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NHPCO offers position statement on palliative sedation

Medical treatment should be used rarely

"*Palliative care refers to patient- and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice.*[1]

The National Hospice and Palliative Care Organization (NHPCO), in a special article outlining its position statement on palliative sedation, starts by indicating what it believes palliative care actually is. That's because, according to the paper's authors, what is meant by palliative care — and palliative sedation, in particular — is often misunderstood, even within the medical community.

One of the primary misunderstandings about palliative sedation is that it hastens death, according to **Timothy W. Kirk**, PhD, chair of the Palliative Sedation Task Force at NHPCO and assistant professor of philosophy, City University of New York (CUNY) -York College, in Jamaica, NY.

Because of this lack of clarity, as well as a growing body of literature and conversations on the topic, the NHPCO decided to issue the position statement, Kirk tells *Medical Ethics Advisor*.

"There was a minority of folks who were thinking that this was equivalent to euthanasia and should be banned, so that the discussion in the health care literature, and especially the palliative care literature, was really starting to accelerate," Kirk explains. "And in the past five years or so, there was a . . . flurry of studies published with empirical data that enabled the discussion to move from kind of a theoretical discussion of what is this — to actually, what are the outcomes?

"So, if people thought that this hastened death, there were now studies to show that it didn't hasten death. Because there was new evidence, [and] because there was accelerated discussion in the literature . . . we

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thought it was a good time to revisit the issue and to offer an updated resource based on those developments."

In a special article on the position statement published in the May 2010 issue of the *Journal of Pain and Symptom Management*, the NHPCO accepts the National Quality Forum's definition of palliative sedation as the "lowering of patient consciousness using medications for the express purpose of limiting patient awareness of suffering that is intractable and intolerable."[1]

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The article goes on to say, "For the limited number of imminently dying patients who have pain and suffering that is (a) unresponsive to other palliative interventions less suppressive of consciousness and (b) intolerable to the patient, NHPCO believes that palliative sedation is an important option to be considered by health care providers, patients, and families."[1]

Importantly, the NHPCO position paper indicates that "this statement addresses the use of palliative sedation only for patients who are terminally ill and whose death is imminent."

The treatment has been referred to in the past as "total sedation" or in some instances, "terminal sedation."

"I think if you were to do a search in Medline, and look at the publications in the last five years or so, you would see a shift [in terminology] toward palliative sedation," says Kirk. "And the shift was intentional, because the shift was away from terminal sedation, because there's now evidence that it doesn't hasten death. And it was away from total sedation, because if it's done properly . . . it's going to be titrated where the patient's going to be sedated just enough, so that their suffering becomes tolerable."

What palliative sedation is not

Palliative sedation is not euthanasia, which is intentionally causing another person's death, and it is not physician-assisted suicide, in which a physician provides drugs that the patient then ingests to bring about his or her own death, according to the authors.

Importantly, euthanasia is not legal, whereas physician-assisted suicide can be selected by terminally ill patients in only three states in the United States currently: Oregon, Washington, and Montana.

"Palliative sedation is legal and is an appropriate clinical option . . . Indeed, the U.S. Supreme Court has acknowledged palliative sedation as a safe, legal, and reasonable alternative to assisted suicide. Palliative sedation does not ask patients, family members, or health care providers to violate the law."[1]

Position statement basics

Describing palliative sedation as "an important tool among the spectrum of therapies available in hospice and palliative care" for patients who meet the description outlined previously, "NHPCO "supports making the option of palliative sedation,

delivered by highly trained health care professionals, available to patients."[1]

"Part of what we found both in an informal survey of NHPCO member hospices and what we found in the literature, and what I've been finding, because I've been doing a lot of speaking around the country on this topic, is that there are folks who are delivering palliative sedation — or who think they're delivering palliative sedation — who really aren't doing it in a way that is driven by evidence," Kirk notes.

"They're just kind of turning up pain medicines to the point where they begin to have a sedating effect," he says. "And I think they might be doing this because they don't know that there are tested and evidence-based protocols using different drugs, not pain drugs, to safely induce palliative sedation. Because if you just start turning up pain drugs until patients fall asleep, [then] you are in danger of hastening their death. But that's not really palliative sedation."

There are, Kirk explains, "evidence-based protocols" available that largely use benzodiazepines, as well as some anesthesia drugs, "to directly bring the patient into a state of reduced consciousness, where that's the primary intent . . . You can administer the drugs safely, and you don't run the risk, of, say . . . suppressing the central nervous system, like you would if you just turned up opioids in a way that wasn't careful or safe."

Another declaration from the position statement, in part, is: "Since the goal is symptom relief (and not unconsciousness per se), sedation should be titrated to the minimum level of consciousness reduction necessary to render symptoms tolerable. For some patients, this may be total unconsciousness. For most, however, it will be less than total unconsciousness, allowing the patient to rest comfortably but to be aroused."[1]

The position statement also recommends that because "palliative sedation is a medical treatment, there must be a physician with expertise in palliative care leading the intervention."[1] Also, NHPCO "recommends the practice of convening an interdisciplinary conference specifically about the use of palliative sedation for each patient for whom it is being considered. Such conferences should include practitioners from many disciplines . . ."[1]

Palliative sedation to be used "rarely"

The most challenging aspect of determining when to use palliative sedation is that "it would be easy to go to it too quickly," explains **Margaret M. Mahon**, PhD, RN, FAAN, advanced practice nurse in an inpatient hospice, and associate professor, School of Nursing, George Mason University College of Health & Human Services, Fairfax, VA. Mahon co-authored the paper and is also on the NHPCO palliative sedation task force.

"My biggest hesitation or reservation is that I think it's too easy to say, 'Let's just sedate him,' instead of using exquisite assessment skills to say, 'What can we do for this person, what are the symptoms with which she's living, and how can we make them better?' And too few people have that knowledge," Mahon says.

In Mahon's experience, palliative sedation is utilized extremely rarely.

Mahon describes her experience with palliative sedation as having it occur "in [the] single digits over a multi-decade career." Researchers have found that it happens, and several of the reports suggest upwards of 45% of cases, she says. However, Mahon, working with physicians she says she "respects a lot," has seen it used eight times in 30 years, "so this would be very, very rare."

The paper suggests that the "use of palliative sedation in terminally ill patients has been reported between 1% and 52%. NHPCO supports the use of palliative sedation only in cases where alternative interventions have been exhausted or are otherwise unadvisable . . . ." and refers to the upper range as "problematic."[1]

"It's kind of hard to make judgments about which percentage of your patients should be receiving this sedation . . . because some hospices deal with very sick patients, and, as such, we would expect them to use sedation more frequently," Kirk explains. "Other hospices . . . have a more disparate sample of patients who are less complicated, less acute, and you would expect them to use it less. I think that what we were trying to highlight is that one way to think about whether or not you're using sedation appropriately is to look at the prevalence of cases per year with which you're using sedation," he tells *MEA*.

"The way we recommended sedation, which is consistent with how the experts in the field recommend it, is that you do this when everything else has failed, because it limits or takes away patient consciousness, and that's a real loss . . . they can no longer communicate well with families; they can no longer express their wishes; and hospice has always been about really trying to preserve

[the] patient's control until the end," Kirk says.

No consensus on existential suffering

Despite the fact that, traditionally, hospice has been geared toward treating all types of patient suffering, the task force could not reach a consensus on whether palliative sedation should be utilized for existential suffering.

In the commentary section of the paper, the authors define existential suffering as "suffering that arises from a loss or interruption of meaning, purpose, or hope in life."[1]

"Importantly, there is no widely agreed-on definition of existential suffering. In the palliative care literature, it is often used to connote suffering that is not physical in etiology. In this document, the term is used to refer to suffering arising from a sense of meaninglessness, hopelessness, fear, and regret in patients who knowingly approach the end of life."[1]

Kirk explains that "one of the great strengths of the hospice model historically is that it has gone beyond physical suffering, and it has addressed psychosocial distress and family distress — things like that.

"So, we wanted to keep sending the message that suffering that was primarily nonphysical is still an important thing for hospice to address. What we couldn't decide as a task force . . . and we did exhaustive literature reviews, and we had 10 internal and external peer reviewers look at this, and what we came up with was kind of a state of the literature, which found, interestingly enough, people are for and against it," Kirk says.

The more the task force discussed the topic of existential suffering, the more it "became clear" that there were "very practical difficulties in endorsing sedation for existential suffering,"Kirk says.

"One of the main practical difficulties is that although there is a very small amount of evidence out there — it's still growing — what it shows is that in the timeline of the disease . . . from diagnosis to death, whereas the uncontrolled physical suffering tends to happen in the last few days of life, the uncontrolled existential suffering tends to happen very soon after the diagnosis, when the patient begins to realize that they're going to die — that projects and goals they had for the future might turn out to not be accomplished, that they're going to be leaving their families…," Kirk says.

Therefore, because the paper only addressed sedation at the end of life, "if you were to sedate someone for existential suffering, you would likely be sedating them when they still had months left to live," Kirk adds.

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Hospice treats physical, emotional suffering

"Everyone's suffering is different"

Margaret M. Mahon, PhD, RN, FAAN, who serves on the Palliative Sedation Task Force of the National Hospice and Palliative Care Organization (NHPCO), says that too few people know what palliative sedation truly is.

"I think most of us who take care of patients didn't get a very good education in excellent symptom management, so [many] people don't know how to take care of pain and dyspnea and anxiety and delirium and all these symptoms that truly, truly cause physical suffering," Mahon tells *Medical Ethics Advisor*.

"So sometimes, instead of saying, 'This patient has three sources of pain, and we really need to be aggressive about addressing each of them, it's easier just to sedate someone, because it's not part of basic education; so it's a challenge," she says.

Mahon maintains that "there never can be" general assessment tools to determine if a patient is a good candidate for palliative sedation.

"Because again, everyone's suffering is different; everyone's disease gives them different symptoms,

so even if we just keep talking about physical symptoms, we know, for example, that depending on what you read, 80% to 95% of patients' pain can be taken care of with oral medications," she says.

"So, what does that pain mean? Belly pain is different from pain that comes from the spine, feels different from pain that comes from a heart attack, and each of them would be managed differently — and that's just dealing with pain," she explains.

Patient- and family-centered focus

"In all cases, care must be patient- and family-centered." This is one of the statements in a paper co-authored by Mahon and published in the *Journal of Pain and Symptom Management* in May 2010 on the NHPCO's position statement on the use of palliative sedation in terminally ill patients for whom death is imminent.

The paper also suggests that all health care providers who provide palliative sedation "should be engaged in ongoing education. This education should address symptom assessment and management as well as the ethical considerations related to use of palliative sedation."

When the health care team suggests palliative sedation as a medical option to alleviate patient suffering, there is "a real range" of responses from the family, Mahon notes. Sometimes, the families themselves suggest it as an option.

"Sometimes families will say, 'Look, I know you can do this; will you just make it be over?' So, sometimes families will put in a request for assisted suicide or assisted death, which is a completely different thing. That being said, when we bring up sedation, sometimes families will misunderstand . . . [when we say] that we have not been able to get her symptoms under control, and we would like to sedate her for 24 hours and then lighten the sedation and then see how she does. So, some families would see it as a request to hasten death. . .," she says.

Mahon says that health care providers also suffer when they are unable to get patients' symptoms of pain or other suffering under control.

"Now, again, for the people who do this really, really well — and there are too few, but those are the ones who do it very, very rarely — they are truly suffering, in my experience, at the inability to get the symptoms under control," she says. "If you're trying everything, and as we say, we just can't get ahead of the patient's pain, that's agonizing."

Existential suffering and palliative sedation

Mahon maintains that "suffering is more than physical." She also suggests that "this is where the [NHPCO position] statement can be challenging for people, and it's why we chose not to address existential suffering."

The statement says: "As with any other type of suffering, NHPCO believes that hospice and palliative care professionals have an ethical obligation to respond to existential suffering using the knowledge, tools, and expertise of the interdisciplinary team.

"Whether palliative sedation should be a part of that response is an important, growing, and unresolved question. Having carefully reviewed the data and arguments for and against using palliative sedation for existential suffering, the Ethics Committee is unable to reach agreement on a recommendation regarding this practice."[1]

NHPCO suggested that providers "carefully consider" the question and engage in further ethical discussion on the topic. "NHPCO also encourages research within and across disciplines to build an evidence base supporting multiple interventions for existential suffering."

"I've taken care of a lot of people who are dying, and true existential suffering is very, very rare," Mahon says. She says most people live with the disease from which they will die for sometimes years before they die. This time is a good opportunity to work on such things as relationships.

"So, if we view suffering as physical, but also psychological and spiritual and interpersonal, and have the resources and the team to address those things, then that is a much better way to approach the pain rather than to say, 'Let's sedate the patient' as a way of getting around the suffering, rather than truly addressing it," Mahon explains.

Although the task force concluded that existential suffering exists,"we don't have the resources to describe it well enough right now," Mahon says. "There is no consensus on what it is; and because there is no consensus. . . it might be a bit of hubris to say, 'Even though we can't tell you exactly what it is, here's what you should do for it.'"

Regarding existential suffering, Mahon says, "I'm not sure we will come up with a consensus, and I'm not sure we should."

"No, I think we have a responsibility to assess patients extremely well, and we have an equally important — but separate — responsibility to know how to address their symptoms very well. And once we do those extremely well, the perceived need for palliative sedation as a first-line therapy, rather than a last-line therapy, hopefully will be obviated," Mahon notes.

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QI initiatives and ethical oversight

Study sought "systematic data"

In light of "substantial attention in both professional and popular literature" regarding ethical oversight of quality improvement initiatives, researchers at Johns Hopkins University sought systematic data on this topic — and they believe that's what they found.

The resulting study was published online in *Quality and Safety in Health Care* on May 27.[1]

"The . . . contemporary history that led us to this was there's been, probably over the last 10 years, a strain of debate in the literature about what is quality improvement practice — is there a subset of that that we ought to be considering human subject research?" says **Holly A. Taylor**, PhD, MPH, assistant professor, Department of Health Policy and Management, Bloomberg School of Public Health and Berman Institute of Bioethics, Johns Hopkins University in Baltimore. Taylor is a co-author of the study.

The debate over whether QI initiatives should be considered human subject research heated up when Peter Pronovost, MD, another co-author of this paper, did a study in the ICUs in Michigan, which involved the implementation of a checklist of procedures. While most considered that checklist standard practice, "It was not clear that all [of the steps] were used systematically every time," she says.

"Their hypothesis was: If we do have a checklist that everybody follows, every time, maybe we can reduce the likelihood of hospital-based infections," Taylor explains. "and then they showed in this project that that was, indeed, true — that they were able to radically reduce the number of hospital-acquired infections in the ICU by implementing the checklist."

Once the results of that research were published in the *New England Journal of Medicine*, someone forwarded that study to the Office of Human Research Protection, she says. However, that project had already been reviewed by the institutional Review Board at Johns Hopkins, which considered the QI research project exempt from IRB review, according to Taylor.

But the ensuing controversy sparked in the researchers the question of whether QI initiatives and research actually do meet the criteria for human subject research, which always requires approval and oversight by an IRB, she says.

"If you imagine a . . . diagram [where] on one side of the circle is labeled human subject research and the other side is labeled quality improvement initiative — there may be some overlap in the center, where the quality improvement activity does meet the criteria for human subject research, and would be reviewed, or re-reviewed, or overseen, according to [OHRP] regulations," Taylor tells *Medical Ethics Advisor*.

"But there's lots of quality improvement work that goes on that doesn't meet that criteria," she notes. "But we were interested in how that body of work is reviewed, if it's reviewed, and whether, in that review process, ethics is brought to the table, as it were, in the review of that initiative."

In the paper's introduction, the authors note, "there are no systematic data regarding the institutional mechanisms currently in place to review the conduct of QI initiatives or the ethical considerations that guide quality improvement practitioners (QIP) in their efforts. This is unfortunate, as attempts to develop policy regarding the ethical review and oversight of QI initiatives ought to be evidence-based."[1]

Survey of QIPs conducted

First, the researchers conducted a focus group of "QI stakeholders," which included patient safety officers, QI program managers, and IRB chairs or administrators from urban, suburban, and rural

community hospitals.

Focus group members identified that QI practitioners "seek approval from an IRB," among other factors, due to "an absence of an alternative institutional oversight body that is available to review and ensure that QI initiatives are ethically acceptable.

"In addition, focus group participants indicated a number of ethical considerations they believe guide their work in QI, including transparency, minimal risk to patients, and patient privacy," the article states.

Ultimately, the study was conducted, and 132 QIPs responded, with a 26% response rate.

According to the abstract, "Respondents strongly agreed that ensuring minimal risk to patients, and privacy and confidentiality are relevant ethical considerations for QI initiatives conducted at their institution. A majority of respondents also agreed that assessing established practices, scientifically sound design, transparency, and the identification of minimization of potential conflicts are relevant ethical considerations for QI initiatives."[1]

The survey found that 83% of QI projects are routine reviewed, meaning that "some oversight . . . is happening," according to Taylor.

"What we also found is that a lot of the oversight is happening by the team, either the medical team that is implementing the project, or perhaps if the institution has a quality improvement team," Taylor says. "That's good, right . . . but one piece of oversight is that it's important to have some independence."

That's how the IRB became the default oversight body in these circumstances, because such initiatives should have oversight from "someone other than the investigator, who may have a vested interest in the project itself; there ought to be an independent review of that project before it goes into the field," Taylor says.

Conclusions drawn

"What we're saying is: Not all of that quality improvement work that's happening must go to the IRB, but we wanted to say, 'Given that oversight is routine, are there ways in the future that we could contribute to finding out more about how that happens, how ethics might be incorporated, could ethics be incorporated; and if it was, what sort of principles would one interested in maximizing the likelihood that the patients, or the physicians for that matter, that are involved are protected . . .,'" Taylor says.

For example, one of those principles might be: Physicians participating in a QI study should not be compromised in delivering the standard of care they would like to their patients, she says. From a patient perspective, a principle might be: Any initiative should not compromise the physician-patient relationship.

While the principles involve "very basic things . . . there is general consensus about the types of principles that [survey respondents] already believe are in place at their institutions," Taylor says.

Such principles could serve as "standards that they might promote as what's guiding their decisions in whether or not to adopt a particular quality improvement initiative in their institution," she notes.

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Family care physicians and DSM-5

Mental health a major part of primary care

The chair of the task force responsible for the fifth edition of *Diagnostic and Statistical Manual of Mental Disorders*, David J. Kupfer, MD, and Darrel A. Regier, co-authors of a recent commentary in *JAMA*, suggested their perspective in the commentary title: "Why All of Medicine Should Care About DMS-5."[1]

Although the next edition is not scheduled for publication until 2013, the authors maintained that all health care professionals — not just psychiatrists and other mental health care professionals — should be interested in the development of

DSM-5.

"For instance, in primary care settings, approximately 30% to 50% of patients have prominent mental health symptoms or identifiable mental disorders, which have significant consequences if left untreated," the authors write.

The commentary indicates "several major goals of the DSM-5 process, which include facilitating further integration of psychiatry into the mainstream of medical practice, facilitating the clinical feasibility of addressing the diagnostic challenges posed by mental disorders in general medical settings, and emphasizing the importance of attending to patients with mental disorders regardless of the clinician's medical specialty."1

Family docs already on board

Lori Heim, MD, of the American Academy of Family Physicians in Leawood, KS, tells *Medical Ethics Advisor* that mental health care is already a "major part of our training — in family care in particular, but I think primary care in general is much more aware of the impact of mental health than many of the other sub-specialties."

In family medicine, she notes that the goal is to treat the "entire family within their community."

"It's very apparent from primary care research and from what we train our residents that if you're going to affect behaviors, you have to include the mental health component of that," Heim says. "Much of the old sort of non-compliant patient really had to do with mental health issues that were layered on top of their either acute or chronic disease. And so without dealing with the mental health issues, you really weren't successful in trying to help optimize the health of the patient. So, that has permeated our training and our practices."

Heim also notes that in the health care reform legislation passed in March 2010, the Medicare Innovation Center has "demonstration projects dealing more with team care."

"So, the patient-centered medical home, accountable care organizations, whenever you start looking at outcomes-based care, as opposed to volume-based care, then mental health issues have to be part of that if you're going to be successful," she says.

Other factors impact care

Two other factors affect how much access patients have to mental health services — and how physician are paid for providing mental health services, Heim maintains.

"One is that, in many states, [primary care physicians are] not paid if we code for a mental health diagnosis," she says.

However, some states, such as North Carolina, have mental health parity laws in place. What that means, she says, is that "if the insurance company paid for [about eight or nine codes] by anyone, then they have to pay for them for everyone."

Mental health parity legislation is "an issue in all states that have not passed this" type of legislation, she says. But part of what such legislation does is skew much of the research, according to Heim.

"So, for example, if you look at North Carolina before the legislation and after the legislation, and you go to the insurance company and you say, 'How many primary care physicians were treating patients with depression?' — well, before the law was passed, we didn't code for depression. We coded for fatigue and weight loss, or sleep problems — all these symptoms of depression, but not the depression," Heim explains.

"Now, if you looked at it, you might think, 'Gee, there's a whole lot more depression in the state of North Carolina,' but it's simply because we've been able to code for bipolar disease and depression and some other mental health conditions," she says.

Heim emphasizes that primary care patients were getting the treatment before, which one could see by looking at the medication prescribed. "But if you just looked at the code, it can be misleading," she says.

The second challenge Heim sees is that there simply are not enough mental health services available to patients — and for physicians to refer to — in the United States.

"There's not a physician that I talk to that thinks they have a wide enough network for additional mental health services," she says. "So, we can screen; we can treat; but there are many things where I would really want to have the patient be able to see somebody for a weekly or biweekly counseling session, and that is often just not available. And it's either not available because there aren't the professionals in place, or it's not available because their insurance doesn't cover mental health issues . . ." And it can be limiting to self-paying patients to try to access such services.

"So, I think that's the next step in trying to

beef up the integration of mental health with primary care delivery services," Heim says.

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Informed consent nightmares

Legal experts offer advice

Sue Dill Calloway, RN, Esq., BSN, MSN, JD, a nurse attorney and medical legal consultant in Columbus, OH,has had considerable experience in dealing with informed consent. Calloway recently presented an audio conference on "Informed Consent 2010: The Latest in CMS and Joint Commission Consent Requirements" for AHC Media, publisher of *Medical Ethics Advisor*.

Calloway has experienced her own issues with informed consent. When she tore her anterior cruciate ligament and went in for surgery, the registration clerk handed her a consent form and said, "Here you need to sign this that the risks, benefits, likelihood of achieving the results have all been discussed." "And I looked at her and I said, 'I'm extremely embarrassed because I'm a nurse, I teach this stuff, but you know I haven't talked to the doctor about the risks and benefits and alternatives,'" Calloway says. "And being very unsympathetic she looked at me and she said, 'Look, lady, if you don't sign this, you're not having surgery today.'"

Calloway's husband and mother had woken at 4 a.m. to take her to the hospital and were waiting with her, so she signed it. "If the surveyor had come to me and said, 'Oh, how was that informed consent process?' and I just repeated what happened, they would actually cite the hospital," Calloway says. "That registration person has now violated this requirement."

The reason? Informed consent is a process, not a piece of paper, Calloway says, "and when she knew that process had not been accomplished, just saying 'sign this form or you're not having it' is violating the standards." The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) are emphasizing that informed consent is a process, she says.

Don't wait for a lawsuit to be filed before you develop a thorough informed consent process, Calloway warns. When she was doing medical malpractice legal work, she had three examples of what she considered to be the best informed consent. "I found out that they had all been sued before for informed consent, and that's when they got great informed consent," Calloway says.

Consider these suggestions:

• Establish policies on intraoperative consents.

Ambulatory surgery programs should have policies about how intraoperative consents are obtained and who may grant such consent, says **Patricia S. Calhoun**, JD, associate at Buchanan Ingersoll & Rooney in Tampa, FL.

"Emergencies are different, but ASCs frequently run into the argument that they could have stopped and asked the patient," Calhoun says. "Because elective surgery can always be rescheduled, I think juries are less likely to understand going forward with a decision like this [different type of breast implant] from someone not authorized to grant consent in an elective surgery."

• Policies must address right to refuse treatment.

Ensure your policies and procedures address the right to request or refuse treatment, Calloway says. "...I need to know what all the risks and alternatives are so I can make an informed decision, so that's part of the informed consent process," she says.

• Have the consent on the chart before surgery.

CMS requires providers to have a consent form in the chart before patients go to surgery, except for emergencies, Calloway says. "You've got to have a policy to make sure it happens, so they should have had a process when that person knew I hadn't been given any information, that should have told her what to do," she says. The form must be signed before administration of medications/anesthetics.

If the consent form is signed outside the facility, then you have to include in your policy how you're going to get it into the chart, Calloway says. "Make this easy," she advises. "They can fax it in; they can e-mail it in; the patient can bring it with them; the doctor can bring it with

him."

• Ensure thorough documentation.

From a medical malpractice perspective, the best defense is good documentation, say sources.

Calhoun says, "Documentation that the patient stated they had no questions, that they understood the risks and benefits, that they understood or that their physician had answered all their questions, are all helpful when the patient alleges that they did not give informed consent, because the basis of that allegation is that the patient just signed the paper."

The physician also should document the same information or even more, she says. "In addition, careful documentation any time a consent is changed in the pre-op holding room is very important," Calhoun says. "In particular, documentation about the patient's level of awareness and the timing of any medications can be key."

Anesthesia providers sometimes administer a small amount of medication for anxiety, but the exact time that medication is administered is frequently missed, she says. "Pre-op nursing can document that sedation was given per anesthesia and note the time, just in case the anesthesia provider doesn't," Calhoun says.

• Beware of electronic medical records.

Problems with electronic medical record documentation is increasing in frequency, Calhoun says.

"In order to make the charting easier and more complete, many facilities use a template," she says. "I've seen it be wonderful, but I've also found that complacency causes a template to end up with some really goofy results."

Staff might check the wrong boxes or forget to check the right boxes, Calhoun says. The end result can be a poor medical record, she says. "I'd recommend that facilities pull a sample number of the template records every quarter or so, and share the results with the staff," Calhoun says.

• Follow guidance from national organizations.

Several national organizations have developed informed consent guidance, including The American Congress of Obstetricians and Gynecologists (www.acog.org/from_home/publications/ethics/co439.pdf), the American Association of Nurse Attorneys (www.aana.com/practicedocuments.aspx), and the American College of Surgeons (www.facs.org/fellows_info/statements/stonprin.html), Calloway says.

"So whatever area you're in, always be familiar with your organization's, because if you follow those you can use them in the court room, and if you don't follow them they can be used against you," she says.

REFERENCES

1. Calloway SD. Informed Consent 2010: The Latest in CMS and Joint Commission Consent Requirements. Audio conference, AHC Media. March 17, 2010. ■

Bishops urge Congress to remedy reform law

In a May 20 letter to Congress, the chairman of the U.S. Bishops' Committee on Pro-Life Activities called on Congress to remedy what he characterized asthe abortion and conscience flaws in the Patient Protection and Affordable Act (PPACA), according to a news release from the United States Conference of Catholic Bishops in Washington, DC.

Cardinal Daniel DiNardo of Galveston-Houston said PPACA was an important step toward ensuring access to health coverage for all Americans but was "profoundly flawed in its treatment of abortion, conscience rights, and fairness to immigrants."

He urged members to support H.R. 5111, sponsored by Reps. Joseph Pitts (R-PA) and Dan Lipinski (D-IL) with 91 other House members, and added, "Efforts to ensure that our health care system truly serves the life, health, and conscience of all will be a legislative goal of the Catholic bishops

CME ANSWERS

1. A; 2. A; 3. B; 4. B.

in the months to come."

This legislation, wrote Cardinal DiNardo, "will bring PPACA into line with policies on abortion and conscience rights that have long prevailed in other federal health programs" by ensuring PPACA funds are covered by the Hyde Amendment, along with other provisions. ■

Uninsured working-age Americans at risk

An analysis of more than 150,000 hospital discharges has revealed that there are significant insurance-related differences in hospital mortality, length of stay, and costs among working-age Americans, ages 18-64, hospitalized for acute myocardial infarction (AMI), stroke, or pneumonia.

These three conditions are among the leading causes of non-cancer, inpatient deaths in patients under 65 years old.

The analysis was published June 10 in the *Journal of Hospital Medicine*.

Compared with the privately insured, hospital mortality among AMI and stroke patients was significantly higher for the uninsured, 52% and 49% higher odds, respectively, and 21% higher among Medicaid recipients with pneumonia.

Length of stay was significantly longer for Medicaid recipients for all three conditions, while hospital costs were higher for Medicaid recipients for stroke and pneumonia, but not AMI. These disparities in hospital care were present even after accounting for differences in baseline health, socioeconomic status, and disease severity. ■

Worse outcomes for black heart transplant patients

Transplant surgeons at Johns Hopkins who have reviewed the medical records of more than 20,000 heart transplant patients say that it is not simply racial differences, but rather flaws in the health care system, along with type of insurance and education levels, in addition to biological factors, that are likely the causes of disproportionately worse outcomes after heart transplantation in African-Americans.

In a report published in the *Annals of Thoracic Surgery* online June 1, the Johns Hopkins team showed that race-matching donor hearts did nothing to extend life in organ recipients. Race-

CME INSTRUCTIONS

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a credit letter will be mailed to you.

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

- Physician paternalism
- Current conscience provisions for health care providers
- European body determines position on palliative sedation
- Neuroimaging and ethics

CME QUESTIONS

1. According to the NHPCO position statement on palliative sedation, this medical treatment should be used rarely.
   A. True
   B. False

2. According to the NHPCO position statement on palliative sedation, this medical treatment is very different from euthanasia or physician-assisted suicide.
   A. True
   B. False

3. According to the NHPCO ethics committee, palliative sedation should be used routinely for existential suffering.
   A. True
   B. False

4. According to Johns Hopkins researchers in their paper, "Ethics, oversight, and quality improvement initiatives," published in the May 27, 2010, issue of *Quality and Safety in Health Care,* what institutional oversight body has become the primary oversight body for QI iniatives?
   A. Hospital ethics committees
   B. Institutional review boards
   C. Patient safety managers
   D. Physicians

matching is the practice of transplanting donor hearts into patients of the same ethnic group.

"It does not matter whether a black, white, Hispanic, or Asian donor heart is transplanted into a patient of any other particular race," said senior study investigator and Johns Hopkins transplant surgeon, **Ashish Shah**, MD, in a Johns Hopkins Medicine news release. ■