern with industry relationships is clinicians can make choices that do not benefit their patients. Decisions are made, often under pressure, in the OR. "These relate to device choices that are profitable for firms but may not improve patient outcomes," says **Genevieve P. Kanter**, PhD, assistant professor of medical ethics and health policy at Perelman School of Medicine at the University of Pennsylvania.

The latest, most expensive device is lucrative for the manufacturer, but sometimes of no additional value to the patient on the operating table. The device rep should not be the clinician's sole source of information on this. "Clinicians need to be independently informed about the range of choices and consider only their value to the patient," Kanter cautions.

Reps can influence various types of financial benefits for physicians. It does not mean cash is exchanged directly. Sometimes, the rep arranges for a lucrative consulting role or offers perks like travel to meetings. "There may be some kind of quid pro quo in that relationship," Kanter observes.

Other times, the clinician is not really providing legitimate services to the device manufacturer. It is more a case of a company providing compensation to the clinician for using the manufacturer's devices.

"A common unethical practice relates to misleading or biased information provided to the clinician," Kanter says, listing some examples:

• Reps may overstate the evidence associated with a particular device by talking about poorly designed clinical trials;

• Reps may not be comprehensive about complications or adverse events reported to be associated with a device unless they are asked about them directly;

• Reps may talk inappropriately about off-label uses, especially with a weak evidence base. "It is difficult to police those one-on-one interactions," Kanter acknowledges.

She suggests clinicians rigorously challenge claims made by the reps and mention the claims made by one firm to a rep in a competing firm. "The competing firm will be more than happy to point out weaknesses in what is presented, and to report violations in the code of ethics made by their competitors," Kanter says. ■

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Data Reveal Knowledge Gaps on Physician-Assisted Suicide

There are some physicians who support the legalization of physician-assisted suicide (also known as physician-assisted death or aid-in-dying), but they may have different feelings about actually practicing it themselves. Sixty percent of U.S. physicians believe physician-assisted suicide should be legal, according to the results of a recent study.[1] Yet of that group, only 13% indicated they would be willing to perform the practice if it were legal. "The idea for this nationwide study came from an earlier study that we performed," says **Lydia Dugdale**, MD, MAR (ethics), one of the study's authors. Dugdale is associate director of clinical ethics at NewYork-Presbyterian and director of the Columbia Center for Clinical Medical Ethics in New York City.[2]

In that previous study, 488 faculty physicians at the Yale School of Medicine were surveyed on their attitudes regarding physician-assisted suicide. Most doctors (73%) thought assisted suicide should be legalized. Only 29% of those doctors also indicated willingness to perform it.

"We wanted to know if this held true nationally, and, if so, we wanted to know why," Dugdale explains. Researchers were surprised to find how little doctors actually understand about assisted suicide. "They are unclear about why it is requested. They think that safeguards protect patients, yet question their adequacy," Dugdale notes. Some key findings:

• About half (49%) of physicians think pain is the reason most patients seek physician-assisted suicide. This reveals physicians are generally misinformed about the reason for patients seeking physician-assisted suicide, according to Dugdale. In fact, the vast majority of patients seeking to end their lives reported concerns about a loss of autonomy and dignity, according to 2018 data from Oregon, the first state to legalize assisted suicide.[3] Only 25% of patients actually reported concern about pain.

• Most physicians (58%) believe current safeguards are inadequate to protect patients. One concern is physicians who are not psychiatrists are not adequately trained to screen for depression, Dugdale says. Respondents also were skeptical physicians can predict with certainty that a patient has six months or less to live.

"Doctors feel that doctors are poor prognosticators," Dugdale observes. "Yet ability to prognosticate is key to eligibility for lethal drugs."

• Some physicians are wary of legalization. About one-third of physicians believe legalization of assisted suicide will lead to legalization of euthanasia.

• Almost half (46%) of physicians believe health plans would preferentially cover lethal drugs over more expensive, potentially life-saving treatments like chemotherapy. "When it comes to matters of life and death, healthcare professionals have a moral obligation to understand clearly the ramifications and nuances of their participation," Dugdale says. ■

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Residents' Compassionate Behaviors Vary During Informed Consent

When patients give informed consent for surgery, they are likely to be anxious and ask many questions. Some also are in considerable pain.

The authors of a recent study examined how compassionate 65 anesthesia residents were during a simulated preoperative evaluation of a patient in acute pain scheduled for urgent surgery.[1] "We found substantial variability in the compassionate care behaviors of anesthesiology residents during the informed consent procedure," says **Richard Blum**, MD, MSE, FAAP, the study's senior author and senior associate in perioperative anesthesia at Boston Children's Hospital. Residents also were inconsistent in the way they elicited questions from patients.

"At stake is the patient's ability to give fully informed consent, which lies at the heart of respecting patient autonomy," Blum explains.

It is not that residents lack compassion. "Most residents are truly compassionate. But the system they work and train in can lead to the appearance of a lack of compassionate behaviors," Blum observes.

The authors of a different larger study investigated anesthesia resident competency overall.[2] Certain participants reported the sedating effects of pain medications would render patients unable to participate.

"Some residents were not treating patient pain for fear of invalidation of the informed consent," Blum reports. In their follow-up, researchers studied the presurgery informed consent process.[3] Most residents ordered pain medication as soon as the simulated patient experienced pain. However, many waited until after the informed consent was signed. Notably, 14% did not order pain medication at all. "This supported our clinical observations," Blum says.

Residents possibly feel pressure to secure a signed consent form, or they lack knowledge on pain management or ethical principles for informed consent. "These and other factors may be driving the process at the expense of attending more compassionately to patients," Blum offers. All these findings suggest medical training inadequately

addresses how providing or withholding pain medication can affect the informed consent process.

"Not treating pain may be considered a harm to patients," Blum notes. The ethical concern is patients in severe pain cannot fully participate in the informed consent process. Some probably are willing to sign anything to relieve pain. "One could make the argument that withholding pain medication is a form of coercion," Blum suggests.

Informed consent is more than just a document with a signature. "The process is dynamic, and involves ongoing communication. Yet many healthcare professionals and scientists do not view it as a process," says **Julie M. Aultman**, PhD, director of the medical ethics and humanities program at Northeast Ohio Medical University in Rootstown.

Informed consent is individualized. Certain patients may need special resources such as Braille documents or translated materials because of disability or language barriers. "This could potentially be overlooked by busy residents or residents who are uninformed on, or insensitive to, the importance of an ethical informed consent process," Aultman says.

For some residents, training on informed consent is minimal. It amounts to little more than a list of core elements that need to be in the consent form. "Resident training should take a deeper dive at the informed consent processes for both clinical interventions and research," Aultman argues.

Ideally, this covers the ethical principles of autonomy, beneficence, and justice in the context of informed consent. "There is also a need for residency education that addresses the importance of moral courage and patient advocacy as steps toward preventing abuses of informed consent," Aultman adds.

Branavan Ragunanthan, MD, a resident at Summa Akron City Hospital, has seen firsthand that a strong ethics foundation is necessary for informed consent. "The biggest misconception residents tend to have is believing that the informed consent process ends after obtaining a signature on a document," Ragunanthan says.

In Ragunanthan's experience, residents do not always understand certain ethical considerations. Informed consent can involve multiple parties and multiple encounters with the patient. Patients have the right to continue asking questions about an intervention even after the consent form is signed. Notably, patients can terminate their voluntary consent at any time.

In his own training, Ragunanthan found simulated patient scenarios dealing with informed consent particularly helpful. In the hospital setting, he says it was helpful when physician faculty emphasized the need for patients to be consented "in a matter that respects their human dignity."

To ensure residents are prepared to obtain informed consent, Aultman says that ethicists should design educational and training sessions, and emphasize the need to recognize diverse patient and human subject populations. Further, ethicists should identify resources to ensure everyone can participate in voluntary decision-making. Also, ethicists should ensure patients and subjects can consent based on their capacities, interests, and care goals. The process of informed consent takes "time and patience," Aultman notes. "Ethicists can play a significant role in addressing the need for slower medicine and research." ■

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CME/CE OBJECTIVES

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;
2. Explain the implications for new developments in bioethics as it relates to all aspects of patient care and healthcare delivery in institutional settings;
3. Discuss the effect of bioethics on patients, their families, physicians, and society.

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CME/CE QUESTIONS

1. **Which is true regarding the role of surrogates?**
   a. Even when the patient's wishes are known, the surrogate's responsibility is to override these and act as he or she thinks is in the patient's best interest.
   b. Surrogates should not be given specifics of medical choices when asked what the patient would want, since surrogates would become confused by this information.
   c. Surrogates should obtain recommendations directly from each involved specialist.
   d. Ideally, one designated physician should convey information to the surrogate.

2. **Which is true regarding ethical issues with pragmatic research?**
   a. There is a general consensus that most pragmatic trials are unethical.
   b. A greater percentage of pragmatic trials exclude historically under-represented groups than clinical trials.
   c. Whether consent is needed depends on multiple factors, such as whether the individual's welfare is adversely affected.
   d. Rights of participants cannot be protected without traditional informed consent.

3. **Which is true regarding relationships between device reps and clinicians?**
   a. Clinicians should rely on the expertise of reps to ensure safety.
   b. Policies should allow device reps to open sterile supplies.
   c. Policies should clearly delineate the role of the rep.
   d. It is not feasible to inform patients of the presence of a device rep during surgery, so consent from the patient need not be sought.

4. **Which did a recent study reveal regarding physician-assisted suicide?**
   a. Most physicians support the allowance of physician-assisted suicide, but some in this group are unwilling to perform it themselves.
   b. Few doctors thought assisted suicide should be legalized.
   c. Physicians correctly named pain as the reason most patients seek assisted suicide.
   d. The vast majority of physicians were confident in their ability to prognosticate.