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AHC Media

Study's findings leave no doubt: End-of-life wishes aren't always met or known

Only 30% related wishes to family physician

Many patients don't discuss their end-of-life wishes with physicians, but even if they do, those wishes often fail to be added to patients' medical records, according to a recent study.[1] "We expected to see some problems — that's why we did the study — but we were surprised by the magnitude of the problem!" says **Daren Heyland,** MD, MSc, scientific director of the Clinical Evaluation Research Unit at Kingston General Hospital in Ontario, Canada.

Researchers surveyed 278 elderly patients deemed at high risk of dying during the subsequent six months and 225 of their family members at 12 acute care facilities in Canada between September 2011 and March 2012. They learned that before hospitalization, 76% of patients had given thought to end-of-life care, 48% had completed advance care plans, 73% formally designated a surrogate individual to make decisions regarding their care, and only 12% expressed a preference for life-prolonging care.

Of the group of patients who had talked about their wishes, the majority had done so with their families. Only 30% had related those wishes to their family physician and 55% had discussed their preferences with any member of their health care team. As a consequence of

EXECUTIVE SUMMARY

Patients' end-of-life wishes often fail to be added to patients' medical records, according to a recent study, and even if the physician is notified of the patient's advance directive, it might not be readily available to the health care team. To prevent inadequate communication, bioethicists can:

- Ascertain if electronic medical records have an "advance care planning discussion" note.
- Encourage clinicians to document a standardized set of information.
- Offer support and guidance to patients, families, and health care providers.

this inadequate communication, patient wishes for end-of-life care agreed with the medical order documented in medical records only 30% of the time, says Heyland.

The majority of the disagreements involved a situation in which the patient preferred comfort care, and the medical record documented full resuscitation. "The ethical imperative is to first do no harm, provide only beneficial treatment, and focus on patient-centered care. We have described a situation in which we are signing up patients for aggressive treatments at the end of life that are not desired and may prolong suffering," says Heyland.

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Availability is issue

Even if the physician *is* notified that the patient has an advance directive, it isn't always readily available to the health care team. Patients might complete the form with their lawyer, place it in a drawer at home, and forget to bring it to their doctor.

Increasingly, hospitals are entering advance directives into electronic medical records (EMRs). "Some states are developing registries so advance directives can be downloadable at a variety of locations," says **G. Kevin Donovan**, MD, MA, director of the Pellegrino Center for Clinical Bioethics at Georgetown University Medical Center in Washington, DC.

EMRs at many hospitals, such as the San Francisco VA Hospital, have an "advance care planning discussion" note that can be updated at any time. "Then all advance directive documents and consecutive notes are displayed in one place with a click of a button," says **Rebecca Sudore**, MD, associate professor of medicine at the University of California, San Francisco. "The problem is that most EMRs do *not* have standardized places for this information. Even if they do, it is hard to find and use."

While clinicians are used to the idea of advance directive forms and check boxes, some are unfamiliar with the idea of documenting conversations about goals of care. Clinicians should document a standardized set of information in addition to any forms the patient has completed, urges Sudore. "It is more than just copying and pasting a 'Do Not Resuscitate,' 'Do Not Intubate,' or full code order," she says. "What is the patient's story? What is important to them in life? How do they want to live their life? Who is their surrogate?"

Clinicians are often uncomfortable bringing up the topic or do not have the time. "In our pilot work, 60% of individuals with chronic illness had never thought about speaking to their doctor about their goals for medical care," says Sudore. "It didn't occur to them that they should bring this up in the outpatient setting."

Choices "almost limitless"

Patients and their family members are faced with ever-increasing decisions to be made, says **Barbara J. Daly**, PhD, RN, FAAN, professor of bioethics at Case Western Reserve University in Cleveland, OH. "The decisions are always fraught with uncertainty," she says. "In past decades, the choices were fairly limited and the outcomes somewhat easier to predict." Patient wishes to forego what were considered as "life-saving treatments" were simpler to implement — typically to

withhold dialysis, mechanical ventilation, and cardiopulmonary resuscitation.

"In today's world of almost limitless choices, patients and families are taxed with a series of decisions about feeding tubes, amputations, repeated surgeries, and third and fourth regimens of chemotherapy," says Daly. "Even in the presence of a living will, it is rarely clear precisely how to perform the benefit/burden calculus in very complex conditions with uncertain outcomes."

Physician Orders for Life Sustaining Treatment (POLST), Medical Orders for Life-Sustaining Treatment (MOLST), Clinical Orders for Life-Sustaining Treatment (COLST), and Physician Orders for Scope of Treatment (POST) forms attempt to address one of the limitations of current living will forms, says Daly. "Most living wills are 'all or nothing' documents, but treatment decisions are much more nuanced than that," she explains.

In many situations, patients are willing to have a trial of an intervention, such as a short period on a mechanical ventilator, but do not wish to have the treatment continued indefinitely. "The POLST paradigm forms allow the signer to indicate this 'trial' choice, as well as to indicate refusal of any use of the treatment, or to indicate willingness to use the treatment, and allow the signer to choose among treatments, rather than having to refuse all," says Daly.

Conflicts with family

Even when the medical team is fully aware of the patient's preferences and an advance directive is in place, the patient's wishes aren't always followed. "The physician may choose to override the advance directive if the family is adamantly opposed to those preferences. This is something that is often not discussed," says Donovan.

It is increasingly common for family members, acting as surrogates for a patient who can no longer speak for him- or herself, to insist on continuing interventions that the clinician believes will do more harm than good, according to Daly. "Well-meaning family members, under enormous stress of the illness of a loved one, may insist on adding more treatments and more interventions, even when informed that the proposed treatment cannot work," she says. "This can lead to adversarial relationships if not managed carefully and with great sensitivity."

Bioethicists can be helpful on both sides of this interaction. "Patients and their families often need support and guidance in making difficult choices," Daly explains. "Health care providers often seek assurance that they are fulfilling their obligations, or help in finding approaches that can satisfy the ethical demands of complicated situations."

Donovan says the ideal scenario is for patients to have a health care proxy who fully understands their values and is willing to insist that the patient's wishes are followed. "The advantage to having a proxy is that a surrogate can be somewhat flexible in the application of those values in different clinical situations that may not have been envisioned by the patient themselves," he says. "If EMRs identify the patient's proxy, the team not only knows what the patient wants done, but also who they ought to be talking to. That person can then speak with the patient's voice." ■

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End-of-life planning too often inadequate

Conversation rarely happens in advance

The past 50 years in medicine have brought amazing advances in technology and pharmacology that have been able to defer death for many more people until much later in life, notes **Nancy E. Havas**, MD, FAAFP, associate professor at the Center for Bioethics and Medical Humanities at Medical College of Wisconsin in Milwaukee.

"The common occurrences of family members dying at home from a heart attack, stroke, or cancer, or even a bad infection, have become very uncommon in our modern health care experiences. This results in death being something that happens 'later' and something that we don't often encounter," says Havas. "But the reality is that it eventually happens to 100% of all patients, and is something we should plan for."

Because dying is now such a foreign experience for so many people, it is an uncomfortable topic of discussion, says Havas. "This makes the conditions that often precede death, such as dementia, respiratory failure, and functional decline, very uncomfortable for us to discuss, too. We don't want to imagine ourselves in that situation," she says. "As humans, we avoid those uncomfortable conversations for as long as possible." This means discussions often happen too late when patients can't participate in the decisions that directly impact their futures.

Havas says that many times, patients tell providers and their families something along the lines of, "I don't want to be living on machines. If it gets to that point, pull the plug!" "But the reality is that most people become disabled somewhere between playing golf and independent and living on a machine," says Havas. "I see many people who are unable to talk, or swallow enough food to survive, who are no longer able to interact with their families." These individuals cannot participate in the discussion about having a feeding tube placed to supplement nutrition, for example.

"Their families struggle terribly about making choices," says Havas. "If this scenario would have been discussed before the patient was disabled, the family would have known that the patient would not want a feeding tube, and would be at peace with the decision making, even with the knowledge that the patient would continue to decline."

Conversation needed earlier

Havas says that too often, discussions occur during "acute" times of decision making, such as during a hospitalization. Having these discussions early, preferably with the facilitation of a health care provider, generally results in a better discussion about goals and preferences than those made during the stress of a sudden change in condition.

Often, physicians are waiting for patients to tell them when they want to have the discussion, while families believe that the physician will initiate the discussion at the appropriate time. "So neither of them initiate the discussion until the discussion *has* to be held," says Havas. "Ideally, these conversations would be held routinely every three years, every time a major life change or serious health concern warranted revisiting the conversation, such as a new diagnosis or recent hospitalization."

When Havas becomes involved as a palliative care consultant, she finds that these conversations have rarely been held in advance. "When I work with families who need to make choices for a loved one who is unable to participate, it's important for me to know who the patient is and what they enjoyed doing before I met them as an incapacitated person," she says.

Havas asks questions such as "Was she active?" "Did she enjoy socializing?" "Did she like to hike in the mountains?" "Or was she more of a solitary person, reading or watching movies?" "What does she like to do?" "How has her health been during the past year, and what has she said about it?" "What does she value?" "How do her spiritual or religious beliefs help her make decisions?"

"Going back to the preferences and beliefs of the individual patient helps us provide care that is high-quality and ethically sound," says Havas.

Then, Havas asks additional questions about how the patient would feel about her specific situation, such as, "If Susan were sitting here with us and knew that she would have to have her leg removed to recover from this infection, would she be willing to do that knowing she could have more time with her children, but also knowing she would never walk again?"

Havas says the final part of the conversation should include a discussion about code status and should include a recommendation from the treating physician if relevant to the situation, and should always be framed in the context of the overall goals. "As physicians, we do a very poor job in making recommendations on this," she says. "We are quick to recommend medications that may have serious side effects, and yet hesitate to recommend against an intervention that has a very poor success rate." ■

SOURCE

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Genetic testing of children: Ethical considerations are evolving

Less harm than anticipated

Decisions about whether to offer genetic testing and screening to children should be driven by what is in the best interest of the child, emphasizes **Lainie Friedman Ross**, MD, PhD, Carolyn and Matthew Bucksbaum professor of clinical ethics and associate director of the MacLean Center for Clinical Medical Ethics in Chicago, IL.

"The ethical principle is constant, but how it is interpreted changes with changes in science and changes in our understanding," she says. "The growing literature on the psychosocial and clinical effects of such testing and screening can help inform best practices."

A 2013 joint policy statement from the American Academy of Pediatrics (AAP) and the American College of Medical Genetics and Genomics (ACMG) provides ethical justification and empirical data in support of proposed policy recommendations regarding genetic testing and screening in a myriad of settings.[1,2] *(To view the policy statement, go to http://bit.ly/16NB4kd.)*

The only previous statements that addressed ethical implications of genetic testing of children by U.S. professional organizations were a 1995 statement from the American Society of Human Genetics and the ACMG and a 2001 statement from AAP.[3,4] "This report is more comprehensive," says Ross.

EXECUTIVE SUMMARY

A 2013 joint policy statement from the American Academy of Pediatrics and the American College of Medical Genetics and Genomics provides ethical justification and empirical data regarding genetic testing and screening in a myriad of settings, with these recommendations:

- Testing for conditions that present in adulthood is discouraged in most cases.
- The use of direct-to-consumer and home-kit genetic testing of children is strongly discouraged.
- Health care providers and parents should address disclosure issues *before* predictive testing is done.

The 2013 report addresses genetic testing in adoption, histocompatibility testing for stem cell transplantation, pharmacogenomics, and direct-to-consumer testing. Both the old and new reports emphasize the need for greater education of general pediatricians in genetics.

Genetic testing of minors is more common than in any other group, with newborn screening done on virtually 100% of newborns. "There is a need for greater education of parents regarding the benefits," she says. "We need to ensure that they are aware of the screening, and what to do if their child receives a positive screen." Most other genetic testing is performed on children with multiple anomalies, autism spectrum disorders, and intellectual disabilities. "There is less genetic testing of older children, but it will increase in importance as our knowledge expands," says Ross.

Informed consent

The AAP's 2001 statement emphasized concerns about the potential harms of predictive genetic testing. "In the intervening decades, some empirical data have emerged," says Ross. "They suggest less harm than anticipated, with considerable resiliency and ability of minors to successfully incorporate these risks into their self-concepts and life plans."[5]

However, these studies disproportionately represent white individuals of higher socioeconomic status, and the effects on lower-educated and underserved populations is largely unknown, acknowledges Ross. Here are some recommendations included in the 2013 statement:

- **Testing for conditions that present in childhood is permitted, although when feasible, the child's assent should be obtained.**
- **Testing for conditions that present in adulthood is discouraged, although it may be permitted with appropriate counseling and the minor's assent, depending on the circumstance.**
- **Health care providers should be cautious about providing testing to minors without the collaboration of their parents, as results may disclose information about parental status, thus compromising parental privacy.**

Data show that adults have difficulty understanding the full implications of genetic information, and they often involve other adults in their decision making. "Permitting an adolescent to make similar choices without the benefit of parental guidance is problematic," says Ross.

- **The use of direct-to-consumer and home-kit genetic testing of children is strongly discouraged**

due to risks of inaccurate results, inaccurate interpretations, and altered family dynamics.

"This is not supposed to occur, as you are supposed to only do direct-to-consumer testing on adults. But it is happening, and it will continue," notes Ross.

• Ideally, health care providers and parents should address disclosure issues *before* predictive testing is done.

"In general, there is support for disclosure to the child done in an age-appropriate manner at appropriate teaching moments," says Ross. ■

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Clinical medical students given "booster shot" in ethics education

The majority of third-year medical students were able to recall the four ethical principles, appreciated the relevance of preclinical ethics education, and had positive self-assessments of their clinical-ethical reasoning abilities, according to a recent study.[1]

However, they were less able to recall other sources of ethical value and infrequently used ethical terms spontaneously in written reflections about ethically or professionally challenging issues.

"We were interested in trying to understand how much of what we teach in preclinical course work actually 'sticks' when students go into the clinical terrain," says **Lauris C. Kaldjian**, MD, PhD, the study's lead author and director of the Program in Bioethics and Humanities at the University of Iowa Carver College of Medicine in Iowa City. Kaldjian is medical director for clinical ethics at University of Iowa Hospitals and Clinics.

For the past few years, Kaldjian and his colleagues have asked students to write about patient-based experiences that raised some type of ethical or professional concern. "We give minimal directions for this assignment, intentionally. We don't prompt them to make references to formal ethical principles," he says. The researchers analyzed the students' writings to see whether they used the language of ethics that they had been taught previously, and also surveyed the students to see whether they could recall certain ethical principles when directly asked.

"By their responses to explicit prompts, we know that most of them remember at least the four ethical principles. But when they are writing about ethical and professional issues, they are not frequently using the language of principles and other sources of moral value," he says.

As a result of these findings, Kaldjian and his colleagues now use Medical Professionalism in the *New Millenium: A Physical Charter*, jointly authored in 2002 by the ABIM Foundation, the American College of Physicians foundation, and the European Federation of Internal Medicine,[2] to guide fourth-year students in writing about a patient-based experience they have during a professionalism seminar run for sub-interns doing rotations in internal medicine and pediatrics.

EXECUTIVE SUMMARY

The majority of third-year medical students were able to recall the four ethical principles, but infrequently used ethical terms spontaneously in written reflections, according to a recent study. To improve ethics education, bioethicists at University of Iowa Hospitals and Clinics ask students to:

• Write about patient-based experiences that involved an ethical or professional concern.

• Consider which ethical principles or commitments are most relevant to what they are writing about.

• Participate in a group discussion about particular cases.

"We ask them explicitly to consider which of the Charter's ethical principles or commitments is most relevant to what they are writing about," he says. "What we have found, not surprisingly, is that the frequency with which they make reference to such principles and values is much higher."

Kaldjian says this approach works as a kind of "booster shot" to remind students of ethical principles while they are actually involved in clinical experiences. "Rarely is it enough to present things to someone once," he says. "One of the great things about teaching in the clinical environment is you do not have to persuade students that this is serious business. Students have already wrestled with these issues and come to group discussions prepared for dialogue."

During group discussions during each rotation, faculty facilitators select some of the students' writing for group discussion, keeping the name of the author anonymous unless the student chooses to disclose his or her identity. "This becomes a very powerful experience," says Kaldjian. "It's one thing to present hypothetical situations in a lecture hall. It is a very different thing when students come to a discussion with their own cases in hand that they have already written about themselves."

Kaldjian says it's important for students to learn the language of medical ethics and to use the terms appropriately. "Like in other areas of life, if you don't have a language to describe things, you cannot identify or understand those things as well," he says. "The language of ethics is an important issue. How we communicate about moral matters in health care has implications for how we interact with our patients and colleagues, especially when differences of moral judgment arise." ■

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"Mystery patient" research: Ethically justified or not?

When the Department of Health and Human Services announced plans in 2011 for a "mystery shopper" study of access to primary care, some physicians raised ethical concerns about the use of deception with human subjects without soliciting their informed consent.[1]

"Just two days after *The New York Times* reported the administration's plans, it reported that the study had been shelved," says **Michelle N. Meyer**, JD, PhD, an academic fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School.[2]

Mystery patients can be used to assure and improve the quality of all aspects of the health care system, and health care providers should be supportive of that goal, argues Meyer. "In fact, in some cases, the sponsor of this kind of research might have an ethical *obligation* to conduct it," she says, adding that it is the only effective way of producing evidence of discrimination. "One can imagine mystery patients used to help investigate some forms of health disparities that might result from either explicit or implicit bias against certain kinds of patients."

Context matters

In 2012, researchers from the University of Pennsylvania's Perelman School of Medicine used a case study to explore ethical principles relating

EXECUTIVE SUMMARY

A "mystery shopper" study of access to primary care was shelved due to ethical concerns about the use of deception with human subjects without soliciting their informed consent. However, an ethical analysis concluded that minimally intrusive simulated patient research can in some cases be ethically justified. Some considerations:

• Mystery patients can be utilized to investigate some forms of health disparities.
• Bioethicists can analyze the ethical issues at stake in this sort of study design.
• Mystery shopping might be more ethically troubling when extended to the actual examination room.

to deceptive research without informed consent.[3] They concluded that minimally intrusive simulated patient research that gathers policy-relevant data on the health system without the consent of individuals working in that system can, in some cases, be ethically justified.

"It might seem surprising to take the position that research that involves a deceptive interaction and without any process of consent might be ethically justified. But the context matters," says **Franklin G. Miller**, PhD, one of the study's authors and senior faculty in the Department of Bioethics at the National Institutes of Health in Bethesda, MD.

Simulated patient studies facilitate socially valuable and scientifically valid research to obtain accurate data about access to health care with virtually no risk of harm to subjects, explains Miller. "We offer a set of guidelines for when this type of research is ethical, and discuss the applicable federal regulations," he says. "I see the role of bioethicists as analyzing the ethical issues at stake in this sort of study design."

Ethical justification

If approved by an Institutional Review Board (IRB), mystery shopping can be justified by the inability to obtain accurate observations when people know they are being observed, according to **Mark A. Hall**, JD, professor of law and public health at Wake Forest University in Winston-Salem, NC.

When patients are involved in research, they are almost always being asked to do something to benefit future patients or society that would not be required for their own course of treatment, says Meyer, such as consenting to having an extra vial of blood drawn.

"The potential conflict between the interests of society and researchers pursuing generalizable knowledge, on one hand, and patient subjects on the other hand, is the chief reason we have the IRB system," says Meyer. Health care professionals, by contrast, are trained and paid to serve the interests of their patients and of the health care system more broadly, rather than primarily to serve their own interests, she adds.

"A mystery patient study thoughtfully designed to determine the extent to which providers are in fact meeting their professional obligations and goals, likewise serves patients and the health care system," adds Meyer.

Mystery shoppers might be viewed as more ethically troubling, however, when extended beyond a physician's front office to the actual examination room. "Doing that could compromise the trust-based fiduciary relationship that is at the core of medical ethics, and so, would require extra justification," Hall says. "But simply contacting a physician's office to make an appointment or inquire about prices does not step into this special protected realm."

Here are some ethical concerns involving mystery patients:

• Mystery patients might interfere with the care of actual patients or waste scarce resources.

"This concern can largely be addressed by limiting these kinds of studies to non-emergency medical settings," says Meyer.

• If health care providers know or suspect that they will be approached by mystery patients, they might view every patient with distrust, which could undermine the patient-provider relationship.

Rather than viewing mystery patients as out to deceive providers, however, providers might choose to keep in mind that mystery patient studies are intended to assure and improve the quality of the health care system. "Every stakeholder in that system, including providers whose livelihoods depend on it, has an interest in its health and longevity," says Meyer.

• The privacy of providers whose behavior is studied is potentially being violated.

"It's not immediately obvious that a health professional's behavior on the job should be treated as private information. In some cases, the public may have an interest in this information," says Meyer. "But to the extent that it is a legitimate issue, researchers can focus on aggregate or de-identified data."

• The practice necessarily involves deception.

"As is the case with much psychology research, concealing the true purpose of the patient-provider interaction is very useful — and with respect to some research questions, necessary — in order to prevent 'priming' the research subject — here, the provider, and obtain meaningful data," says Meyer. "It's important to see that the deception is not gratuitous." ■

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Do physicians market products? Patients could be unduly influenced

Financial conflict "impossible to avoid"

Although not subject to the provisions of the Physician Payment Sunshine Act, which become effective in September 2014, sales of medications or products in provider offices could unduly influence patients, says **Margaret R. McLean**, PhD, associate director and director of bioethics at Markkula Center for Applied Ethics at Santa Clara (CA) University.

"As data accumulates regarding the difficulty — if not impossibility — of managing financial conflicts of interest, it seems likely that the Sunshine provisions will reach physician offices," she predicts. Patients might wrongly assume products sold in provider offices are somehow superior to those available elsewhere. On the other hand, they might wonder whether the physician is getting a "kickback" on each package sold.

"Financial conflict of interest, in this case, seems impossible to avoid," says McLean. "And, even if it can be avoided, patient *perception* that a conflict of interest exists is ethically troubling, as the trust so necessary to good patient care is threatened."

Acting in the best interest of the patient includes not exploiting the power differential inherent in the physician-patient relationship and avoiding the exertion of undue pressure on the patient, notes McLean. "As patients, we are all vulnerable. We are worried, frightened, confused, and dependent on our doctor's knowledge and know-how," she says. "We may feel obligated to buy that vial of eye drops or tube of sunscreen displayed at the front desk, mistakenly believing it to be medically necessary or wanting to please the doctor."

Remove financial gain

Inherent patient vulnerability mandates that financial conflicts of interest be managed and minimized, if not excised altogether, argues McLean.

"One way to do this would be to erase financial gain from the picture by giving away health-related products to patients or selling them at cost," she says. McLean says that at a minimum, all office sales should be accompanied by full disclosure, including the financial arrangements between the physician and manufacturer and the availability of the item elsewhere.

"Once again, honesty — in the form of transparency — is the best policy," she says.

Selling vitamins or skin products for profit and with no clear evidence to suggest medical benefit, clearly places the physician's profit interest ahead of the medical and financial welfare of the patient, says **David A. Fleming**, MD, MA, FACP, professor of medicine, chairman of the Department of Medicine and director of the Center for Health Ethics at University of Missouri School of Medicine in Columbia, MO, pointing to increasing oversight and compliance policies.

"As licensure and privileging are regulated by such oversight practices, physicians' livelihoods might be threatened if practice revenues are in any way dependent on the income of product sales," he says. "Most will choose not to take the risk, however — nor will they likely be allowed to, by whatever administrative structure controls their practice."

Benefit to patient

If products are offered at cost as a service to

EXECUTIVE SUMMARY

Sales of medications or products in provider offices pose ethical concerns involving financial conflict of interest, and are likely to receive more focus due to the soon-to-be-implemented Physician Payment Sunshine Act. Ethicists argue that physicians should:
• Give away health-related products to patients or sell them at cost.
• Provide full disclosure with all office sales.
• Offer products solely to serve patients' medical needs, without a profit motive.

patients for their convenience, solely for the purpose of serving their medical needs, without a profit motive; and if recommendations about purchase are fully informed by what the patient needs based on the shared decisions made by physicians and their patients, then such sales could be considered altruistic and benevolent on the physician's part, says Fleming.

The only justification for physicians dispensing medical products in their offices is if it serves to benefit the patient, argues **Lawrence Schneiderman**, MD, professor emeritus in the Department of Medicine at the University of California, San Diego. For example, a rural physician might provide a drug or device that might not be possible for the patient to obtain within a convenient distance, or a patient might not be mobile enough to travel.

"The physician should not seek to make a profit from these activities, unless willing to become a full-fledged pharmacy, meeting all the legal requirements. Rather, the physician should just cover the minimal costs of storing and dispensing," says Schneiderman.

Ideally, says Schneiderman, the physician should post the wholesale cost paid along with the charge to the patient. The physician should avoid dispensing any drug or device made by a company in which the physician has a financial interest, and at the very least, the physician should clearly reveal that conflict of interest.

"It should go without saying — but unfortunately, in my experience, it needs saying — the physician should dispense only drugs of proven benefit, and not 'alternative medicine' nostrums," he adds. ■

REFERENCE

1. American Medical Association Code of Medical Ethics. Opinion 8.063 — Sale of health-related products from physicians' offices (1999). Available at http://www.ama-assn.org/ama/pub/physicianresources/medical-ethics/code-medical-ethics/opinion8063.page.

SOURCES

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Some benefit, but at a high cost? Patients deserve "even-handed" description

Providers face difficult decisions on treatments

The continuing development and dissemination of high-cost medical treatments poses significant ethical questions regarding access to health care and just distribution of the benefits of these treatments, according to **John C. Moskop**, PhD, chair of the Clinical Ethics Committee at Wake Forest Baptist Medical Center in Winston-Salem, NC. The potential benefits of medical treatments, including new, high-tech, high-cost treatments, are virtually unlimited — that is, they can prolong life, or improve function or quality of life, for at least some patients, he says.

"The resources we can devote to providing these treatments, though very substantial, are limited by our ability or willingness to pay for them," says Moskop. "We are loathe to deny beneficial treatments to patients, even when those treatments are very costly. But at some point, we — as individuals and as a society — simply cannot afford to provide those benefits."

Cost-benefit ratio

High-cost treatments might have a much poorer cost-benefit ratio than very effective, low-cost treatments, notes Moskop. "We are not talking about what is sometimes called 'futile' or 'wasteful' treatment that confers no benefit for the patient," he explains. "Rather, we are talking about treatments

EXECUTIVE SUMMARY

Providers face new ethical challenges regarding high-cost medical treatments, and will need to determine which treatments to provide and which to forgo. Some concerns:

• High-cost treatments could have a much poorer cost-benefit ratio than very effective, low-cost treatments.

• Patients might not be given adequate and objective information about all treatment options.

• Patients could be manipulated into accepting high-tech treatments that they otherwise would forgo.

that are able to provide some benefit for some patients, such as a short prolongation of life, or some relief from suffering, but at a very high cost."

The question is how providers can decide which high-cost treatments to provide and to forgo, and who should make these decisions, says Moskop. Treatment providers, including individual health care professionals, health care facilities, and drug and device manufacturers, might have vested interests in providing these treatments, if their income is linked to the number of treatments provided.

"So there is some risk that patients may not be given adequate and objective information about all of their treatment options, or may be manipulated into accepting high-tech treatments that they would otherwise forgo," Moskop says.

Guaranteed access?

Patients deserve an even-handed description of all of the recognized treatment options for their condition, argues Moskop. Many will choose the expected benefits of less costly treatment plans, such as hospice care, over the expected benefits of high-cost treatments that offer short-term prolongation of life.

"Some patients, however, will seek out and choose any treatment, no matter how costly, that offers some potential for life prolongation," says Moskop. "Should access to such treatments be guaranteed? Or should it depend on the individual patient's ability to pay for the desired treatment, or on the patient's private or public health insurer's decision to cover the high-cost treatment?"

Implementation of the Affordable Care Act will give many more patients access to health insurance, but it will also pose difficult questions about what should be included in the essential benefit package of approved health insurance plans. It is still unclear how the reformed U.S. health care system will expand access to care and control health care costs without making difficult decisions about the coverage limits, says Moskop.

"Adopting limits on coverage — 'rationing' treatments — will meet strong resistance," he predicts. "But if most or all new high-cost treatments must be covered, the costs of the system will likely not be contained, and the reformed system will not be sustainable." ■

SOURCE

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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. 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.

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.

COMING IN FUTURE MONTHS

- Updated bioethic core competencies
- Human egg donation concerns
- Families asking providers to override patient's wishes
- Challenges with informed consent and adolescents

CME QUESTIONS

1. Which is true regarding advance care planning, according to **Nancy E. Havas**, MD, FAAFP?
   A. Discussions ideally occur during "acute" times such as a hospitalization.
   B. Patients should have discussions early with the facilitation of a health care provider.
   C. Major life changes or serious health concerns typically don't warrant revisiting the conversation.
   D. Physicians should wait for patients to tell them when they want to have this discussion.

2. Which is recommended in a 2013 joint policy statement on genetic testing and screening in pediatric patients?
   A. Testing for conditions that present in adulthood is encouraged.
   B. The use of direct-to-consumer and home-kit genetic testing of children is strongly encouraged.
   C. Health care providers and parents should address disclosure issues only after predictive testing is done.
   D. Health care providers should be cautious about providing testing to minors without the collaboration of their parents, as results may disclose information about parental status.

3. Which is true regarding a study on ethics education of medical students at University of Iowa Hospitals and Clinics?
   A. Only a minority of students were able to recall the four ethical principles.
   B. Students frequently used ethical terms when writing spontaneously about ethically challenging issues.
   C. Students were unable to use the language of ethics even when prompted to make references to formal ethical principles.
   D. When students were explicitly asked to consider which ethical principles are most relevant to patient experiences, they used this language more frequently in their writings.

4. Which was concluded by a case study analysis to explore ethical principles relating to deceptive research without informed consent?
   A. Minimally intrusive simulated patient research can never be ethically justified.
   B. Minimally intrusive simulated patient research that gathers policy-relevant data on the health system can in some cases be ethically justified.
   C. No research that involves a deceptive interaction and without any process of consent can be ethically justified.
   D. Mystery shopping cannot be justified even by the inability to obtain accurate observations when people know they are being observed.