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Patients' end-of-life wishes often not included in EHRs

Advance care planning process not accessible to providers

Often, providers fail to ask seriously ill patients about their wishes for end-of-life care. Other times, providers do inquire about the patient's wishes, and include this information in a visit note. "But that information can get lost among all of their other clinic notes," says **Jennifer S. Temel**, MD, clinical director of thoracic oncology at Massachusetts General Hospital in Boston. "Documenting patients' goals and wishes and advance directives ensures that they receive care in accordance with their preferences."

Patient wishes often aren't accessible to providers via the electronic health record (EHR). "Including sections in the EHR to enter data about patients' goals and wishes and advance directives would ensure that patients who have communicated these preferences to their clinicians receive the care they desire," says Temel.

Adequate documentation of the advance care planning process offers the opportunity to help ensure that patients receive the care they want at the end of life, and that family members are provided with the support and information they need when placed in the difficult position of being a surrogate decision-maker for a loved one, says **J. Randall Curtis**, MD, MPH, director of the UW Palliative Care Center of Excellence at University of Washington in Seattle.

A 2013 study assessed how well electronic prompts can encourage

EXECUTIVE SUMMARY

Electronic health records (EHRs) often do not contain advance directives, documentation of the advance care planning process, or other information that can help guide decision-making at the end of life. To ensure patients receive the care they want, bioethicists can:

- Enter data on patients' goals and wishes.
- Encourage patients and families to participate in the advance care planning process.
- Train clinicians in conducting and documenting advance care planning.

oncologists to document a patient's code status in the outpatient EHR. Of 100 patients with advanced lung cancers who agreed to participate, 34% had a code status documented in the outpatient EHRs, compared to 14.5% previously.[1]

"The findings were encouraging that oncologists can alter their practice behaviors, initiate conversations, and document patients' resuscitation preferences," says Temel, the study's lead author.

Data automatically added to EHR

Worchester-based UMass Memorial Healthcare partnered with a technology firm to develop an Internet-based tool to allow patients to share their values, goals, and medical wishes with the people of their choosing, and automatically publish this information in the EHR. "This documentation will be able to be updated at any time after discussion with their physician, a change in health status, or perhaps change of mind. We are aiming to roll this out in the coming months," reports **Suzana Makowski**, MD, assistant professor of palliative medicine.

EHRs are traditionally repositories for clinician documentation, while advance directives are principally completed by patients, she notes, "and the variation on the design of these forms makes it difficult for health systems to automate the input into the EHR," she says.

As patient-reported data become more important and patient portals become more prevalent, Makowski anticipates EHRs will address the need to integrate end-of-life directives into the record. "Unfortunately, when a patient is unable to express those wishes and their directives are unknown, medical decisions are made without the patient's guidance," she says.

Lack of EHR integration of the patient's directives harms the patient due to unwanted medical procedures performed at the end of life, burdens the health system with providing unwanted and often costly procedures, and imposes despair and moral distress on health care providers and family members, says Makowski.

Importance of planning process

EHRs typically contain information about whether patients report that they have advance directives, as a result of the Patient Self-Determination Act passed by Congress in 1990, which requires hospitals to ask patients this question and document the result during a hospital admission. "However, it is much less common that the medical record contains the actual advance directive, or information that can help guide decision-making," says Curtis.

The process of advance care planning is often more important than the advance directive itself, adds Curtis. This offers patients and their families the opportunity to place the patient's values and goals into the context of treatment preferences and potential treatment decisions.

"Since most patients don't know exactly what decisions they and their family will be facing when they get sick, this process allows patients and their families to be prepared to make the best in-the-moment decisions," says Curtis.

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EDITORIAL QUESTIONS

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Including advance directives in the EHR is important and increasingly occurring, says Curtis. However, advance directives are limited by the fact that many patients can't predict exactly what decisions they will be making and what their preferences might be in that context.

"Some EHR systems are finding ways to capture the advance care planning process by documenting patients' goals and values as well as treatment preferences," says Curtis, "This can inform family members and physicians when decisions need to be made." ■

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All families of potential donors aren't offered opportunity

"Dual advocacy" for donor family and those awaiting transplantation

The primary ethical consideration when approaching families for organ donation is to ensure that the donation authorization process is voluntary and that it respects the wishes of those who want to donate, according to **Alexandra K. Glazier**, Esq., vice president and general counsel at the New England Organ Bank in Waltham, MA.

Current donation authorization practices are generally based on the idea of "dual advocacy" — to respectfully advocate for the donor and donor family's interests, as well as the interests of those awaiting transplantation. "This approach is based on the fact that the vast majority of adults support organ donation, and that there are 120,000 people awaiting transplantation," says Glazier.

Glazier says another important ethical consideration is that all families of potential donors are offered the donation opportunity.

Research has shown that practitioners cannot accurately predict which families will want to donate.[1] "It would be unethical to deny families the ability to evaluate for themselves information about the potential for donation, including the positive impact on the grief process and on the life of those receiving transplantation," she says.

In a growing number of cases, the potential donor has already authorized donation through a donor registry. "In fact, in the United States, there are now over 110 million registered donors," says Glazier. "Approximately half of the actual organ donors in the United States last year had legally authorized donation themselves."

This has fundamentally changed the nature and purpose of the family approach in those instances, from requesting donation authorization to explaining the donation process. "This process also better aligns the ethical considerations of ensuring donation is voluntary and consistent with the donor's known wishes," says Glazier.

Potential for unethical practices

The organ donation community is keenly aware that unethical practices involving organ donation are likely to erode public trust in the process, says **Randall S. Sung**, MD, surgical director of kidney and pancreas transplantation and associate professor of surgery at University of Michigan Health Systems in Ann Arbor, and, thus, are very sensitive to the need to conduct themselves ethically. Most of the major advances in the development of organ donation, such as the recognition of brain death and the advent of donation after cardiac death, received a full vetting from the medical community and general public from an ethical perspective, he explains.

"Nevertheless, the potential for highly unethical practices exists," says Sung. "Where misperceptions among the public persist, they usually focus

EXECUTIVE SUMMARY

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• Current donation authorization practices are generally based on the idea of "dual advocacy."
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• It is important that all families of potential donors are offered the donation opportunity.

on fear of organ donors not receiving all the care they could have to save their life."

For this reason, the transplant community takes great pains to make the demarcation between end-of-life care and care of the donor once declared dead very clear and not to be crossed, says Sung.

An exception is sometimes made for donation after cardiac death, in which anticoagulation and vessel cannulation can, on occasion, be given prior to death declaration — but only after families indicate intent to withdraw life support and subsequently consent to organ donation. In one highly publicized case, a recovery surgeon was charged with felony abuse of a dependent adult for ordering and giving a potentially lethal dose of narcotic to a donor who was not declared dead yet (although the surgeon was later acquitted by a jury). "This illustrates how any crossing of the line between care of a living patient and care of a deceased organ donor is very highly scrutinized," says Sung.

It is unethical for organ donation professionals to provide misleading information about the impact of donation in order to obtain consent from families, says Sung. "Although unlikely, any attempt by organ donation personnel to provide information about prognosis for recovery in the case of a potential donor after cardiac death, or to otherwise influence decisions about withdrawal of life support, would be unethical," he adds. ■

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Discussions often don't occur on use of sedation at the end of life

U.S. patients rarely proactively informed on options

The justification for sedation, and the openness with which it is discussed, differed in the accounts of respondents from the United States and the Netherlands, according to a 2014 study.[1] Researchers did qualitative interviews with 36 physicians in 2007 and 2008. Here are key findings:

• Most Dutch respondents justified the use of sedation by stating that it does not hasten death. Most American respondents indicated that it might hasten death, but that this was justifiable as long as that was not their primary intention.

• Many Dutch respondents indicated that they initiated open discussions about sedation proactively to inform patients about their options and to allow planning. American respondents reported fewer and less-open discussions, mostly occurring late in the dying process and with the patient's relatives.

"The biggest issue for ethical consideration regarding terminal sedation is around dosing," says **Nneka O. Mokwunye**, PhD, director of the Center for Ethics and Spiritual Care Department at MedStar Washington Hospital Center in Washington, DC.

"The problems I hear the most from the clinical team are related to their discomfort in giving high doses of morphine and other medications that are known to have the double effect of respiratory suppression," says Mokwunye. "Although it takes a lot to have that 'side effect,' oftentimes at the end of life a large continuous dose is needed."

Developing a comfort level with the appropriate dosing of pain medications so that the patient is kept comfortable, and so that the clinical staff feel comfortable, is the main reason for having palliative care clinicians, says Mokwunye.

"The typical ICU [intensive care unit] team benefits from assistance in making good terminal sedation decisions," she says. "A 'one size fits all' approach to terminal sedation is not appropriate. Having trained palliative care physicians and nurses helps to improve care."

Bioethicists can help to address the discomfort of the staff, help with the family's understanding of end-of-life practices, and address any conflict that may arise during this time.

EXECUTIVE SUMMARY

While most Dutch respondents to a 2011 survey indicated that they initiated open discussions about sedation proactively, American respondents reported fewer such discussions, with most occurring late in the dying process.
• A "one size fits all" approach to terminal sedation is not appropriate.
• Having trained palliative care physicians and nurses helps to improve care.
• Bioethicists can educate the family on end-of-life practices.

"The bioethicist would also address educational needs to help improve understanding of terminal sedation and how it is a patient autonomy issue, as well as any hospital policies and practices around terminal sedation, including any potential conscientious objection issues," says Mokwunye. ■

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Public disclosure linked to far fewer payments to physicians

Transparency encourages trust

Many believe that the precipitous decline in industry payments to physicians over the past few years can be attributed to The Physician Payment Sunshine Act, says **David A. Fleming**, MD, MA, FACP, chairman of the Department of Medicine and director of the Center for Health Ethics at University of Missouri in Columbia. "It has been widely reported that payments from pharmaceutical companies to physicians have gone down as much as 50% to 60%," he adds.

The Physician Payment Sunshine Act, part of the Affordable Care Act, requires manufacturers of drugs, medical devices, and biologicals who participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. The data will be posted on a public website after September 30, 2014, giving patients access to the information without asking their physician directly.

There is little doubt that the pharmaceutical industry has provided tremendous benefits to patients and to society in general, says Fleming. "New and amazing drugs and other treatment modalities have been introduced over the years, thanks to investment in research and development," he notes.

Physicians have been "invaluable partners in this effort," says Fleming, by serving as consultants for new drug development and enrolling patients in clinical trials. Physicians can also benefit professionally by taking advantage of teaching and learning opportunities provided by industry regarding new forms of treatment that may benefit their patients.

"Unfortunately, however, the healing relationships that doctors have with patients cannot help but be influenced by the monetary and material relationships they may also have with industry," says Fleming. "Such relationships influence the prescribing behavior of physicians." Here are some ways in which this can occur:

- Brand-name drugs are almost always more expensive than generic forms; the difference in cost often comes out of patients' pockets.
- Physicians may be tempted to deviate from guidelines and known standards of care, such as with off-label use of free drug samples. This, in turn, may pose risks to patients.
- Early adoption of new treatments may lead to as yet unknown complications.

Most physicians adamantly deny that they are influenced in any way by gifts such as drug samples, meals, or money for consulting and speaking. "But even with the best intentions, evidence suggests that prescribing and other professional behavior in the treatment of patients is influenced by such relationships," says Fleming.

Patient-physician relationship

Getting information about payments to physicians via a third party, such as the Centers for Medicare & Medicaid Services, "can avoid awkward conversations that both doctors and patients would probably like to avoid," says **Genevieve Pham-Kanter**, PhD, assistant professor in the Department of Health Systems, Management, and Policy at University of Colorado's School of Public Health in Denver.

It is unclear whether either physicians or patients will have any incentive to bring these issues up in

EXECUTIVE SUMMARY

Patients will soon be able to access information about their physicians' financial relationships, as a result of The Physician Payment Sunshine Act. It is unclear how this information will affect the patient-physician relationship.
- Knowing that physicians receive payments from drug or device firms may result in a loss of patient trust.
- Some patients may view payments as a sign that doctors are in high demand.
- Patients with long-standing satisfying relationships with their doctors may simply disregard the information.

the context of an office visit, says Pham-Kanter. It is also unclear how patients will react to learning about physicians' financial relationships.

"We do not yet know how patients will respond to the payments information that will be released, but this will be an important empirical question to answer," she says. "We do hope to be able to answer this question in due course."

Knowing that physicians — either one's own or physicians in general — receive payments from drug or device firms may result in a loss of patient trust in physicians, and perhaps more broadly in medicine and the medical profession, says Pham-Kanter.

"Research using hypothetical vignettes suggests that knowing that their doctors receive some kinds of payments leads patients to have diminished trust in their doctors," she notes.[1,2]

Some patients may view payments as a positive sign that the physician is in high demand, on the other hand. "It will be important to keep an eye on how patients actually respond to this information, if they respond to it at all," says Pham-Kanter. "Many patients may not be aware of the payments data release or may not care, especially if they have long-standing satisfying relationships with their doctors."

Fleming says it's likely that the new regulatory requirement will enhance patient-physician relationships. "Physicians and industry alike have good intentions and are interested in improving the plight of patients and the health of the public," he says. "The Sunshine Act helps physicians and industry remain vigilant."

This level of transparency, he says, is one way that patients can be reassured that their physicians are adhering to their ethical responsibility to assess any corporate relationship. "Transparency encourages trust that physicians are being honest and acting primarily in the interest of their patients," says Fleming. ■

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Quality of palliative care training, bedside tools reduce end-of-life ICU use

Definition of "unnecessary" is subjective

The quality of palliative care training in critical care medicine programs and the use of bedside tools were independently associated with reduced intensive care unit (ICU) use in the last six months of life for patients with chronic illness, according to a 2014 study.[1]

"We hear a great deal about the use of ICU at the end of life. Looking at the policy literature, there seemed to be a disconnect between the research and what happens in the ICU," says **Howard Saft**, MD, MSHS, the study's lead author and assistant professor in the Division of Pulmonary, Critical Care and Sleep Medicine at David Geffen School of Medicine at University of California, Los Angeles.

Critical care program directors at 89 hospitals evaluated the quality of palliative care education in critical care fellowships, the number of bedside tools, and the presence or absence of an inpatient palliative care consultation service. For each additional level of education quality, there was a 0.57 day decrease in ICU days. For each evidence-based bedside tool, there was a 0.31 day decrease in ICU days.

"We attempted to bridge the modifiable characteristics that impact clinical practice with the same level of data — in our case, the Dartmouth Atlas — that often stimulates the national conversation on the subject," says Saft.

The chosen characteristics — education, bedside tools, and palliative care consultation — begin to help answer the question of how training program and practice environments should be designed, he adds.

EXECUTIVE SUMMARY

The quality of palliative care training in critical care medicine programs and the use of bedside tools were independently associated with reduced intensive care unit (ICU) use at the end of life. Bioethicists can play a role in decreasing ICU use by working with program directors to:
• Implement evidence-based bedside tools such as protocols for comfort measures or for withdrawal of life-sustaining treatment.
• Improve palliative care education.
• Help clinicians to explain risks and benefits of critical care interventions.

"The degree of impact of the quality of education and bedside tools used by the trainees had a higher impact than we expected," reports Saft.

Although the study didn't look at which training approaches were most effective, Saft says the findings suggest that bioethicists can play a role in decreasing ICU use by working more closely with critical care program directors. Tools such as comfort measure protocols, ordering protocols, or withdrawal of life support protocols, used in daily practice, "streamline the process and promote physician communication with the patient and family for shared decision making whenever it is needed," says Saft.

Critical care medicine program directors typically have many responsibilities and training priorities, and often lack time and resources to focus on this issue. "An ethicist can contribute to this area by talking with the critical care program directors and seeing how the ethicist can help the program directors with education or integrating some of these tools," says Saft.

Approaches to decreasing ICU use

The definition of "unnecessary" ICU use is very subjective, says **Mitchell M. Levy**, MD, FCCM, FCCP, medical director of the Medical Intensive Care Unit at Rhode Island Hospital and professor of medicine and division chief of pulmonary and critical care medicine at The Warren Alpert Medical School of Brown University in Providence, RI.

"The literature has long reported a discordance between the perception of the medical staff — physicians, nurses, respiratory therapists, and social workers — and the family," he notes.

Patients and families sometimes have unrealistic expectations for the potential benefits of critical care. "In Europe, families and patients place more trust in physicians, and it's the physician who makes the decision," says Levy. "In the United States, patient autonomy is a primary principle of ethics, and, therefore, it's the family or the patient who makes the decisions."

While most patients would not want therapies if there was no chance of benefit, says Levy, the meaning of "no benefit" is subjective. "It's a challenge to explain the risk and benefits of different interventions in critical care, or for that matter, the value of critical care altogether," he says. "That's why the shared decision-making model has become so important."

Levy says the answer lies in better communication between clinicians, patients, and their loved ones, so that a partnered decision-making process can be utilized. This gives both sides a deeper understanding of the patient's wishes and the likely outcome, so they can work together to come to the best conclusion for the patient.

"Families have to be willing to let clinicians help make the decision. And clinicians have to be willing to help," he says. "I think it's fair and good for clinicians to say, 'Here's what I recommend. Here's what I would do.'"

There is a need to publicize data on critical care outcomes, so that the public has a better understanding of how likely it is to survive an infection, a heart attack, kidney failure, or combinations of those, argues Levy. "I think we still have the view of medicine that we see on TV, where someone is snatched out of the jaws of death by a miracle worker in the critical care unit," he says. "Outcomes can vary. Not everything has a happy ending."

Proactive ethics consults can facilitate communication, says Levy, "but it is also important for bioethicists to teach clinicians how to recognize the ethical principles operating in a given situation. That can guide decision-making and resolution." ■

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New recommendations on how to ethically manage findings

Currently, there are no consistent guidelines for how to ethically manage unexpected results discovered through procedures and tests, says **Lisa M. Lee**, PhD, executive director of The Presidential Commission for the Study of Bioethical Issues. "Recent reports show how unsettled the issue of incidental findings is," she adds.

While one report recommended scans for early cancer screening, another report released the following month suggested early scans can cause more harm than good by detecting too many problems, thus leading to overtreatment, she notes.

The Bioethics Commission's December 2013 report "Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts" provides recommendations on this issue. (To download the report, go to: http://bioethics.gov/node/3183.)

"Incidental findings typically include findings that lie outside the aim of a test or procedure," says Lee. "However, sensitive and unexpected results in the direct-to-consumer context merit many of the same ethical considerations."

There is no specific formula by which clinicians, researchers, and direct-to-consumer providers identify the right action when it comes to incidental findings. Each is operating on its own set of professional duties and ethical obligations, which vary widely.

"Consequently, patients, research participants, and consumers have inconsistent experiences and expectations when it comes to learning about incidental findings," says Lee.

Lee says that in clinical care, clinicians have a fiduciary duty to their patients that requires them to act in the patient's best interest. In research, investigators have more limited duties to research participants. "In the commercial, direct-to-consumer context, the ethical obligations are unclear and still developing," she says.

More information is not always better. Incidental findings might, but do not always, have important, actionable implications for a patient's health and well-being.

"It would be rash — both ethically and practically speaking — to conclude that everything that can be sought should be sought, and reported, in all contexts," says Lee.

Regardless of the setting or the type of test or procedure, when it comes to incidental findings, the Bioethics Commission has one overarching piece of advice — to "anticipate and communicate."

The Bioethics Commission recommends that all practitioners anticipate and plan for incidental findings. Patients, research participants, and consumers should be informed ahead of time about what to expect, and incidental findings should be aptly communicated if they are found.

"The best way forward is shared decision-making between practitioners and potential recipients," says Lee. "Informed consent and open communication between providers and potential recipients is essential."

New questions continuously emerge

The problem of what to do about incidental findings is not new, says **Judy Illes**, PhD, FRSC, FCAHS, Canada Research Chair in Neuroethics and professor of neurology at the University of British Columbia in Vancouver, Canada.

"We started working on the problem about 10 years ago, and new questions and new solutions continuously emerge," she says. "These are never black and white, but I think we are doing a better job every day."

In the clinical context, there are very good guidelines for disclosure of unexpected findings, says Illes. "If there is something that is discovered in addition to the target or instead of the target, then the physician has to decide what to do and has good professional guidance to refer to," she says.

Historically, the physician was the one who decided if the patient should be contacted. The move toward shared decision-making means physicians disclose more to patients than they used to, says Illes. "The fundamental principles have not changed," she adds. "Clearly, if there is a finding of urgency, it must be followed up on right away. Other decisions can be more cautious, like watchful waiting or further testing."

The response to incidental findings in research is more complicated, says Illes, in part because the information obtained is often more limited in scope. "The duty to warn exists," she says. "There must be disclosure to participants in a research study what kind of procedure will be followed if something is accidentally found."

Researchers are obligated to act in the best interest of their participants in the most logical way, given the nature of the study being conducted. "We've heard some frustration from neuroimaging researchers about having too many choices," says Illes. "These were once welcomed, but now have become burdensome."

Researchers might follow different protocols because these vary depending on the institution. In

EXECUTIVE SUMMARY

All practitioners should anticipate and plan for incidental findings so that patients, research participants, and consumers are informed ahead of time about what to expect, and so that incidental findings are aptly communicated if they are found, according to a report from the Presidential Commission for the Study of Bioethical Issues.

- Clinicians have a fiduciary duty to their patients that requires them to act in the patient's best interest.
- Investigators have more limited duties to research participants.
- In the commercial, direct-to-consumer context, ethical obligations are unclear and still developing.

2013, representatives from the National Institutes of Health, the University of British Columbia, Stanford University, and other institutions collaborated to find ways to harmonize their protocols, which are also consistent with the Presidential Commission guidelines.

"If the researcher is concerned about a participant's incidental finding, the researcher must be able to tell the participant," says Illes. "Otherwise, the burden on the researcher is just too great."

"Uncharted territory"

What to do if an incidental finding is discovered involving the brain's functionality is "almost completely uncharted territory," says Illes. She gives the example of unusual patterns that might be predictive of diseases such as Alzheimer's. "One could be obtaining resting scans from 20-year-olds, and we may later find out, when we know more about the resting state, that we had stumbled upon something that's predictive of something ominous in the future," she says.

Another question is what duty researchers have to act on information such as changes in oxygenation noted on functional MRIs that could be suggestive of a mental health disorder. For instance, a study of sexual arousal with 20 participants might use both behavioral and physiological measures. "If an individual was measured to have a signal that is different from the other 19, how would we interpret that information?" asks Illes. "It is unknown space, but it is definitely a frontier that we have to be thinking about." ■

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PC measures must be applicable across variety of illnesses, settings

While the Affordable Care Act (ACA) mandates quality reporting for hospices, the same is not true for palliative care delivery in other settings.

"One core benefit of palliative care is that it can be delivered to seriously ill patients with a variety of illnesses and across multiple settings," says **Sally A. Norton**, PhD, RN, FPCN, FAAN, co-director of research in the Department of Medicine's Palliative Care Division and associate professor in the School of Nursing at University of Rochester (NY).

As a result, palliative care clinicians have been challenged to find measures of quality that are applicable to all patients in a variety of settings. The Hospice and Palliative Nurses Association and the American Academy of Hospice and Palliative Medicine are moving forward with a project to recommend a set of measures that are cross-cutting, says Norton, which will begin to measure quality across populations and settings.

The goal of the Measuring What Matters project is to recommend a set of five to 10 quality measures that are not site- or disease-specific. "That will provide us a foundation to establish quality measures and benchmarks for palliative care," says Norton. (For more detailed information, go to http://bit.ly/1nFINal.)

"The ethical considerations involving assessment center on what constitutes quality, and for whom," says Norton. "Performance measures drive care practices."

As a geriatrician, **Christine Cassel**, president and CEO of the National Quality Forum (NQF), cared for many patients who were experiencing serious illness or were in need of end-of-life care.

"I know firsthand how important this type of care is and how vital it is to see continued improvements in the quality of care in this area," she says. Performance measurement and public reporting in this area is still relatively new, acknowledges Cassel. In 2006, NQF released its National Framework and Preferred Practices for Palliative and Hospice Care Quality.

"This framework served as a foundation upon which quality measurement and reporting could be built, offering practices designed to improve hospice and palliative care," says Cassel. A total

EXECUTIVE SUMMARY

Palliative care clinicians have been challenged to find measures of quality that are applicable to all patients in a variety of settings. Some recent developments:
- The goal of the Measuring What Matters project is to recommend a set of five to 10 quality measures that are not site- or disease-specific.
- "Meaningful use" incentives include a measure that encourages recording of whether patients 65 years of age and older have an advance directive.
- Hospice programs are required to submit quality data or incur a financial penalty.

of 38 preferred practices were endorsed as suitable for implementation by palliative care and hospice programs, based on eight domains. These are structures and processes of care; physical aspects of care; psychological and psychiatric aspects of care; social aspects of care; spiritual, religious, and existential aspects of care; cultural aspects of care; care of the imminently dying patient; and ethical and legal aspects of care.

"Since then, the field of measurement has progressed," says Cassel. NQF has endorsed several end-of-life care measures, including a measure related to whether pain is brought to a comfortable level within 48 hours of initial assessment, and a post-death survey for families to answer questions about their perception of care.

"Additional NQF-endorsed measures related to end-of-life care specifically focus on patients with cancer," says Cassel. "Discussions have encouraged an exploration of expanding these beyond this patient population."

Until now, data on hospice program quality have primarily been collected on a voluntary basis, and aggregated to report on quality at a national level. Here are some recent developments:

• The Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs provide financial incentives for meaningful use of certified EHR technology, including a measure that encourages hospitals and eligible providers to record whether patients 65 years of age and older have an advance directive stored in the record.

• Section 3004 of the ACA directs the Department of Health and Human Services (HHS) to establish reporting requirements for hospice programs through the Hospice Quality Reporting Program. Beginning fiscal year 2014, hospice programs are required to submit quality data or incur a financial penalty.

• In 2012, NQF, through its multistakeholder Measure Applications Partnership (MAP), provided input to HHS on performance measures for hospice and palliative care, with an eye toward aligning measures across various settings.

Recognizing that measurement in this area is new, says Cassel, MAP suggested a phased approach to emphasize clinically focused measures at first. This will expand to measures that assess a patient's full set of experiences across time and settings.

"At this time, this is a pay-for-reporting program, and the submission of data establishes compliance with the requirements — not the performance level," says Cassel. "No date has been specified to begin the public reporting of the data." ■

SOURCE

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"Disclosure gap" remains, despite overall trend toward transparency

Despite more than a decade's worth of laws, regulations, and guidelines about the requirement for disclosure after medical errors, there a remains a large "disclosure gap," says **Robert D. Truog**, MD, director of Harvard Medical School's Center for Bioethics in Boston "that is, there is a significant gap between what we say we should do and what we actually do."

This has become less of an issue when major errors occur, as systems are in place to assure that the events are not covered up or slip through the cracks. "But we have not been fully successful in creating a culture of transparency, where clinicians see patients and families and partners in care with a commitment to free and open communication," says Truog.

Truog says that one of the biggest impediments to this transformation remains fear of lawsuits. "Although clinicians systematically overestimate the true magnitude of this risk, there is no doubt that until the malpractice system is reformed, this will remain a substantial impediment to full and open disclosure," says Truog.

Trend toward nonpunitive approach

The trend toward early, proactive error disclosure is clearly going to continue, says **Jon C. Tilburt**, MD, MPH, Division of General Internal Medicine

EXECUTIVE SUMMARY

Disclosure after medical errors is still not done consistently, partly due to clinicians' continued concerns regarding liability exposure. Some ethical considerations are:

• organizations' lack of success in creating a culture of transparency;

• the potential need to simultaneously hold systems and individuals accountable;

• the importance of the concept of forgiveness to the medical profession.

and the Biomedical Ethics Program at Mayo Clinic in Rochester, MN. "I think at some point in the history of the profession, providers felt like it was within our control to just slip on error disclosure, partly because of benevolence and partly self-serving intent," he says. "The backdrop of that was largely an ethic of personal responsibility and blame."

The pendulum has now swung in the opposite direction, says Tilburt, toward a nonpunitive approach that focuses more on system factors and avoids placing blame on a specific individual.

"At some point, we might find that this generally positive trend, of continuing to maintain this non-punitive framework, will be tested," says Tilburt. "Sometimes individuals make wrong choices and we can't entirely get them off the hook, either." Future approaches may need to simultaneously hold systems and individuals accountable, he suggests.

Public expectation will drive trend

There is a great deal of focus on potential engineering solutions that can prevent medical errors, notes Tilburt, but the complexity of medicine presents some unique challenges.

"So this utopian fantasy that we can somehow engineer our way to a perfectly safe health care culture is probably ill-conceived," says Tilburt. The question then becomes how to assign responsibility when mistakes inevitably occur, he adds.

The trend toward disclosure mirrors a similar movement toward transparency in all areas of health care. "That train has left the station and we're not going back," says Tilburt. "Whether day-to-day practice lives up to that ideal is an area of ongoing concern."

Public expectation is one component driving the trend toward disclosure. "We have gone from 'This is not an expectation, and we do not do it,' to 'This is an expectation and we do it sporadically,' and that's happened in the last 20 years or less," says Tilburt.

Tilburt expects to see a continued increase in disclosure of errors, along with systems designed to help that process. "I think incoming generations of medical students and residents are going to see this modeled a little bit more," he says. "They will bring in some of their own expectations. That will nudge the profession in the right direction."

One ethical consideration is whether the concept of forgiveness gets lost in the engineering approach to patient safety. "All of that work is wonderful, but if you can have an authentic human encounter with another person and be vulnerable, all sorts of unexpected things can come out of that," Tilburt says. "I would hate to see us beat that out of the profession." ■

SOURCES

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COMING IN FUTURE MONTHS

- Educating families on end-of-life choices
- Efforts to restore patients' trust in their physicians
- Giving patients access to electronic medical records
- Ethics of neuroscience research

CME QUESTIONS

1. Which of the following statements is true, according to **Alexandra K. Glazier**, Esq?
   A. Current donation authorization practices advocate only for the interests of those awaiting transplantation, not the donor or donor family's interests.
   B. In a growing number of cases, the potential donor has already authorized donation through a donor registry.
   C. Only a small percentage of families of potential donors should be offered the opportunity to donate.
   D. Organ donation representatives should not pursue organ donation when families have not given consent for donation, even for potential donors who have formally indicated a desire to donate.

2. Which is an ethical concern involving physicians' financial relationships with pharmaceutical companies, according to **David A. Fleming**, MD?
   A. Brand-name drugs are typically more expensive than generic forms, and patients are often responsible for the extra cost.
   B. Physicians may be tempted to deviate from guidelines and known standards of care.
   C. Early adoption of new treatments may lead to as yet unknown complications.
   D. All of the above.

3. Which is recommended to ethically manage incidental findings, according to a December 2013 report from The Presidential Commission for the Study of Bioethical Issues?
   A. Practitioners should anticipate and plan for incidental findings.
   B. Investigators should not inform research participants about the possibility of incidental findings ahead of time.
   C. Whether investigators should inform research participants about incidental findings should be determined by legislation.
   D. Incidental findings should always be reported to patients, regardless of the context.

4. Which is true regarding palliative care, according to **Sally A. Norton**, PhD, RN, FPCN, FAAN?
   A. Measures of quality are necessary only for the hospice setting.
   B. Measures of quality must be applicable to all patients receiving palliative care in a variety of settings.
   C. Hospice programs are not required to submit quality data.
   D. "Meaningful use" incentives don't address whether patients have an advance directive.

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.