MEDICAL ETHICS ADVISOR®

For 25 years, your practical guide to ethics decision making

February 2014: Vol. 30, No. 2
Pages 13-24

IN THIS ISSUE

FOLLOW US ON twitter

@MedEthicsAdv

Statement of Financial Disclosure: **Arthur R. Derse**, MD, JD (Consulting Editor), **Shelly Morrow Mark** (Executive Editor), **Leslie Hamlin** (Managing Editor), and **Stacey Kusterbeck** (Contributing Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

AHC Media

Hospice use increasing — but so is ICU utilization, say new data

Bioethicists must advocate for informed decision-making

Are Americans' end-of-life choices shifting? "It's sort of a question of whether the glass is half empty or half full," says **Joan M. Teno**, MD, MS, professor of health services, policy, and practice at Brown University's Warren Alpert School of Medicine, Providence, RI.

A decade ago, researchers demonstrated that cancer care was becoming increasingly aggressive among Americans near the end of life during the 1990s.[1]

"Patients became more likely to receive chemotherapy near death and to visit the emergency room, be hospitalized, and be admitted to the ICU [intensive care unit]," says **Jennifer W. Mack,** MD, MPH, co-director of the Pediatric Hematology/Oncology Fellowship Program and assistant professor in pediatrics at Harvard Medical School in Boston, MA.

On the other hand, the study also found that fewer patients died in the hospital, and more used hospice care at the end of life. A 2013 study by Teno and colleagues found similarly mixed results.

Researchers looked at end-of-life care among Medicare beneficiaries with cancer, chronic obstructive pulmonary disease, or dementia. They found that while hospice use steadily increased from 2000 to

EXECUTIVE SUMMARY

While hospice use steadily increased and deaths in the hospital declined, intensive care unit care in the last month of life increased, according to two recent studies.

- Many patients do not receive hospice care until within three days of the end of life.
- Readmission penalties could increase referrals to home care services.
- Quality of care at the end of life is not currently measured.

2009 and deaths in the hospital declined, ICU care in the last month of life increased.[2]

While hospice use at the time of death increased from 21.6% to 32.3% to 42.2%, 28.4% of patients used a hospice for three days or less in 2009. Of these late hospice referrals, 40.3% were preceded by hospitalization with an ICU stay.

In her own practice, Teno often sees patients admitted to a hospice after being in an inpatient unit for more than 24 hours. "My concern is that after 24 hours, they are not really getting the true benefits of hospice," she says. "You are still then dealing with all the problematic care that occurred prior to that."

The mean number of health care transitions in the last 90 days of life increased from 2.1 to 3.1 per decedent. "Is this really what we hope and expect out of our health care system — to have a lot of loose ends occurring in the last days of life?" Teno asks.

Rethink financial incentives

Although the use of hospice care for Medicare patients with advanced cancer is increasing, many patients do not receive hospice care until they are within three days of the end of life, according to a 2013 report from the Lebanon, NH-based Dartmouth Atlas Project.[3] In 2010, more patients were treated in ICUs in their last month of life than in the period from 2003 to 2007.

The researchers were surprised that end-of-life care at cancer centers was not different from the care at community hospitals, says **David C. Goodman**, MD, MS, professor of pediatrics and health policy at The Dartmouth Institute for Health Policy and Clinical Practice in Lebanon, NH, and co-principle investigator of the Dartmouth Atlas of Health Care.

"While we found marked variation across all types of hospitals, on average, end-of-life care fell short of the care most patients want — care that provides comfort and allows patients to spend as much time in a home-like environment with their families," he says.

Penalties for hospital readmissions may lead hospitals to work toward better outpatient management of patients so they can avoid readmission, suggests Mack. Hospice, other palliative care, or home care services could offer better care for dying patients post-discharge, resulting in a lower likelihood of readmission. "Thus, it's likely that readmission penalties could bolster referrals to home care services that may be quite helpful to dying patients," says Mack.

Of Medicare's $550 billion annual budget, 17% is spent on patients' last six months of life, according to the Dartmouth Atlas Project's analysis. Between 2007 and 2010, Medicare spending on patients in the ICU in the last two years of life increased 13% to nearly $70,000 per patient.

"We have to seriously rethink the financial incentives of fee-for-service Medicare and dual eligibles, and move to a system that rewards quality," urges Teno.

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media, LLC, One Atlanta Plaza, 950 East Paces Ferry Road NE, Suite 2850, Atlanta, GA 30326. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Medical Ethics Advisor®, P.O. Box 550669, Atlanta, GA 30355.

AHC Media, LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media, LLC designates this enduring material for a maximum of *18 AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for acute care physicians, chiefs of medicine, hospital administrators, nurse managers, physician assistants, nurse practitioners, social workers, and chaplains. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $519. Add $19.99 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $83 each. (GST registration number R128870672.)

Editorial Director: **Lee Landenberger**.
Managing Editor: **Leslie Hamlin** (leslie.hamlin@ahcmedia.com)
Executive Editor: **Shelly Morrow Mark** (shelly.mark@ahcmedia.com).

AHC Media

EDITORIAL QUESTIONS

Questions or comments? Call Leslie Hamlin at (404) 262-5416.

Quality not measured

Accountable Care Organizations (ACOs) are moving in the right direction, says Teno, by experimenting with payment systems in order to find a way to encourage both better quality and more cost-effective care.

"We want to be sure that we are not just doing another procedure or spending another day in the ICU without talking to that dying patient or family member," she says.

The newer payment models don't measure the quality of care at the end of life any better than previous payment models, however. "When you think about who are the high utilizers of health care, people who are dying are one of those groups of people," says Teno. "It's important to make sure that this vulnerable population gets high-quality care."

There is a need to report back to providers what they are doing well, and what they need to improve, when providing end-of-life care, underscores Teno. "Sometimes we get stuck in measuring what's easy to measure. Quality is much more complex than giving aspirin to patients with an acute [myocardial infarction]," she says.

ACOs could use a shared savings approach, she suggests, to incentivize physicians to do a better job of helping seriously ill patients and families formulate goals of care.

"That is an opportunity for ACOs, but there are also risks," says Teno. "If you don't end up using expensive care for this population, you could save even more money by just not providing high-quality care at all."

The goal is to find the right fit for the individual patient. "Somehow we have to figure out how to align payment to do that," says Teno. "Right now, the system rewards another day in the ICU. It doesn't reward talking to a patient about their goals of care."

Providers need to "rise to the occasion"

Providers need to be more proactive in educating patients about their prognosis, helping them formulate goals of care and care plans, and ensuring that those goals are honored, says Teno.

This is a difficult task for a dying patient and their family to take on all by themselves. "I would hope that health care providers rise to the occasion, and will do what's best for the patient and family during some of the more difficult events in a family's life," Teno says.

Bioethicists can play an important role in advocating for informed decision-making. "Honest patient-physician discussions about prognosis and end-of-life care planning allow patients the ability to make thoughtful decisions about the care they wish to receive at the end of life," says Mack.

Patients often don't know they are dying, or don't know that they have incurable disease. These patients may be more likely to pursue aggressive care over palliative measures at the end of life.

"While receipt of aggressive care is not necessarily wrong, it is associated with poorer quality of life at the end of life," says Mack. "Any decision to pursue aggressive measures in the face of a poor prognosis should be informed." ■

REFERENCES

1. Earle CC, Landrum MB, Souza JM, et al. Aggressiveness of cancer care near the end of life: Is it a quality-of-care issue? *J Clin Oncol* 2008; 26(23):3860–3866.
2 . Teno JM, Gozalo PL, Bynum JPW, et al. Change in end-of-life care for Medicare beneficiaries: Site of death, place of care, and health care transitions in 2000, 2005, and 2009. *JAMA*. 2013;309(5):470-477.
3. Goodman DC, Morden NE, Chang C, et al: Trends in cancer care near the end of life. Lebanon, NH; The Dartmouth Institute. September 4, 2013.

SOURCES

• **David C. Goodman**, MD, MS, Professor of Pediatrics/Health Policy, The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, NH. Phone: (603) 653-0815. E-mail: David.C.Goodman@dartmouth.edu.
• **Jennifer W. Mack**, MD, MPH, Co-Director, Pediatric Hematology/Oncology Fellowship Program, Assistant Professor in Pediatrics, Harvard Medical School, Boston, MA. Phone: (617) 632-5430. E-mail: jennifer_mack@dfci.harvard.edu.
• **Joan M. Teno**, MD, MS, Professor of Health Services, Policy, and Practice, Warren Alpert School of Medicine, Brown University, Providence, RI. Phone: (401) 863-9627. E-mail: joan_teno@brown.edu.

Expand bioethics role: Become more involved in organizational ethics

Bioethicists have much to contribute

The expansion of clinical bioethicists' activities into organizational ethics has, at times, been

criticized, largely on grounds that clinical bioethicists lack the appropriate expertise, says **Anne Lederman Flamm**, JD, staff in the Department of Bioethics at the Cleveland Clinic, and director of e-Ethics, a program to help other health care organizations respond to ethical challenges in delivering care, at the Cleveland (OH) Clinic's Center for Ethics, Humanities & Spiritual Care.

"Lacking support and direction from leadership, or from major stakeholders in a particular organizational issue, would be a significant obstacle," she adds.

Setting boundaries on bioethicists' role as case-based consultants may short-change the organization in terms of the contributions bioethicists might make, suggests Flamm. This is especially true in light of new expectations that health care organizations will establish the quality and value of their services in an environment with limited resources.

"Beyond the analytical skills bioethicists might bring to organizational ethics issues, they can offer experience in facilitating communication about sensitive topics, summarizing stakeholders' positions, and articulating options and reasons why one action may be better than others," says Flamm.

Flamm adds that bioethicists might be perceived as more neutral or objective than particular factions with longstanding affiliations or clear self-interests within the organization. Here, she suggests some specific activities that bioethicists could consider to expand their role beyond case consultation into organizational ethics:

• Participate on an operations or quality assurance committee.

The committee can provide an entry point for the bioethicist to learn more about the organization's delivery of health care and the people who deliver it.

EXECUTIVE SUMMARY

Some bioethicists are expanding their role beyond case consultation into organizational ethics, but may encounter barriers such as lack of support from leadership. Bioethicists can:

- Identify members of the Ethics Committee who can obtain executive support for a particular initiative.
- Use an in-depth case study to illuminate systemic issues.
- Propose grand rounds on an organizational ethics issue that impacts a particular department.

"Committee settings often generate decisions that are 'organizational,' in that they direct or guide actions for groups extending beyond the committee," says Flamm. Such decisions can raise explicit or implicit ethical issues, such as resource allocation or access to care.

"Moreover, hearing about the challenges caregivers and non-clinical employees face exposes the bioethicist to systemic issues," says Flamm. These may be related to issues the bioethicist often encounters in the context of a specific patient's case.

Hearing about patient flow through pre-operative care, surgery, and peri-operative care might illuminate consent or handoff challenges. "Learning how tissue samples are stored and retrieved might inform the ethicist's perspective on research consent or incidental findings," says Flamm.

• Engage the Ethics Committee in consideration of organizational issues.

In this way, the Ethics Committee can become an intermediary among the various stakeholders within the organization. "The Ethics Committee can have a breadth of perspective conducive to seeing the 'forest' of organizational systems and practices above the 'trees' of individual cases brought to the consultation service," says Flamm.

Leadership's receptiveness to the Ethics Committee's involvement in organizational issues may depend on how it views the Committee's role. Flamm says the diversity of members' roles within the organization could "ease the path" if the Committee identifies an issue outside a narrower case-based function.

"A committee-wide endorsement that an issue deserves broader attention may compel leadership's attention to it," she says. For instance, if an entire committee comprised of physicians, nurses, social workers, chaplains, and community members agrees that the organization's commercial advertising campaign is misleading, the vice president of media relations might consider the claim more seriously than if asserted by a lone voice.

Members of the Ethics Committee might also be willing to act as "champions" for a particular initiative that significantly affects their area. For instance, an obstetrician/gynecologist member may be interested in crafting ethical guidelines for a new high-risk delivery unit, or an intensive care unit nurse may want to lead a task force designing a bed allocation scheme.

• Incorporate organizational ethics issues into education events.

Even when bioethicists' primary responsibility is case-based consultation, education opportunities can

encompass organizational ethics. Flamm offers an example of using an in-depth study presentation to illuminate a systemic issue, such as how shortcomings in caregiver training resulted in a delayed discharge.

"Bioethicists might also propose grand rounds on an organizational ethics issue that impacts a department, such as examining privacy and truth telling for the psychiatry department following an organization's decision to release clinic notes directly to patients," says Flamm. ■

SOURCES

• **Anne Lederman Flamm**, JD, Staff, Department of Bioethics/ Director, e-Ethics, Center for Ethics, Humanities & Spiritual Care, Cleveland (OH) Clinic. Phone: (216) 636-0287. E-mail: flamma@ccf.org.

Educate long-term care providers on end-of-life issues

Go outside the walls of hospital or academic setting

At a family council meeting at an long-term care meeting, **Bob Parke**, BA, BSW, MSW, MHSc, a bioethicist at Toronto's Humber River Hospital, asked the question, "How successful do you think CPR [cardiopulmonary resuscitation] is?" He defined success as the person remaining at the present functional level.

"One spouse put up their hand and stated boldly, 'Eighty percent successful.' It was then I learned that we have a lot of work to do upstream; not in the hospital emergency or later in the ICU [intensive care unit]," says Parke.

With some education and discussion, Parke typically finds families come to understand the actual poor success rate of CPR, and that it is not a therapy for a disease.

Bioethicists should strongly consider "going outside the walls" of the hospital or academic setting to educate patients, providers, and family on end-of-life issues, urges Parke.

He suggests incorporating community care into the rotation of bioethics fellows and students. This can help proactively address resuscitation status, feeding problems or other anticipated health care decisions where a crisis decision could be avoided.

"The vast majority of health care occurs in the community," says Parke. "It is in places such as extended care homes, such as nursing homes, where a lot of work has to be done."

Misconceptions on dementia

Parke often finds that families aren't aware that feeding and swallowing difficulties are a normal part of the dementia trajectory.

"Families know and experience the memory loss, behavior change and increasing frailty; but don't know about feeding and swallowing problems," he explains. Bioethicists can encourage earlier discussion about this, says Parke, so individuals can make an informed decision for their incapable loved ones before a crisis occurs.

During a meeting at one extended care home, the staff acknowledged to Parke that discussions about swallowing and feeding problems at the end stages of dementia did not routinely take place. The physician who oversaw medical care at the home committed to making a focused effort to talk to the families of residents in the home or his practice about the issue.

"In a subsequent meeting, this home reported fewer crisis decisions for feeding tubes being made," says Parke. "Additionally, when a decision is made for a feeding tube insertion, it is a better informed decision."

In this case, a short time spent in a productive meeting led to a change in practice. There was a positive outcome for the person affected by dementia, the family and the health care team.

"Arguably, spending some money upfront on the bioethicist's time saved on the use of emergency departments and other acute care resources required to assess and do a feeding tube insertion," says Parke.

Providers in extended care homes often have

EXECUTIVE SUMMARY

There is a need for bioethicists to educate patients and providers at extended care homes on end-of-life issues.

- Families overestimate the success of cardiopulmonary resuscitation.
- Families are often unaware that feeding and swallowing difficulties are a normal part of the dementia trajectory.
- Residents lack information on advance care planning.

misconceptions about the decisionmaking capability of patients with dementia, says **Amy M. Corcoran**, MD, CMD, FAAHPM, assistant professor of clinical medicine at University of Pennsylvania's Perelman School of Medicine.

"Just because someone has dementia doesn't mean that they cannot be involved in the decision-making, " she says. "Unless it's the very end-stage of dementia, they might be able to have some understanding and participate in the decision-making process."

In-person education rarely occurs

Bioethicists don't typically reach out to provide this type of education in person due in part to the number of extended care homes and lack of time, says Corcoran. She suggests these approaches:

- Reach out to local, regional, and national organizations for long-term care, including the American Medical Directors Association and the American Geriatrics Society;
- Contact administrators and medical directors of extended care homes;
- Invite staff to the hospital for educational inservices;
- Provide inservices that offer nursing or social worker education credits onsite to providers;
- Offer to provide education to surrogate decision-makers of individuals who reside in nursing homes.

Keith M. Swetz, MD, MA, associate professor of medicine at Mayo Clinic in Rochester, MN, recommends identifying frequently encountered ethical dilemmas in local long-term care facilities. Then, make them part of continuous education and improvement.

Staff members at a religious-affiliated extended care facility in the community reported to Swetz that residents lacked information on advance care planning, and had misconceptions about the perceived benefit of dialysis or nutrition. Swetz notes this is one strong example of preventative ethics. Unfortunately, he believes this type of proactive approach doesn't happen as much as it possibly could between bioethicists and extended care facilities.

"We did an inservice, not only with the workers but also the residents of the facility," says Swetz. "We talked about some of the challenges with surrogate decision-making and advance care planning so they could bring up the issue with their individual clinician."

Bioethicists encouraged providers to engage with patients with recurrent hospitalizations, advanced cancer or dementia earlier in the process.

"Then, when the time comes to make the decision, it's not new information," he says. "Even if people's goals change over time, having a discussion you can reference back to is often helpful." ■

SOURCES

- **Amy M. Corcoran**, MD, CMD, FAAHPM, Assistant Professor of Clinical Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia. E-mail: Amy.Corcoran@uphs.upenn.edu.
- **Bob Parke**, BA, BSW, MSW, MHSc Bioethics, Humber River Hospital, Toronto, Ontario, Canada. E-mail: BParke@HRRH.ON.CA.
- **Keith M. Swetz**, MD, MA, Section of Palliative Medicine, Division of General Internal Medicine, Mayo Clinic, Rochester, MN. Phone: (507) 284-9039. E-mail: Swetz.Keith@mayo.edu.

Ethical responses when cost of care becomes the issue

Many providers uncomfortable discussing cost

It's no longer just the patient and the doctor in the examination room, says **Michele Meltzer**, MD, MBE, clinical associate professor of medicine at Thomas Jefferson University in Philadelphia, PA.

"You have the payer — insurance company or government — and society as a whole, in addition to the patient and physician, as stakeholders in the office," she says. "We don't talk about that nearly enough."

Concerns about the cost of health care are increasingly becoming part of the patient-physician relationship. "It may not be just paying for the visit. It may be paying for the copay," says Meltzer. "There are

EXECUTIVE SUMMARY

More than half of rheumatologists who responded to a 2013 survey reported the high cost of treatment for their patients as an ethical concern.

- Some providers embellish symptoms to help patients obtain prior authorization from insurance companies.
- Patients and even providers are often unaware of the cost of care.
- Physicians may over-order costly tests because of liability risks, or because patients demand a particular test.

no guidelines for providers on what to do in this situation. Many of us are just beside ourselves."

"Slow adoption" of knowledge on costs

Conversations about costs are more likely to happen, given continuing focus on the implementation of the Affordable Care Act and pharmaceutical pricing in the United States, according to **John Henning** Schumann, MD, Gussman/Adelson chair in internal medicine and program director of internal medicine residency at University of Oklahoma School of Community Medicine in Tulsa.

"Many physicians are not comfortable discussing these issues, mostly out of the profession's slow adoption of knowledge about costs," he says.

Medical education has primarily focused on the most effective and appropriate diagnostic pathways and treatments, with little or no regard to costs. "But that simply is no longer the case," he says. "If one is to practice 'sound' medicine, taking the patient's likely adherence into account has become the norm."

Survey data show that patients want doctors to take costs into consideration when recommending treatments, and that doctors are increasingly aware of the importance of out-of-pocket costs to patients as part of the calculus of adherence.[1,2]

"Some physicians have argued that the ethical imperative is to provide the best treatment recommendations regardless of cost," says Schumann. "But that position ignores reality."

Providers "bending" ethical standards

More than one-half (51%) of 771 rheumatologists who responded to a 2013 survey said they grapple with the high cost of treatment for their patients.[3] Physicians reported ways in which they see themselves as "bending" ethical standards, and presented their justifications for doing so.

Examples included "embellishment" of symptoms to help patients obtain prior authorization from insurance companies; stretching the truth to obtain needed drugs and testing for patients; and providing patients with certain diagnoses to obtain coverage for needed medications or physical therapy.

"The number one issue that we found was the societal costs of expensive medications and profits from infusions," says Meltzer, one of the study's authors.

While there is a great deal of focus on transparency in health care, patients, and even providers, are often unaware of the cost of care. "Even if a patient's copay is high, they still may not grasp what their medications actually cost a month," she says. "Most of the time, the patient is insulated from the complete cost."

A 2014 study asked 503 orthopedic attending physicians and residents at seven academic medical centers to estimate the costs of 13 commonly used orthopedic devices.[4] Attending physicians correctly estimated the cost just 21% of the time, and residents were able to do so 17% of the time. However, more than 80% of respondents indicated that cost should be "moderately," "very," or "extremely" important in the device selection process.

"As physicians, we are often unaware of the costs of what we are ordering," says Meltzer. "We should take that into account, all things being equal."

Physicians may over-order costly tests because of liability risks, or because patients demand a particular test. "With time constraints, it's sometimes just easier to take the path of least resistance," Meltzer says.

There is a need to compare and contrast newer therapies with older ones and do a cost-effectiveness analysis, she urges.

"For example, febuxostat, a drug used to treat gout, was released in 2009. It costs substantially more than allopurinol, an older generic drug," says Meltzer. Both drugs lower serum uric acid, which causes gout, but the analysis of the effectiveness of older drugs may be obscured by the way some clinical trials are set up.

Discussion over the cost of care, says Meltzer, "needs to be the venue of the public press, the medical press, and our professional meetings."

Guidelines often ignore cost

There is an ongoing debate as to whether treatment guidelines, whether from an insurance company or a professional society, should take cost into account.

The American College of Rheumatology's guidelines discuss different agents to treat gout without addressing cost. "For first-line therapy, there are two drugs that are vastly different in price. They didn't make a distinction that you should start with the less expensive one first," Meltzer notes. In contrast, a similar set of guidelines from England's National Institute

for Clinical Effectiveness recommend that the less costly drug be used first because it is equally effective.[5]

A very costly drug may allow a patient to continue working, however, or a less expensive drug might require extensive monitoring.

"You have to look at the total picture," says Meltzer. "But we need to be transparent about what things actually cost, and who is paying for it." ■

REFERENCES

1. Alexander GC, Casalino LP, Meltzer DO. Physician strategies to reduce patients' out-of-pocket prescription costs. *Arch Intern Med* 2005; 165(6):633-636.
2. Alexander GC, Casalino LP, Meltzer DO. Patient-physician communication about out-of-pocket costs. *JAMA* 2003; 290(7):953-958.
3. MacKenzie CR, Meltzer M, Kitsis, EA, et al. Ethical challenges in rheumatology: A survey of the American College of Rheumatology membership. *Arthritis & Rheumatism* 2013;65: 2524–2532.
4. Okike K, O'Toole RV, Pollak AN, et al. Survey finds few orthopedic surgeons know the costs of the devices they implant. *Health Affairs* 2014; 33(1):103-109.
5. Meltzer M, Pizzi LT, Jutkowitz E. Payer decision-making with limited comparative and cost effectiveness data: The case of new pharmacological treatments for gout. *Evid Based Med* 2012; 17(4):105-108.

SOURCES:

• **Michele Meltzer**, MD, MBA, Clinical Associate Professor of Medicine, Jefferson Medical College, Philadelphia, PA. Phone: (215) 955-1410. E-mail: Michele.Meltzer@jefferson.edu.
• **John Henning Schumann**, MD, Gussman/Adelson Chair in Internal Medicine/Program Director, Internal Medicine Residency, University of Oklahoma School of Community Medicine, Tulsa. Phone: (918) 660-3456. E-mail: john-schumann@ouhsc.edu.

Improve ethics consults based on feedback and critique

Prompt follow-up can identify necessary changes

If you are interested in whether consults in the intensive care unit reduce costs, then you might run a randomized trial of whether cases in which ethics consults are offered are more cost-effective than those in which they are not. If your concern is whether a specific procedure is followed when conducting consultations, then a chart review of notes and documentation can evaluate the quality of the process. If you want to know whether consults make participants satisfied, you could do a satisfaction study.

However, "none of this gets at the centrally intractable question of how you measure whether ethics consultation helps people do things in a better, good, or right way," says **Paul J. Ford**, PhD, director of the NeuroEthics Program at Cleveland (OH) Clinic.

Attention to some combination of process, outcomes, and professionalism constitutes a good approach to effectiveness outcomes in ethics consultation, says Ford. This requires mixed methods, including regularly scheduled peer review of consults; surveys of stakeholders; and demonstration of continuous improvement of policies based on questions that emerge from consultations.

"With these methods, the ethicist can improve her own practice from peer critique, understand gaps in services through stakeholder feedback, and provide institutional change to avoid unneeded consultations," says Ford.

Here are methods that ethics consultation services can employ to improve their own practice:

• Obtain written or verbal feedback from various stakeholders involved in a particular case.

These quality improvement requests focus on various components of the systematic approach to conducting a clinical ethics consultation, such as promptness of the consultant's response, the helpfulness of the consultant, or overall satisfaction, says **Adam M. Pena**, MA, a clinical research associate at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, TX.

Other fields of the quality improvement request may address maintaining or facilitating communication between various stakeholders during a consultation, the impact of the ethics consultation on the case, or the process of conducting an ethics consultation, says Pena.

EXECUTIVE SUMMARY

Regularly scheduled peer review, surveys of stakeholders, and demonstration of continuous improvement of policies are some approaches to improve ethics consults. Bioethicists can:

- Discuss cases with a trusted peer or mentor.
- Assure that everyone doing ethics consultation has an opportunity for peer feedback.
- Review contentious or precedent setting cases with a full ethics committee.
- Follow up promptly with participants in a given consultation.

• Conduct **a detailed review of the case by senior members of the ethics consultation service and other stakeholders.**

This review includes a presentation of the case, a discussion of the various ethical issues involved in the case, and, at times, a review of the consultant's chart notes.

"The discussion helps a consultant sharpen his or her present skill set and identify areas for improvement, such as data gathering, leading family meetings, or ethical analysis," says Pena.

Ethicists need "sounding board"

Having a trusted peer or mentor to discuss cases with can help resolve and improve practice issues, particularly for less experienced clinical ethicists.

"Even those with years of training and practice benefit from having someone to talk with as a sounding board to assure they have a balanced view of the situation," says **Jane Jankowski**, LMSW, MSB, a clinical ethicist and assistant professor at Alden March Bioethics Institute at Albany (NY) Medical College.

A regular review of cases as a team can also assure that everyone conducting ethics consultation has an opportunity for peer feedback.

"Particularly contentious or precedent-setting cases may warrant review with a full ethics committee to assure that a broader group has an opportunity to provide input," says Jankowski.

To best utilize stakeholder feedback, prompt follow up is required with active participants in a given consultation.

"When feedback suggests that the situation was not helped by the ethics consultant, or that the participant would not seek another consultation, it is important to try to identify in what way the process failed to meet expectations," says Jankowski.

When an ethics consultant or a team of consultants notice a pattern of recurring themes in the course of ethics consultation, this suggests there is confusion or frustration about the issue within the institution.

"Education, policy changes, or procedural suggestions may be proposed to institutional leadership when the ethics consultant feels this will serve the institution and avoid unneeded consultations," says Jankowski. ■

SOURCES

• **Paul J. Ford**, PhD, Department of Bioethics, Cleveland (OH) Clinic. Phone: (216) 444-8723 E-mail: Fordp@ccf.org.

• **Jane Jankowski**, LMSW, MSB, Assistant Professor, Alden March Bioethics Institute, Albany (NY) Medical College. Phone: (518) 262-7125. E-mail: JankowJ@mail.amc.edu.

• **Adam M. Pena**, MA, Clinical Research Associate, Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, TX. Phone: (713) 798-2515. E-mail: Adam.Pena@bcm.edu.

Data collection at point of care: Does project require IRB approval?

Requirements seen by some as overly burdensome

There is a need to observe how care is delivered and to make improvements on the basis of what is learned, underscores **Mildred Z. Solomon**, EdD, president of The Hastings Center in Garrison, NY. "In the United States, we've finally awakened to the fact that in order to improve health care, we have to study it," she says.

U.S. health care is twice as expensive as health care in other developed nations, says Solomon, "yet our quality is poorer, our medical error rates unconscionable, and disparities in access and utilization unacceptable."

Solomon believes that clinicians need guidance from bioethicists with expertise in research ethics on how to apply the current regulatory framework to quality improvement (QI) research, comparative effectiveness research (CER), and implementation science.

Solomon would like to see a set of research protocols analyzed and discussed and organized into a casebook with guidance from bioethicists as to the nature and extent of oversight each type of protocol requires.

EXECUTIVE SUMMARY

More data are being collected at the point of care with the goal of improving quality, but there is widespread uncertainty as to what kind of oversight quality improvement research requires.

• There is growing interest in comparative effectiveness research (CER) to improve quality and lower cost.

• In CER, two drugs, devices, or interventions, both a form of usual care, are compared.

• Some argue that since both interventions are known to be efficacious, institutional review board approval and informed consent are overly burdensome.

"Working from particular protocols from the ground up would also test whether fundamental changes in the regulations need to be made, or whether people simply need to be helped to apply existing regulations with greater flexibility and nuance," she says.

QI researchers want to make things better, but it's unclear what kind of oversight is needed, says Solomon. For example, researchers may want to identify the best way to motivate patients with hypertension to adhere to their prescribed medications. "It's well known that a large percentage of patients do not take their drugs as prescribed," says Solomon. "So now the QI folks decide to design an enhanced intervention."

To find out whether the intervention — a follow-up call from a nurse, perhaps — is worth the extra cost, half the patients diagnosed with hypertension are assigned to get the call, and half get only the prescription and a brochure.

Does this type of QI activity constitute research and does it require institutional review board (IRB) approval, and must patients give consent? There is widespread uncertainty within health care systems across the country as to how to answer these questions.[1]

"Observing how care is delivered means collecting patient data at the point of care," says Solomon. "Inevitably, the line between research and treatment is going to be blurred."

New paradigm is suggested

In traditional research, the goal is to determine the effectiveness of an as-yet unapproved drug or device. "The gold standard way of doing that is to enroll people in randomized, controlled trials, with half the research participants receiving the drug or device and the other half not," says Solomon.

Now that more research is being done as a way of enhancing quality and lowering cost of care, there is growing interest in QI research and CER. In CER, two proven drugs, devices, or interventions are compared to find out which ones work better with subgroups, which are easier to implement, or which are less expensive.

Since both interventions are a form of acceptable care and are known to be efficacious, the question is whether assigning patients to receive one rather than the other really needs IRB approval and informed consent.

"Some people believe that there should be disclosure about the fact that they are being asked to enter into a trial and their informed consent sought," Solomon says. "Others ask, 'Why create so many layers of approval, and create burdensome procedures, when all we want to do is learn by observing usual care?'"

Some researchers point out that the main purpose of human research participant protection is to protect people from undue risk, and argue that some treatments bring more risk than some forms of QI research or CER.[1]"They want to see a new paradigm — one that is based on level of risk — rather than on whether something is categorized as research or treatment," says Solomon.

The question to ask, says Solomon, is "Is participation in the study adding more risk than would otherwise be the case from receiving the treatment alone, if it weren't being studied?"

"In my view, if enrollment in the study truly does not add more risk, consent may be waived," says Solomon. "But the level of likely risk and its potential magnitude must be authentically, wholeheartedly examined."

Another ethical question is whether, simply on the grounds of truth telling and respect for persons, there is an obligation to reveal that a person has been assigned to one arm of a study rather than another. Even if there is no increased risk, patients may have preferences about what arm they go into.

"When patient preferences are likely, that is, when reasonable people may have very different views about receiving a given intervention, consent should be requested," says Solomon. "In those cases, researchers should not assume a willingness to participate, or a willingness to be assigned to either arm."

QA enmeshed with clinical care

Regardless of whether a project is research or QI, the need for adherence to good ethical standards is an imperative, according to **Blair Henry**, an ethicist at Sunnybrook Health Sciences Centre in Toronto, Ontario, Canada. Henry's interest in quality assurance (QA) ethics started during his tenure as vice chair of the organization's institutional research ethics board.

"For many years, we saw considerable 'ethics creep' from QI leaders bringing their projects to the IRB for approval to facilitate future publication efforts," says Henry. He says that both QI and research projects necessitate good ethical practice, and that the difference between research and QI is more related to the oversight mechanism used to meet that end.

"Given that research is voluntary, and it entails a burden or risk not typically borne by patients, the field of research ethics has evolved to ensure good oversight of research projects occurs before enrollment of subjects begins," he says. "The world of QA has lagged behind on this."

In many organizations, no similar oversight body exists to review QI projects. "This can be concerning when we consider that it is now expected that all patients will engage and support quality endeavors, thereby throwing the concept of voluntariness into question," says Henry.

In addition, the enterprise of improving quality is now seen as the responsibility of all staff, but many are not trained in the privacy/confidentiality requirements of QI and evaluating additional risks.

As an ethicist involved in the organization's QA structure, Blair developed learning modules to help front-line staff understand basic ethical principles and how they should be applied to QI work.

"Additionally, experienced QI and patient safety specialists have increased the rigor of QI measurements," says Henry. "This has pushed the line between QI and research even closer."

Clinical staff consult with ethics more frequently for assistance addressing the complex ethical issues involved in larger QI projects. "This enmeshing of QA with daily clinical care has resulted in a renewed engagement between clinicians and ethicists at a very foundational level," reports Henry. ■

REFERENCES

1. Solomon MZ, Bonham AC. Ethical oversight of learning health care systems. *Hastings Center Report Special Report* 2013;43:
S2-S3.
2. Kass N, Faden R, et al. The research-treatment distinction: A problematic approach for determining which activities should have ethical oversight. Ethical Oversight of Learning Health Care Systems, *Hastings Center Report Special Report* 2013;43:S4-S15.

SOURCES

• **Blair Henry**, Ethicist, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada. Phone: (416) 480-6100 ext. 7178. E-mail: Blair.henry@sunnybrook.ca.
• **Mildred Z. Solomon**, EdD, President, The Hastings Center, Garrison, NY. Phone: (845) 424-4040, ext. 201. E-mail: solomonm@thehastingscenter.org

COMING IN FUTURE MONTHS

- Ethical concerns involve microbes
- Evaluate effectiveness of ethics consults
- Ethical approaches for "difficult" doctors
- Translating neurotechnology to clinical practice

CME QUESTIONS

1. Which is true regarding recent trends in end-of-life care, according to a study published in *JAMA*?
   A. Hospice use steadily declined.
   B. Deaths in the hospital increased significantly.
   C. Both hospice use and intensive care unit care in the last month of life increased.
   D. Readmission penalties will make it much less likely that patients will be referred to home care services.

2. Which is true regarding ethical considerations of cost of care, according to **Michele Meltzer**, MD, MBE?
   A. All clinical guidelines in the United States now take cost into account.
   B. There is strong evidence that providers consistently share information on the cost of care with their patients.
   C. No surveyed physicians reported "embellishing" patients' symptoms to obtain coverage.
   D. Patients and even providers are often unaware of the cost of care.

3. Which is recommended to improve ethics consults, according to **Jane Jankowski**, LMSW, MSB?
   A. It is not necessary to identify in what way the process failed to meet a particular clinician's expectations.
   B. Bioethicists should assure that everyone conducting ethics consultation has an opportunity for peer feedback.
   C. It is not advisable to review contentious or precedent-setting cases with a full ethics committee.
   D. Demonstration of continuous improvement of policies should not be based on questions that emerge from consultations.

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.