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IN THIS ISSUE

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Most Americans lack advance directives — but they also report concerns about end-of-life care

Bioethicists must "speak up and speak loudly"

In a 2014 survey of more than 7946 adults, only about one-fourth (26%) had an advance directive.[1] "Our study provides information from a large sample of adults on their attitudes and behaviors regarding advance directives," says **Lynda A. Anderson**, PhD, one of the study's authors and director of the Centers for Disease Control and Prevention's Healthy Aging Program.

The most frequently reported reason for not having an advance directive was lack of awareness. Here are other findings:

- Advance directive completion was associated with older age, more education, and higher income, and was less frequent among non-white respondents.
- Respondents with advance directives were more likely to report having a chronic disease and a regular source of care.
- The majority (68%) of study participants reported having concerns about end-of-life care, including concerns about the costs of the care, the pain they might experience, or their comfort and dignity.

EXECUTIVE SUMMARY

Only 26% of 7946 adults surveyed had an advance directive, according to a recent study. Lack of awareness was the most frequently reported reason for not having an advance directive. Most participants reported concerns about end-of-life care. Bioethicists can consider:

- Establishing educational partnerships with community long-term care facilities.
- Avoiding assumptions that providers are aware of the components and advantages of advance care planning.
- Making the long-term care community aware of their availability to consult pre-transfer.

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Another 19% reported no end-of-life concerns, and 14% responded that they did not know if they had end-of-life concerns. Those who responded they "did not know" if they had an end-of-life concern were less likely to have an advance directive.

"People who lack the knowledge to have end-of-life concerns, or about the role of advance directives in facilitating end-of-life decisions, may represent important audiences for intervention," says Anderson.

• Older adults were more likely to have an advance directive, but only 29% of those aged 55 to 65, and about half (51%) of those 65 or older, indicated having an advance directive.

"Given the current discussions about implementing various models of health care delivery, including the patient-centered medical home, end-of-life issues need to come to the forefront of planning efforts," underscores **Jaya K. Rao**, MD, the study's lead author. At the time the work was performed, Rao was an associate professor in the Division of Pharmaceutical Outcomes and Policy at University of North Carolina's Eshelman School of Pharmacy.

"Hopefully, these findings will contribute to the current national conversations about end-of-life care," says Rao.

Efforts have "fallen short"

Questions about end-of-life care often seem to occur to seriously ill patients and families "as if out of the blue," says **F. Keith Stirewalt**, PA, MBA, MDiv, advance care planning coordinator and bioethics committee member at Wake Forest Baptist Medical Center in Winston-Salem, NC. "And we scratch our heads and exclaim, 'How could they not have known?'"

Stirewalt says that despite decades of attention, "attempts to emphasize the 'advance' descriptor in the terms 'advance care planning' and 'advance directive' have fallen short."

There is a need to "normalize" advance planning conversations in order to reduce end-of-life angst for family, patients, and medical caregivers alike, argues Stirewalt. "What we have failed to accomplish is the normalization of advance care planning as discussed in the living room, rather than the side of the sick bed," he says.

Purposeful conversations that incorporate advance directives and Physician Orders for Life-Sustaining Treatment (POLST) documentation at the time of admission allow for advance care planning to be "woven into a greater tapestry of goals of care," says Stirewalt. "Partnership between the patient and family, the long-term care facility, and the referring health care provider(s) are crucial." He says bioethics consultants should consider:

• Proactively reaching out to community long-term care facilities, rather than waiting for the patient to return to the hospital as a future consult.

• Defining the components and advantages of advance care planning. "No assumptions should be made that all know the basics, or agree about their advantages and uses," he says.

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• Emphasizing to the long-term care community their availability to consult pre-transfer.

"As a neutral source, the bioethics committee can facilitate communication with the patient and family within the creation of a safe space," says Stirewalt.

Conflicts at the bedside may be avoided through educational leadership, community involvement, and the setting of realistic expectations for treatment and end-of-life care. "Certainly, bioethical quandaries will not end," says Stirewalt. "They may, however, be alleviated."

Move to values-based model

The Affordable Care Act (ACA) has the potential to improve end-of-life care, in part because it is transitioning away from a fee-for-service model to a values-based model, says **Ira Byock**, MD, a professor at Geisel School of Medicine at Dartmouth University in Hanover, NH. Byock is author of *The Best Care Possible: A Physician's Quest to Transform Care Through the End of Life* (Avery, 2012).

"This means providers just can't keep ordering tests and new treatments when there is no evidence that they are actually helpful," he says. Byock says that the comparative effectiveness research that the ACA advances will promote measurement of meaningful outcomes, including the patient's well-being during late-stage illness.

Byock says too many people are still at high risk for dying in ways they would not have wanted to die. "They are often suffering as they die, in ways that are often avoidable," he says. "We haven't hardly budged the number of people getting late-stage treatment in intensive care units."

Byock argues that "all of us, including bioethicists, have to take a step back and acknowledge that we are failing. If we stay silent or are too meek, we are complicit." The time for incremental improvements in care and the way people die has passed, he underscores.

"We really need to be honest — firstly, with our own disciplines — but most importantly, with the patients and families who come to us for help," says Byock. "So many of them are not getting the best possible care we can provide."

Inadequate palliative care

While many hospitals claim to have palliative care programs, this is often somewhat misleading. "Health care centers must not be allowed to keep stating to the public that they are providing state-of-the-art cancer or cardiac care when they cannot reliably provide palliative care," says Byock. "It is unethical for them to do so."

Byock says that bioethicists must "speak up, and speak loudly" within their own institutions, and state that this needs to become a new standard of care.

"There is now really good clinical research that shows that concurrent models of disease treatment with palliative care clearly improve quality of life, often improve survival, and as an unintended consequence, actually diminish total health care costs," says Byock.[2]

Some hospital CEOs and CFOs don't believe that palliative care is cost-effective. "That's now clearly shown to be wrong, but it is a common prevailing attitude," says Byock. Similarly, some clinical leaders of cancer centers and cardiac care have the misconception that palliative care requires people to give up treatment for their disease.

"All of us who are practicing medicine or providing bioethics consultations need to realize that it's not okay for our institution to be a late adopter here," says Byock. "If a clinical leader or CEO continues to hold attitudes that have become anachronistic, we have to speak up!" ■

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• The Centers for Disease Control and Prevention offers a free online course, Advance Care Planning: An Introduction for Public Health and Aging Services Professionals, to prepare public health and aging services professionals to assist individuals with advance care planning. For a course description, go to : http://1.usa.gov/1kHMqgZ.

Bioethicists set criteria for who can perform clinical ethics consults

Is it acceptable for someone with a masters degree in bioethics without a clinical background to perform ethics consults? What about a physician with an interest in ethics who has never done consults?

In order to resolve such questions about what level of education and experience is necessary for an individual to perform ethics consults, bioethicists at New York Presbyterian Hospital in New York City developed their own set of criteria.[1]

"We really wanted to get a handle on what we should be looking for to have the greatest success in recruiting people," says **Cathleen A. Acres**, RN, administrative director of the Division of Medical Ethics, lecturer in public health at Weill Cornell Medical College, and associate medical ethicist at New York Presbyterian Hospital/Weill Cornell Medical Center in New York City.

It's important that individual institutions recognize that ethics consultation is "a discreet practice discipline that requires a body of knowledge and clinical experience in order to effectively mediate and negotiate ethical issues in the hospital," says Acres.

Every institution is going to find their own "sweet spot" for the necessary qualifications, says **Joseph J. Fins**, MD, MACP, chief of the Division of Medical Ethics at Weill Cornell Medical College and director of medical ethics and attending physician at New York Presbyterian Hospital/Weill Cornell Medical Center.

Fins is also currently working on the The American Society for Bioethics and Humanities' Quality Attestation process to assess clinical ethics consultants at the national level.[2]

EXECUTIVE SUMMARY

A group of bioethicists at New York Presbyterian Hospital implemented a new process to determine who can perform clinical ethics consults.

- The criteria specify the path for how one can progress from an assistant to an associate to a senior clinical ethicist.
- The criteria recognize that clinical bioethics is a profession that people come to from many disciplines.
- A clinical license or clinical ethics fellowship training is a core qualification for non-clinicians.

While it will be several years before there is a working model for quality attestation, "local and national efforts are not mutually exclusive," says Fins. "Until we have a national standard, local institutions will need to step up and begin to do this in a way that works with their local culture."

"It's kind of amazing — this has been a huge lacuna in the clinical space, and it has been very unregulated," says Fins.

As a result, people with the same problems could be treated differently at the same institution. "It's really important that institutions have a sense, as best they can, of the abilities and competency of the people who are doing ethics consults," says Fins.

Three levels of credentialing

Before the criteria were developed, there was no mechanism for the hospital to recognize Acres, a nurse who works for the medical college and not the hospital, as a professional performing medical ethics consults.

"That was our urgent issue, and we took this approach to address it," she says. Acres is not aware of any other institution that has developed similar credentialing criteria for ethics consults.

Part of the challenge was to develop criteria that the ethics programs at both New York Presbyterian — Columbia University Medical Center and New York Presbyterian — Weill Cornell Medical Center would agree to.

Acres and Fins developed a draft of the criteria for three levels of credentialing. The criteria specify the path for how one can progress from an assistant to associate to senior clinical ethicist.

They shared the draft criteria with two of their colleagues at New York Presbyterian Hospital — Columbia Presbyterian Medical Center. "The four of us then went back and forth to discuss the specific levels of expertise required," she says. "It was a very constructive process." The team also consulted with the chairs of pediatrics at both sites to be sure they were requiring enough experience for bioethicists to do pediatrics consults independently.

Next, the criteria had to be approved by senior administration. "From there, it went to the medical board of the institution for their approval, and we went forward," says Acres.

Model for other institutions

"We see this as a model for other institutions that can take this and tailor it to their particular needs," says Acres.

Although other institutions might vary the numbers of educational hours or consults performed, New York Presbyterian's criteria could help identify what experience is necessary for a potential ethics consultant.

"We have a very big institution with considerable expertise, so we were able to set the bar pretty high," she says. Other institutions may not be able to employ multiple clinical ethicists or provide supervision or mentoring, for instance.

The criteria recognize that clinical bioethics is a profession that people come to from many disciplines. "There are certainly physicians and nurses, as we are here, but there are also philosophers, social workers, chaplains, attorneys, and others who have training and expertise," says Acres.

A clinical license or clinical ethics fellowship training is a core qualification for non-clinicians. "Non-clinicians would have had to complete a master's or training program in clinical ethics that afforded them considerable clinical experience," says Acres.

Other institutions may take the approach of partnering a clinician with a bioethicist who has a PhD but no clinical background. "There are a lot of ways to get at this," says Acres. "This is the model we chose — that's not to say you couldn't have a wonderful program with another model." ■

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Ethical issues of genomics applied to infectious disease

"Little or no" consideration of ethical issues

While the application to genomics in the context of clinical medicine has received great attention, there are also great strides being made in applying the same tools to infectious disease, according to **Jeffrey Kahn**, PhD, MPH, Robert Henry Levi and Ryda Hecht Levi professor of bioethics and public policy at Johns Hopkins Berman Institute of Bioethics in Baltimore, MD.

"As the science expands and its results become more meaningful, it is crucial to consider the ethical, legal, and social implications," he says.

Kahn is a co-principle investigator of the GUIDE (Genomic Uses in Infectious Disease & Epidemics) project, along with **Gail Geller**, ScD, MHS. The team is exploring the ethical, legal, and social implications (ELSI) considerations of applying genomics to infectious disease.

"It is known that genes play a role in the human immune system, and in an individual's response to disease infection, vaccines, and treatment therapies," says Dvoskin.

To date, applications of genomics in public health have focused primarily on chronic diseases such as cancer, heart disease, and diabetes, and behavioral risk factors such as obesity and smoking, notes **Rachel Dvoskin**, PhD, genetics research analyst and Exploratory Center of Excellence in ELSI Research (CEER) project coordinator at Johns Hopkins Berman Institute of Bioethics.

While there is literature surrounding the ethical and legal issues of infectious disease control, there has been little or no consideration of the public health–related ELSI issues that could arise with the application of genomics to infectious diseases and epidemics.

"In this three-year exploratory CEER, we are mapping this novel terrain in preparation for an application to create an institutional center to analyze the ethical, legal, and social issues identified and make policy recommendations for how best to address them," says Dvoskin.

EXECUTIVE SUMMARY

The GUIDE (Genomic Uses in Infectious Disease & Epidemics) project is examining ethical, legal, social, and policy issues involving the application of genomics to prevention and treatment of infectious disease.
- Individuals do not respond equally to identical infectious agents.
- The gap between genomics research and public health application remains large.
- Using genomics information to precisely delineate antibiotic sensitivity and resistance is already being done across the country.

The team is exploring these issues in the context of two case studies of infectious diseases that are transmitted from human to human: hepatitis C (HCV), a chronic, blood-borne disease, and pandemic influenza, an acute, airborne disease.

"In both cases, genetic variation among individuals is known to be associated with response to prevention or treatment of disease or to aspects of infectivity," says Dvoskin. For example, IL-28B genotype is associated with response to HCV antiviral treatment and with the ability to clear HCV naturally. Polymorphisms in the HLA class II molecules are associated with non-responsiveness to influenza vaccine; MBL-2 codon 54 genotype is associated with poor or adverse response to flu vaccine.

"The two disease cases we have chosen will highlight different types of genomics applications and ELSI issues," says Dvoskin. The team foresees ethical challenges emerging around three areas in which genomics is being applied to infectious disease:

- disease prevention, in the context of vaccine safety and efficacy and vaccine distribution and allocation;
- disease infection, involving individual differences in disease severity and transmissibility to others;
- disease treatment, including efficacy of and response to potential therapies, side effects or adverse reactions, and allocation of drug therapies.

Here are some of the potential ethical issues surrounding pandemic flu:

- Identifying sub-populations at increased risk of adverse events may lead to policies not to immunize them, reducing herd immunity for the larger community.
- There is a question as to whether genotyping of health care workers should be mandatory, in order to assign the task of "first response" to those with flu-resistant genotypes.

For HCV, several ethical questions emerge from the discovery that IL28B genotype is predictive of treatment response. One is whether physicians should use different treatment criteria for people with and without the protective gene variant. "Another ethical concern is whether the knowledge that the IL28B variant decreases risk for developing chronic HCV is likely to increase risk-taking behavior," says Dvoskin.

"One size fits all" paradigm

Despite advances in antibiotics and vaccines, death from infectious diseases is the second leading cause of death worldwide, notes **Charis Eng**, MD, PhD, FACP, chair and director of the Cleveland Clinic's Genomic Medicine Institute in Cleveland, OH.

"Thanks to policies from the most recent Bush administration and the dire straits of U.S. biomedical research funding, there have been no new antibiotics created in the last 10 years," she says.

A major weakness in current infection prevention and control strategies, says Eng, comes from a "one size fits all" paradigm that fails to sufficiently recognize inherent differences in both host and pathogen.

Individuals do not respond equally to identical infectious agents, and pathogens of the same species are more genomically diverse than once thought. "It is incontrovertible that much of this diversity is attributable to genomic variation," says Eng. "Over the past two decades, genomics has provided remarkable insight into susceptibility, resistance, and progression of infection."

Paradoxically, says Eng, the gap between genomics research and public health application remains large.

Using genomics information to precisely delineate antibiotic sensitivity and resistance is already being done across the country. "This is highly effective, but there is no uniform public health mandate," says Eng.

The U. S. Department of Health and Human Services has designated these two public health genomics objectives for Healthy People 2020:

- To systematically identify Lynch syndrome, the most common adult-onset inheritable colon cancer syndrome, and to get patients to proper genetics care;
- To systematically identify heritable breast cancers and to get patients to proper genetics care.

"Both of these are done to a greater or lesser extent in diverse medical centers," says Eng. For example, the Cleveland Clinic Health System has been successful in implementing universal screening for Lynch syndrome.[1]

Australia has already implemented nationwide screening for Lynch syndrome, and the United Kingdom is about to do so. "This is because it has formally shown value — that patient care is improved, and that this strategy is cost-effective," says Eng.

Efforts to create and maintain centralized databases of genomic fingerprints are needed, urges Eng, to help improve accuracy and efficiency in infectious outbreak detection and rapid effective treatment.

"Ethical issues center around research and the keeping of centralized databases and sample biorepositories regarding identifiability, confidentiality, and ownership," says Eng.

Other ethical issues involve how collected samples

might be used in the future, and the extent to which research projects should support the provision of clinical care for research participants.

"Public health infectious disease ethics are slightly behind organ-specific or process-specific genomics, but should seek guidance from these," says Eng. ■

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Cast a wide net when obtaining feedback on clinical ethics consults

It can result in system-wide improvements

Obtaining good feedback on clinical ethics consultations can be challenging, acknowledges **G. Kevin Donovan**, MD, MA, director of the Pellegrino Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC.

"People are anxious to get your input when the problem is presenting itself," he says. "But once it's resolved, they tend to move on."

Donovan says it's worthwhile to make an effort to "broaden the feedback sources" for ethics consults. For instance, ethics consultations often involve two parties with differing viewpoints. Feedback from both parties would be valuable — not just the individual who requested the consult.

"It's frequently difficult to get feedback from the other party," says Donovan. "The patient may no longer be alive, and the patient's family may not be readily available or may not be interested in being contacted at home."

Bioethicists typically interact with patients and families in the context of an individual ethics consultation, and then never have any further interaction with them.

"Because our interactions with patients and families tend to be 'one and done,' there are a number of methodological issues associated with seeking feedback from them," says **Stuart G. Finder**, PhD, director of the Center for Healthcare Ethics at Cedars-Sinai Medical Center in Los Angeles, CA. Here are some approaches to obtain feedback from various parties involved in ethics consults:

• Professional colleagues — nurses, physicians, and social workers.

Both objective and subjective questions should be asked, says Finder. For instance, individuals can be asked to rate the consult's effectiveness, and also to write a sentence or two about what they understood to be most important about the involvement of ethics consultation in the situation.

• Others who provide ethics consultation.

This feedback is most easily obtained via regularly scheduled "case review" sessions, says Finder. Ethics consultants can discuss what they did, how it was received, and any challenges they encountered.

"The key to this kind of peer review is the ability and willingness to speak directly and explicitly with our clinical ethics colleagues about our own strengths, weakness, and room for improvement," says Finder.

Such discussions may be especially challenging, however, when ethics colleagues are not only also professional colleagues in other contexts — such as physicians in different specialties — but also with roles at different power levels in the institution — such as a physician and social worker.

"To engage in this kind of peer discussion requires clear ground rules that promote honest and open conversation," says Finder.

• The ethics committee.

EXECUTIVE SUMMARY

Feedback on clinical ethics consultations from patients, family, colleagues, and the ethics committee can improve the clinical ethics service and identify systemic problems.
• Where opinions differ, obtain feedback from both of the involved parties.
• Ask professional colleagues both objective and subjective questions.
• Set clear ground rules to promote honest and open conversation.

At Georgetown University Medical Center, feedback that is discussed internally among ethics consultants is also reported back to the institution's ethics committee. "So not only can we tell them about our feedback, but the committee can also tell us their feedback," says Donovan.

The committee has suggested ways to do more preventative ethics by rounding in the intensive care unit to identify ethical problems before they become a crisis, for example.

In addition, ethics consultation reports include the question, "Are there opportunities here for looking at systemic changes?

"Consults can bring to light certain endemic problems for which we can take a more preventative approach," says Donovan. "Those can be brought up with the appropriate nursing service or administration."

Broader issues identified

As a result of obtaining feedback from key stakeholders, ethics consultants are often better poised than others in the institution to identify key ethical considerations particular to the institution, according to Finder.

"In other words, the same kinds of skills necessary for engagement in specific patient care situations may also be useful in identifying broader issues associated with patient care more generally," he says.

The processes by which ethics consultants seek feedback may serve a greater purpose than simply improving clinical ethics consultations, he explains.

"It may also bring to light gaps, challenges, and other systemic dimensions of patient care that, now brought to light, demand attention," says Finder. "When such issues are uncovered or encountered, the role of the ethics consultant bifurcates."

The primary focus is still on helping the patient and providers in the particular situation, but there is also an obligation to work on the larger issue that was uncovered.

"This latter work may or may not be within the scope of the ethics consultation service," Finder says. "If not, what is required is to take what has been discovered to those within the institution who are in a position to address such problems."

For instance, critiquing the medical decision-making of a patient's physician is typically the responsibility of the medical staff peer review process.

"If serious issues are encountered in the midst of ethics consultation, however, the ethics consultant does have a responsibility to report to the appropriate medical staff representative that there may be medical staff issues needing to be addressed," says Finder. ■

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Guideline committee members have conflicts of interest

Organizations have new motivation to improve practices

Of 254 authors of clinical practice guidelines from 14 specialty societies, 53% had conflicts of interest (COIs) and only one of the 45 guidelines disclosed author COI.[1]

Another 2013 study found that 56% of manufacturers of patented drugs recommended in 13 clinical practice guidelines on glycemic control in type 2 diabetes mellitus, on average, had at least one author with a financial interest in their company.[2]

COI were reported by 56% of 498 people who helped write 17 guidelines for the American Heart Association and American College of Cardiology from 2003 through 2008, according to a 2011 study.[3] Of the people who led those groups, 81% had personal financial interests in companies affected by their guidelines.

Eric G. Campbell, PhD, one of the 2011 study's authors, says the findings were not at all surprising. "From a strategic point of view, if you want to influence a field, it's much easier to influence the content of a guideline that everybody follows, than to go out and try to convince a whole bunch of doctors to do the same thing," he says. Campbell is director of research at Mongan Institute for Health Policy and professor of medicine at Harvard Medical School, both in Boston.

While one primary care physician might see several hundred patients, a guideline can influence the care provided by virtually all physicians in the country. "That is why guidelines should receive the highest level of scrutiny possible," Campbell says.

Pharmaceutical companies want access to the biggest names in the field, so they establish financial relationships with those individuals. "The rank-and-file doctors are not on these committees. These are really the superstars, often, of medicine," says Campbell. "And it is that group that is inherently conflicted, often, because they are the people that industry wants."

The guideline committees are often funded by pharmaceutical companies. "It's about the practice of medicine, but it's also about creating a market," says Campbell. "While no one knows what the balance of the two is, it is impossible to deny that drug companies funding organizations that produce guidelines will further their business interest."

Physicians "can't have it all"

In order for things to change, specialty organizations first need to acknowledge that conflicts are important, emphasizes Campbell. "It is up to the profession of medicine to adequately regulate this," he says. "I have not seen any data, but my suspicion is that this is still very much a largely under-regulated arena."

The profession's failure to self-regulate itself could result in increased outside attention from regulatory forces, he warns.

Providers may need to acknowledge that while they are free to be on a speaker's bureau for a pharmaceutical company, or have an equity interest in a device manufacturer, doing so may prohibit them from participating in other professional activities.

"And one of those activities should be chairing committees that develop guidelines or serving as a member," argues Campbell. "You can't have it all."

The 2011 study showed that 44% of guideline writers had no financial interests in the area they reviewed. This rebuts the argument that there are not enough experienced experts who are independent, says **James N. Kirkpatrick**, MD, one of the study's authors and assistant professor in the Cardiovascular Division and the Department of Medical Ethics and Health Policy at the Hospital of the University of Pennsylvania in Philadelphia.

"I don't see why it is necessary to include people with COI on the writing committees," says Kirkpatrick. "It is rather common for the presidents of subspecialty societies to divest themselves of COI, so why not require the same of guideline writers?"

Some organizations adhere to the Council of Medical Specialty Societies' guidance regarding relationships with industry, which states that guideline committee chairpersons should not have relevant COI, and more than half of members should be free of COI. (To view the Code for Interactions with Companies, go to www.cmss.org/codeforinteractions.aspx.)

"These recommendations are similar to what has been promoted by the Institute of Medicine," says Kirkpatrick.

Some organizations do require disclosure of COI. "The organizations assume that disclosure of the COI essentially removes the problem, since the reader of the guideline can decide for himself or herself if the COI leads to bias," says Kirkpatrick.

Other organizations go a step further, requiring participants with relevant COI to the topic at hand to abstain from voting on a specific recommendation, or from discussing the recommendation, or both. "Chairs are supposed to enforce these rules," says Kirkpatrick. "I suspect in some cases there is a 'don't ask, don't tell' mentality, which may mean that the organizations don't believe COI is an issue in guideline writing."

Kirkpatrick says the most commonly voiced ethical concern is unrecognized bias compromising the integrity of guidelines. "However, it is hard to draw a direct line between COI and bias, because the degree to which a COI leads to bias is likely very dependent on the individual," he says.

Kirkpatrick is more concerned about the perception of bias that COI brings. "People already have many critiques of guidelines, and studies show that they are often not followed," he says. "I believe there is no faster way to discredit these otherwise useful documents than to have them open to charges of bias because panel members have COI."

Harold C. Sox, MD, MACP, professor of medicine at Geisel School of Medicine at Dartmouth in Hanover, NH, and former guidelines panel chair for the American College of Physicians, says that

EXECUTIVE SUMMARY

Conflicts of interest are common among members of committees that produce clinical practice guidelines for specialty organizations, according to several recent studies.

- The profession's failure to self-regulate this area could result in increased regulatory scrutiny.
- Unrecognized bias compromising the integrity of guidelines is a primary ethical concern.
- The perception that bias could occur, regardless of whether it did occur, could discredit guidelines.

if guideline panel members have COIs, "regardless of their motives, the seeds of mistrust have been planted."

Recommendations "appropriately tough"

Given the important role that guidelines play in the practice of medicine, the Institute of Medicine (IOM)'s 2009 recommendations are "appropriately tough," says Sox.

"There was a time when the main use of practice guidelines was to serve as a standard of good medical practice, but they had little effect on practice because the movement to improve quality of care was in its infancy," says Sox.

In effect, no one was paying much attention to adherence to standards of practice, says Sox, "but things have changed."

"The most striking example is the U.S. Preventive Services Task Force. The [Affordable Care Act] ACA says that if the Task Force gives a preventive service a strong recommendation, then Medicare will pay for it," says Sox.

More informally, commercial insurers are using guidelines to make coverage decisions. In addition, guidelines are often the starting point for developing practice measures used to assess the quality of care.

"Basically, the stakes are higher with practice guidelines than they used to be," says Sox. "They are influencing policies, rather than simply serving as a standard for physicians to strive to follow."

Sox believes that specialty organizations are likely to take the IOM recommendations seriously. "They are professionals, and in the end, are accountable to the public for their policies," he says. "They also don't want to be identified as non-adherent."

Another factor is the movement toward creating a marketplace for high-quality guidelines. "Guideline developers that want access to the marketplace will have to have strong COI management policies," says Sox.

The Agency for Healthcare Research and Quality, the sponsor of the National Guidelines Clearinghouse, strongly encourages developers of clinical practice guidelines to describe their COI policies, to disclose potential COI, and to describe all funding sources for the development of their guidelines.

According to a newly implemented policy, failure to disclose COI would disqualify a guideline from being posted on the Clearinghouse.[5]

Organizations will be motivated to improve their practices, including their COI policy, says Sox, "so that their guidelines get a chance to be seen by organizations that use the National Guidelines Clearinghouse as a marketplace for guidelines that they can trust." ■

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Organ donor facility is less costly, more efficient: An "ethical must"

Center allows maximum number of organs to be used

Moving organ donors from hospitals to a free-standing organ recovery center resulted in increased efficiency and lower costs, according to a recent study.[1]

The study analyzed 915 liver transplants performed at the center from 2001 to 2011, and found that travel time was reduced from 8 to 2.7hours, with surgeon fly-outs reduced by 93%.

The Center was established in 2001 by Mid-America Transplant Services, which coordinates organ donations and retrievals for eastern Missouri, southern Illinois, and northeast Arkansas. "It was quite accidental, the way we figured it out," says

Maria B. Majella Doyle, MD, MBA, FACS, the study's lead author. Doyle is associate professor of surgery at Washington University School of Medicine and director of the adult liver transplant program at Barnes-Jewish Hospital, both in St. Louis, MO.

When a community hospital was unable to perform a donor operation in 2001, the donor was moved to Barnes-Jewish Hospital so the procedure could be performed. "Once we did that, the organ procurement organization leadership said, maybe we should consider moving it out of the hospital altogether," says Doyle. Several states now have similar centers in place, "but politics often get in the way of making it happen," she explains.

Donors are given low priority in the hospital setting, at times, because of scheduled surgeries or emergency cases. If there is one surgical team and a trauma case comes in, for instance, that takes priority over the donor operation.

"Flying or driving the donor to the facility allows the investigation process to be performed efficiently and quickly, with no waiting," says Doyle.

"Huge comfort" to families

The Center holds a candlelight donor memorial service every year, attended by both recipient and donor families. Doyle frequently overhears comments from donor families such as "My brother saved five people."

"The donor families know how many organs were donated and how many were used," she says. "I feel very strongly that having the facility allows the staff to work with the donors to really maximize utilization. It's an ethical 'must,' if you will."

The maximum number of organs is utilized from every donor. The team is afforded the time to allow the heart to recover from whatever trauma the donor recipient had, for example, and to work with medical treatments to maximize the chances that lungs can be utilized.

"Donation is a huge comfort to a family," says Doyle. "They feel that their loved one is lost, but they are saving someone else's life."

Urgent need for education

There is an urgent need to educate the general public about organ donation and how important it is, emphasizes Doyle. "It's amazing how people still fear that somebody is not brain dead, even though they are brain dead. That's where the education has to come in," she says.

Tours are routinely given to groups of school-aged children, with the goal of teaching them about organ donation. "We talk about recipients and transplants and how people are able to live because of this," says Doyle. "The hope is that they will go home and talk to their families about organ donation."

The center's staff are trained to counsel families about donation. "These are the people who go to the families initially once we get word from the hospital that a donor is available," says Doyle. "They sit with them, they pray with them, they cry with them."

Families who initially refuse to donate often change their minds. Donor families are surveyed about their experience with the process.

"We have a hugely high satisfaction rate from families who have gone through the donation process," says Doyle. "They end up being so grateful for the process." ■

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SOURCE
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EXECUTIVE SUMMARY

Moving donors from hospitals to a free-standing organ recovery center resulted in significantly reduced surgeon hours, air travel, and cost, according to a recent study which analyzed 915 liver transplants performed from 2001 to 2011.

- Flying or driving the donor to the facility allows the investigation process to be performed more efficiently.
- Families who initially refuse to donate often change their minds after counseling.
- The team is afforded the time to maximize the chances that organs can be utilized.

COMING IN FUTURE MONTHS

- Measure quality of end-of-life care
- IC and comparative effectiveness research
- Concerns of collecting data on physicians' prescribing
- The best ways to educate providers on end-of-life care

CME QUESTIONS

1. Which is true regarding advance directives, according to a 2014 study?
   A. The vast majority of adults reported having an advance directive.
   B. Only about one-fourth of adults had an advance directive.
   C. Only a small minority of adults reported concerns about end-of-life care.
   D. Virtually all adults older than 65 had an advance directive.

2. Which is recommended to obtain feedback on ethics consultations, according to **G. Kevin Donovan**, MD, MA?
   A. When two parties with differing viewpoints are involved, obtain feedback from both parties if possible.
   B. Ask professional colleagues only objective questions, as opposed to subjective questions.
   C. Report internal feedback to the ethics committee, only if this is specifically requested by the committee.
   D. Avoid routinely questioning whether ethics consults presented any opportunities for systemic changes.

3. Which is true regarding conflicts of interest (COI) among members of committees that produce clinical practice guidelines, according to recent research?
   A. COI are very uncommon.
   B. Unrecognized bias is not an ethical concern.
   C. Virtually no guideline writers had financial interests in the area they reviewed.
   D. COI are common and are often not disclosed.

4. Which is true regarding moving organ donors from hospitals to a free-standing organ recovery center?
   A. Costs were significantly higher.
   B. The investigation process is performed more efficiently.
   C. Fewer organs are utilized per donor.
   D. Families are less likely to agree to donate.

CME OBJECTIVES

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

- Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems.
- Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings.
- Discuss the effect of bioethics on patients, their families, physicians, and society.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.
1. Read and study the activity, using the provided references for further research.
2. Scan the QR code below, or log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice, or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.