MEDICAL ETHICS ADVISOR®

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February 2011: Vol. 27, No. 2
Pages 13-24

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Statement of Financial Disclosure:
Arthur R. Derse, MD, JD (Peer Reviewer), Karen Young (Managing Editor/Writer), and Russ Underwood (Executive Editor) report no consultant, stockholder, speakers' bureau, research, or other financial relationships with companies having ties to this field of study.

New visitation rules from CMS secure equal rights for all patients

Hospitals will be required to develop policy accordingly

Last November, the Centers for Medicare & Medicaid Services (CMS) issued finalized new rules for Medicare- and Medicaid-participating hospitals designed to protect patients' right to choose their own visitors.

These rules, which update the Conditions of Participation for all Medicare- and Medicaid-participating hospitals, ensure that patients enjoy "full and equal" visitation privileges as requested by the patient or his or her surrogate or representative. The rules apply to all patients at such hospitals, regardless of the payer for their medical care.

The new rules follow from an April 15, 2010, Presidential Memorandum, in which President Obama tasked the U.S. Department of Health and Human Services with developing standards for such hospitals — including critical access hospitals — that would require them to respect the right of all patients to choose who may visit them when the are an inpatient of a hospital.

The President's Memorandum instructed HHS to develop rules that would prohibit hospitals from denying visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability. It also directed that the rules take into account the need for a hospital to restrict visitation in medically appropriate circumstances, according to the HHS news release on the issue.

The new rules require hospitals to have written policies and procedures detailing patients' visitation rights, as well as the circumstances under which the hospitals may restrict patient access to visitors for medical reasons.

The rules impose new requirements on hospitals to explain to all patients their right to choose who may visit them during their inpatient stay, regardless of whether the visitor is a family member, a spouse, a domestic partner — including same-sex domestic partners — or other type of visitor. The rules also require that hospitals explain that

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patients can withdraw such consent to visitation by any such person at any time, the release states.

"These rules put non-clinical decisions about who can visit a patient out of the hands of those who deliver care and into the hands of those who receive it," said CMS Administrator Donald Berwick, MD, MPP. "While we still have miles to go in making care more patient-centered, these rules make it easier for hospitals to deliver on some of the fundamental tenets of patient-centered care — care that recognizes and respects the patient as an individual with unique needs, who [is] treated with dignity and granted the power of informed choice."

Rules follow a decades-long movement

According to **Nancy Berlinger**, PhD, MDiv, deputy director and research scholar at The Hastings Center in Garrison, NY, there's been a movement pushing for equal visitation rights for at least 30 years.

"When you think about it in terms of the AIDS epidemic, this came up very frequently in the 1980s when there was, at least in areas of high incidence . . . a question of who should be with the patient," Berlinger tells *Medical Ethics Advisor*. "You had a person who would be critically ill, often dying, and their partner would not be recognized and sometimes not even allowed in at all. So, there was no protection for what the patient would want and no way for that unmarried partner, same-sex partner, person in another relationship, or friend who's a caregiver to advocate for themselves as well as for the patient."

In many instances, the person whom the patient wanted as a visitor was the caregiver to that patient outside the hospital.

When The Hastings Center prepared its 1987 guidelines on end-of-life care, the center heard from people who were involved in that movement.

"When you talk about the importance of loved ones, for example, it was the acknowledgement that you couldn't just use a word like 'family' or 'spouse' to accommodate everyone who the patient might want to have there and who might have knowledge relevant to the patient's care," Berlinger notes.

The new rules go beyond the idea of patient-centered care, she says.

"It goes to the real issue of what do we mean by all patients being equal even though all patients are individual. Do they have an equal right to have who they want with them? Well, yes. So, how do we honor that right in practice? A policy like this is one of the ways of saying, 'The patient can decide this,'" she says. "Also, the patient can revoke it. The patient can say, 'I prefer not to have so-and-so' . . . it does not restrict the categories to legal or biological categories."

The National National Gay and Lesbian Task Force called the new CMS rules "a significant step forward in ensuring same-sex couples are no longer discriminated against in hospital settings." The new rule, according to a release issued by the Task

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Medical Ethics Advisor®, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $83 each. (GST registration number R128870672.)

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Force, will cover nearly 6,200 hospitals with more than 35 million patient admissions each year.

"Of all the things same-sex couples have to worry about, of all the discrimination and pressures we face, not being able to see our partner or spouse shouldn't be one of them. [This] announcement honors our relationships, our love, and our basic humanity. An end to this discrimination can't come soon enough. We thank the administration for taking this critical stride forward and will continue to work with Health and Human Services as it issues future guidelines to ensure full and clear implementation of this rule," said Rea Carey, executive director of the Task Force.

According to a news release from the National Gay & Lesbian Chamber of Commerce, that organization signed a letter that as of September had the signatures of 54 organizations representing lesbian, gay, bisexual or transgendered (LGBT) organizations and advocacy groups lauding President Obama's "desire to grant visitation rights to LGBT couples."

"The NGLCC is proud to be among those groups submitting comment . . . so that same-sex and domestic partners can finally have equal rights to visit their sick loved ones," said NGLCC President and Co-Founder Justin Nelson.

Berlinger cites a case from several years ago in which two women who were domestic partners were vacationing, and one became very ill and had to be taken to a hospital. The partner of the sick woman was denied access.

"That's the kind of case that reminds us that this can still be with us on an institutional [level],"Berlinger says. "It shouldn't be something that you have to leave to chance depending on what state you get sick in or what hospital you go to, because you don't often have a lot of control over what hospital you're taken to in an emergency."

Hospital policies must be developed

Berlinger describes these issues "major equality issues" and a "civil rights issue."

"It isn't just a same-sex issue; it is also an issue of recognizing caregivers who are loved ones but are not relatives — who are not in a biological or legal relationship," she explains. "That's very important, because when a person is seriously ill, care is often provided by a network of family and friends, and there may also be . . . paid caregivers from home health."

Many hospitals already have what are considered "open" visitation policies. But for those hospitals that don't, they will have to develop new policies, which will have to be accompanied by a "big education process . . . hospitals employ lots of people, and they're never all in the same room at the same time," Berlinger says. "So, when you announce a new policy, it isn't just like you send out a memo one day. It's a way of saying, 'What were we doing before that is going to have to change now.'"

Certain restrictions on visitors are also built into the new CMS rules, but those are restrictions based on medical or clinical decisions.

It should not be an overwhelming challenge to hospitals to develop new policies, according to Berlinger.

"This is another way that we honor patient autonomy, but recognize that autonomy always takes place inside a social relationship," Berlinger notes. "That's one of the ways we make decisions about ourselves is who we want to spend our time with."

SOURCE

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Study: Many physicians not following ICD guidelines

JAMA study was based on NCDR

Many physicians are making the decision to implant defibrillators — specifically, implantable cardioverter defibrillators (ICDs) — in patients in cases where established guidelines based on the results of previous clinical trials do not appear to support implantation, according to a recent study.

The study was published Jan. 5 in the *Journal of the American Medical Association* (*JAMA*) and titled "Non-Evidence-Based ICD Implantations in the United States."[1]

The study authors analyzed data from the National Cardiovascular Data Registry's (NDCR's) ICD Registry, which was initiated in 2006 and is maintained by the American College of Cardiology in Washington, DC. The study was

designed to determine, in part, the extent to which physicians "in routine clinical practice" follow established evidence-based guidelines.

Of the 111,707 patients who met the study criteria and for whom all data was available — and who received an ICD implant between Jan. 1, 2006, and June 30, 2009 — 22.5% were implanted based on a non-evidence-based indication. Those non-evidence-based implantations included implantation within 40 days of a myocardial infarction, implanting an ICD within three months of coronary artery bypass graft (CABG) surgery, and in patients with newly diagnosed heart failure.

"Patients who received a non-evidence-based ICD were significantly older and had more comorbid disease than patients who received an evidence-based ICD. . . In addition, patients who received a non-evidence-based ICD were more likely to belong to a racial minority group (other than black) and to receive a dual chamber ICD," the authors write.

The risk of in-hospital death was also significantly higher in those patients receiving a non-evidence-based ICD vs. an evidence-based device, the study showed. Such patients "are more likely to have worse intermediate and long-term outcomes including mortality. However, this finding needs to be confirmed by future studies," the authors write.

The ACC's President **Ralph Brindis**, MD, MPH issued formal comments regarding the study.

"The study being published . . . in the *Journal of the American Medical Association* will, without a doubt, have major implications for physicians and hospitals in their evaluation of their practice patterns related to ICD implantation for primary prevention of sudden cardiac death," the statement reads.

"The study indicates that there are substantial variations among hospital ICD implantation strategies. This variation clearly demonstrates an opportunity for improvement in care. It is our hope that feedback and education to hospitals and clinicians about this important data will change practice patterns to benefit our patients," Brindis said.

What is the impact?

In an editorial that addressed the study results and was also published in the Jan. 5 issue of *JAMA*, authors Alan Kadish, MD, and Jeffrey Goldberger, MD write that the study's findings should be used "to inform public health policies toward the appropriate use of this life-saving but expensive technology."[2]

"The first question that needs to be addressed involves the reliability of the data. The ICD Registry is a well-audited tool that is robust and provides important information. . . Nonetheless, some variables in the registry may not be accurate. For example, more physicians self-reported being board-certified electrophysiologists in the ICD Registry than have actually been board-certified," Kadish and Goldberger write.

In an interview with *Medical Ethics Advisor*, Brindis suggested that the study results may suggest the need for fine-tuning the established ICD guidelines for implantation and the indications for which an ICD is considered appropriate treatment. However, there is also the necessary component of additional education needed to better inform physicians about the requirements of standards of care, he says.

"Clinical guidelines are just that: They guide us as to what probably is best for our patients, but every patient has nuances that are different; and we appreciate that, and so they're not carried down from Mt. Sinai etched in granite," Brindis tells *MEA*. "But they offer huge guidance and direction for clinicians."

Brindis says "the most fascinating part" of the paper is the "graph that shows that the variation between hospitals in the rate of not following the guidelines was as low as essentially zero, but as high as 50%. So, in my mind, it would tell even a skeptic that we have opportunities for improvement in how we do things."

Brindis points out that from an educational perspective, another interesting finding of the paper was that "the rate of 'inappropriateness' was also dependent on the level of training and expertise of the [implanting physician]," he says.

The data that is being fed back to hospitals from the ACC's NCDR will require those institutions to "reexamine their own care locally and try to understand their own variations locally in terms of improving how we utilize these technologies," Brindis notes.

Ethical issues involved

The paper is important in determining "the variations of potential overuse" of ICDs; however, Brindis notes that the "registries are not really

geared up in terms of issues of underuse, which requires a . . . different type of data set."

"So, I'm concerned, ethically, particularly with some of the understanding that we've learned from the registry related to socioeconomic and racial disaparities — that there's a huge population out there not afforded the opportunities of the implantable defibrillator for primary prevention," Brindis explains.

Another issue of ethical concern related to guidelines, although not addressed in the *JAMA* paper, is that you could conceivably meet the clinical practice guidelines for an implant, but if a patient is 85 or 90 years old with substantial co-morbidities, Brindis explains that as a clinician who works with families, "We might ask: 'Is this the right thing to do?'"

"This raises the question of how involved we are in decision-making. In other words . . . it could be totally appropriate to implant a defibrillator based on the guidelines criteria in a 91-year-old. You and I might say, 'Is that the right thing to do? Are you really prolonging the life of a 91-year-old in a manner that you would want?'"

From an ethics perspective, Brindis suggests that physicians specializing in cardiovascular disease should utilize "more and more the concept of shared decision-making with patients, with families, and the physicians, with true education — understanding the risks of the procedure, the benefits of the procedure, how much longer it would theoretically prolong one's life, what are the downsides of inappropriate shocks, what does it mean to die suddenly vs. not die suddenly. . . I actually do not believe yet that these important conversations are routinely had across the nation."

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SOURCE

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Facebook research poses unique ethical concerns

Consent extends to friends & family

Researchers might find it tempting to collect data for socio-behavioral studies from social websites like Facebook. Their appeal is having fairly easy access and viewing a broad range of behavioral information. However, there are big ethical issues with regard to informed consent and privacy, an expert says.

"There are so many people doing research on sites like Facebook, and they're kind of blithely telling the IRB that 'People put this out there on their Facebook site and on their wall where I can see it, so it's fair game for me,'" says **Montana Miller**, PhD, an assistant professor at Bowling Green State University in Bowling Green, OH. Miller is a popular culture expert.

This attitude is not sound from an ethical perspective, Miller says.

The words people write on their social website walls and the photos they post are not a free-for-all. Researchers will need to obtain informed consent from the people who own the walls and photos, and their responsibility doesn't end there, she adds.

"Maybe you have decided in your study you'll get consent from all the people whose Facebook sites you include in your study, and then you start collecting data," Miller says. "What about all the people you didn't get consent from who are writing stuff on the sites of their friends?"

This is a huge third-party issue that is not being dealt with by most researchers and IRBs, she adds.

The informed consent process in other types of socio-behavioral studies are less complex because the study subject's friends and family members will have to know about the study before they can be inadvertently drawn into it. But when researchers collect data from an Internet website, this is a passive activity that can be invisible to the subject's friends and family members.

"On sites like Facebook, I have no idea if my friend is participating in some study, so I might say something embarrassing or personal or sensitive on the friend's wall, and I do this impulsively," Miller explains. "This happens all the time; people don't want the whole world to know about it, but they don't think anybody significant is watching or that the writings on the wall are collected and analyzed as data."

These third parties have not consented to be included in the study, but their information is recorded because of their friend having provided informed consent.

"The same is true of photos posted online," Miller says. "A lot of people are doing studies of images posted on social networking sites, but what if I'm in those photos? It's a very murky and tricky area."

A changing reality

Further complicating the issue is the reality that protocols and privacy boundaries change regularly on these types of websites.

"Even an expert on the subject can't keep up with the changes," Miller says. "The privacy policies of these sites can be so difficult to read through they're almost deliberately inaccessible to the public."

IRBs need to consider and address these kinds of new technology issues by having at least one IRB member who is concerned about electronic privacy and who keeps up-to-date on this topic, she suggests.

"I get huge numbers of emails from around the country asking for advice about these issues, and I don't have time to answer all of them," Miller notes. "I go to the PRIM&R conference and try to educate people."

IRBs should send members to these sorts of workshops and lectures or at least have them check out discussion boards where these questions are raised.

"There aren't good updated guidelines readily available to people who need help," Miller says. "But there's an Association of Internet Researchers at aoir.org who discuss these things."

It's probably too much to ask the entire IRB to become educated on ethical issues related to technology and the Internet, but at least one or two members could be the point persons when these issues arise, she adds. ■

Privacy issues when reviewing sensitive work

Ask for details about safeguards

IRBs at academic research centers often review international infectious disease research that can raise red flags regarding privacy, confidentiality, and vulnerability. One example might be a study conducted in the Dominican Republic and involving HIV prevention and sex workers. IRB members might question how researchers will collect and store sensitive data, and whether a potential breach of confidentiality poses a serious risk to subjects.

"If data are transferred from other countries, you need to look at how that transfer is being done, whether the identifiers are being destroyed or de-identified," says **Joyce Plaza,** manager of Columbia University's Morningside IRB in New York City.

"Two issues we look at are confidentiality and privacy," she adds.

To address both of these concerns, Plaza suggests IRBs should ask these questions during the application and review process:

- "Is the interview done in a private location?"
- "Are subjects cautioned they don't have to answer if they don't want to answer?"
- "Once researchers have collected the data, what steps are they taking to protect that data?"
- "Are they defining who has access to data?"
- "Are staff trained in confidentiality procedures?"
- "Are data sent electronically? Is there encryption?"
- "Is information being hand-delivered? Is it coded?"
- "Are the data collected or stored with the names of subjects, or are they coded?"
- "Are they transferring codes, linking names with study numbers in separate files than research data?"

Electronic submission recommended

An efficient way to collect answers to these concerns would be to have an electronic submission system for IRB submission that walks investigators through sensitive data questions, making suggestions for what needs to be done, Plaza says.

This serves as both education and a way to ensure all protocol review concerns are addressed.

"Privacy and confidentiality need to be explained in the submission process," Plaza says. "We call it the study description that collects details about the study protocol, and we prompt investigators to enter information about privacy and confidentiality and to be explicit with their answers when they're submitting an application."

The IRB also has continuous education programs for principal investigators and their research staff.

"During the review process, if there are items

missing from a protocol that we need to consider, then we return the submissions to the investigator and obtain these specific details," Plaza says.

The Columbia University IRB electronic submission system requires investigators to describe and explain the privacy and confidentiality protections plan for the study, she adds.

"We ask about the privacy and confidentiality procedures they will implement in the study description," she says. "For example, we ask them to describe how subject privacy will be protected and the limits to that protection."

The electronic form could summarize privacy protection as safeguarding an individual's expectation that the information the individual provides will be offered in confidence. Also, IRBs can inform investigators that privacy protection should cover all screening activities, HIPAA provisions, forums like focus groups where private information may be shared, and recordings of research activities where applicable, Plaza says. "Limitations such as compelled disclosure and mandatory reporting also should be described," she adds.

In the Columbia IRB's electronic protocol submission process, there is also a section called "Confidentiality of the data." In this section, investigators are told to describe how confidentiality will be maintained locally and during transmission to another site.

"We have them include a clear description of how data will be stored, specifically indicating whether the data will contain direct or indirect identifiers," Plaza says. "We ask them to describe protections related to accessing the study data, whether in electronic or paper form."

The IRB's website also provides definitions and descriptions of identifiable, coded data, de-identified data, anonymous data, and confidential data, so the IRB and investigators are using the same terminology.

"We're always reviewing our language on the website to eliminate areas of confusion," Plaza explains. "I'm always referring investigators to our website for the definition of the different types of data, and we have FAQs [frequently asked questions] on our website that define what 'coded' means, 'anonymous' means, and 'confidential' means because sometimes investigators use the words 'anonymous' and 'confidential' synonymously, and we need them to clarify what they mean."

Investigators also confuse the terms "privacy" and "confidentiality," she notes.

Privacy can refer to the location of the subject when investigators are obtaining sensitive information from them. This location might be a private place of the subject's choice. Confidentiality refers to how data are protected once collected, whether data are kept in an identifiable manner, anonymous, de-identified, or coded.

"This is becoming more complicated with all the research activity going on these days, and it is a concern," Plaza says.

The protocol submission process also asks investigators about their staff training and confidentiality procedures that are included in the consent form. Plaza says the process asks these questions:

- "What will happen to identifiable data at the study's end, after publication?"
- "Are data destroyed, including photographs and recordings and tissue samples?"

Secondary use issues

Another issue involves the secondary use of confidential data.

"We have a lot of faculty obtaining secondary data to do an analysis, and often the owners of that data require a data protection agreement, and it may require the signature of an IT person in that department who has reviewed the data protection plan and made sure it's secure," Plaza says.

International research particularly has privacy and confidentiality nuances.

For example, a study that is enrolling women in a country with customs that are different from the United States and Europe might follow local custom and have the women's male heads of household provide consent for the women's study participation, Plaza says.

"But what if the woman doesn't want the male to know about the study?" she says. "We ask the person with knowledge of the local context to guide us."

This is where it's important to have a local review committee or a consultant knowledgeable of the local customs and norms to also address the same privacy and confidentiality issues in the context of their region's traditions and beliefs.

"The consent form should specify what the procedures to protect confidentiality are going to be, and the board could grant a waiver of documentation of written consent so subjects don't have to sign a consent form in order to protect their privacy," Plaza says. "Investigators still have to go

through the whole consent process, but they waive the need for the person to sign the form in the event the principle risk of harm may result from a breach of confidentiality." ■

ACOs emphasize prevention, coordination

Partnerships aim to improve care, eliminate waste

As talk of reimbursement reform and pay for performance escalates and health care stakeholders look at ways to improve patient access and outcomes while reducing waste and costs, payers and providers are joining together to create accountable care organizations (ACOs), partnerships that agree to be accountable for the quality, costs, and overall care of a patient population.

Accountable care organizations are patient-centered partnerships between payers and providers and have an emphasis on prevention and care management across the continuum.

In an accountable care organization, the payer, the providers, and, in some cases, the purchaser agree on a payment model and share the savings as waste is eliminated.

According to **Richard Bankowitz**, MD, MBA, SACP, enterprise-wide chief medical officer for Premier, an alliance of health care providers with a mission to improve the health of the communities, the ACO initiative has a triple mission:

- to improve population health;
- to improve the care experience;
- to reduce the total cost of care.

"To be part of an accountable care organization is any case manager's dream. Accountable care brings to the forefront what case managers have been talking about for decades: the need to have solidly constructed and effective multidisciplinary teams. As case managers, we know how important it is for the patient experience across the continuum of care to be seamless; but it remains a bumpy ride. ACOs are designed to eliminate the bumps and gaps in care," says **Victoria Choate**, RN, CCM, RN-BC, CCP, PAHM, vice president of performance excellence and chief quality officer at Cheyenne Regional Medical Center in Cheyenne, WY.

Cheyenne Regional Medical Center is partnering with a local health plan and a physician organization to develop and implement an ACO.

The accountable care model places the focus in health care back where it belongs — on improving the health of individuals, says **David Epstein**, MD, CIGNA senior medical director for Georgia. The Philadelphia-based health service company and Piedmont Physicians Group, part of Atlanta-based Piedmont Health, have launched an ACO pilot program.

"Health care in the United States has shifted away from prevention and primary care, which has resulted in a 'disease care' system that relies more on specialist intervention and rescue procedures rather than improving health and providing greater value to patients. The patient-centered model places the emphasis on improving the health of individuals through comprehensive primary care services and delivering better outcomes through enhanced care coordination," Epstein says.

The goal of the accountable care organization initiative is to improve quality and moderate costs, Choate says.

"We don't want to eliminate necessary costs, but by anticipating what the patients' care needs are and by shepherding them across the care continuum, we want to eliminate the costs associated with unnecessary care," she says.

Studies have shown that up to 30% of health care funds are spent on unnecessary and duplicative tests, treating complications that could have been avoided, and providing care in an expensive setting when it could have been provided at a lower level of care, Bankowitz says.

"The current system simply is not sustainable. The accountable care model is an exciting concept and one that is badly needed," he says.

The primary problem with the current health care system is that care is fragmented and not coordinated from the patient's point of view, Choate says.

"Patients often see several providers in multiple settings. Sometimes their records are available, and sometimes not. There is a lot of duplication of services and waste. Accountable care organizations provide a mechanism to coordinate care and eliminate duplication across the continuum," she says.

Fragmented care can lead to medical errors and waste, Bankowitz says.

Accountable care organizations are designed to eliminate waste and unnecessary spending and to ensure that patients get preventive care that will keep them well by proactively managing chronic disease and coordinating care provided in multiple

settings, Bankowitz says.

"Everybody tries to eliminate waste, but one of the realities of the current model is that if you eliminate waste and reduce unnecessary emergency department and hospital visits, the savings go to the payer, and hopefully back to the purchaser and the consumer. There is no incentive on the part of the provider to eliminate waste," he says.

Accountable care organizations require an infrastructure that includes a person-centered health home provider, a mechanism for coordinating care, and a way to share information.

"We need health care professionals who are trained to think about the whole continuum of care, how to coordinate care, and how to be proactive to help patients get the level of care they need but not receive wasteful or unnecessary care," Bankowitz says.

The model may differ depending on the needs of the communities and the structure of the collaborating organizations, but all include payer/provider partnerships and reimbursement models that reward providers for providing value rather than on the basis of patient volume, Bankowitz says.

Payers always have been especially interested in cost and quality, he says.

"Their role is to provide for efficient care of the patient, and that hasn't changed. What is changing is that we are looking at the whole delivery model and not just the payment model. The delivery model is changing with better coordination of care and emphasis on the patient's health home," he says.

Premier is partnering with nearly 80 health care systems nationwide to help them develop and implement the accountable care model in their areas.

The ACO Implementation Collaborative is designed to assist health systems in partnering with payers and physician practices to implement the model in their area. Twenty-four health systems with more than 80 hospitals are participating in the collaborative.

More than 50 health care systems are part of Premier's ACO readiness collaborative and are developing the organization, skills, team, and operational capacities needed to develop the model in their areas.

"We brought hospitals to the table because the organization's owners are hospitals, but it can't be solely a hospital activity. Patients receive care along the continuum within multiple levels. If care isn't coordinated, it results in excess services and waste and has the potential for errors," he says.

Regardless of the structure of the model, accountable care organizations all include people-centered health homes that deliver primary care and coordinate with other providers as patients move through the health care continuum, Bankowitz says.

"Historically, continuity of care has been a series of hand-offs. Now, people are sitting at the table and discussing what the patient needs in their environment and what is needed when the patient goes to another level of care," Choate says.

The initiative refers to "person-focused care" rather than "patient-focused" care and "health homes" rather than "medical homes," because an accountable care organization looks at the health of a population and keeping a population healthy.

"Many individuals in that population may be healthy and they're not patients. We want to keep them as healthy as possible. That is why this model has greater emphasis on primary care and preventive care," he says.

Under the accountable care model, the case managers' role will continue to be to promote better coordination of care, elimination of waste, and duplicated efforts, Bankowitz says.

"The scope of work for case managers may change, because now case managers tend to focus on a patient or a case, whereas in the new accountable care organization, their job may be more of health management. We are not interested only in taking care of sick people; we want to keep people healthy and out of the system if they don't need to be there," he says.

The principles and goals of accountable care organizations are similar to those envisioned in the capitated payment programs in the 1990s, Epstein says.

"The premise of the capitation program was to empower the primary care physicians to improve their patients' overall health and to guide them effectively through the health care system when necessary, as opposed to simply referring them to various hospitals and specialists when they need specialty care. Some primary care groups were prepared to take on population health management tasks and did quite well under the capitated system. But the program did not succeed in moving the quality dial due to lack of infrastructure and constructive dialogue between the provider community and the payers. Accountable care organizations have the potential to deliver more efficient care and better health outcomes through enhanced care coordination," he says. ■

Start-up consultations improve site compliance

Ensure informed consent, documentation correct

Researchers often criticize IRBs and see them as barriers to research. One way to turn that attitude around is through the creation of a study start-up consultation. This has another advantage: it can improve clinical trial site compliance with human subjects protection regulations and policies.

This type of consultation has human subjects research (HSR) regulatory experts working with researchers to ensure their study site's documentation and consent processes are in order.

"We've worked hard to collaborate with researchers and work with our research community to provide sound, ethical research," says **Sandra L. Alfano**, PharmD, FASHP, CIP, chair of the human investigation committee I and III, and co-chair of the embryonic stem cell research oversight committee at Yale University in New Haven, CT.

"We view ourselves as facilitators of human subjects research and not as barriers or hurdles that researchers have to get over," Alfano says. "The study start-up consultation is clearly an illustration of that collaborative effort."

Yale started the study start-up consultation with the idea that new and inexperienced investigators would benefit from regulatory assistance before they start their study. From a compliance perspective, a preventive effort is preferable to an audit and punitive action when mistakes are found, she notes.

"We'd like to work with people early on to help them think through different issues and put processes in place at the outset," Alfano says.

While the initial focus was on new investigators, the consultation also has proven popular with experienced investigators, says **Tracy Rightmer**, JD, CIP, compliance manager of the human research protection program at Yale University in New Haven, CT.

"Experienced investigators are asking for it as well," she says. "They say they want to get a better handle on various regulations and policies and requirements."

Investigators want to do the right thing, but they're not always sure they are in full compliance, Rightmer adds.

Typically a researcher will request the study start-up consultation after seeing an educational session where it is mentioned. Sometimes Rightmer might recommend the consultation when an investigator demonstrates the need for closer oversight after study problems arise.

Here's how the study start-up consultation process works:

1. Compliance manager reviews protocol and IC paperwork. "Before the start-up visit, I look at the protocol and consent documents to get an understanding of the study and to identify areas of potential noncompliance," Rightmer says.

For instance, some common problem areas involve the informed consent process, subject payments, medication compliance and storage, she says.

"I encourage investigators to come up with questions, and I have templates and forms for them that are available on our website," she adds. "These include enrollment logs, inclusion/exclusion criteria, checklists, staff responsibility log, regulatory documentation sheets, staff training checklist, and a few others."

2. Consultation visits provide education, advice. Rightmer and a coordinator who works part-time on compliance issues typically conduct start-up consultation visits within a few weeks of the request from investigators.

"We want to have this consultation before they have their first study visit," Rightmer says. "We will take one to two hours on the consultation, depending on the study's complexity."

The consultants will ask to see checklists and other documents, including source documents, case report forms, enrollment logs, inclusion/exclusion criteria, site signature and responsibility logs, etc.

"Then we go over areas that might be problematic for their particular study," she says.

When the consultant finds a potential problem, she discusses it with the investigator.

For example, in one study start-up consultation, Rightmer asked the investigator and study staff how they would verify medication adherence since they didn't have a process in place.

"I asked, 'How are you going to count pills, use a subject diary?'" she says. "I provided them with information about medication adherence."

3. Look closely at informed consent. The study start-up consultation almost always focuses on informed consent.

"If the study involves minors or those with decisional impairment, then you certainly want to go over the consent process and safeguards for those vulnerable populations with investigators," Rightmer says. "If it's a medication study, then I'd want to

know how they store medications and verify it."

Another important area involves subject payment. Consultants want to ensure study staff and investigators are documenting when subjects are paid.

"We take a good close look at the protocol," Rightmer says. "Then we identify areas that are problematic for investigators and address those during the meeting."

4. Educate CT staff on adverse events and unanticipated problems. During the consultation, Rightmer will define unanticipated problems and serious adverse events (SAEs) for investigators and study staff.

"A lot of industry studies want all adverse events reported, while the Office for Human Research Protection (OHRP) wants only serious and related events reported," Rightmer says. "There can be discrepancies between the two."

The IRB follows OHRP's guidance on the issue, but sometimes receives too many reported unanticipated problems, she notes.

"So if I'm meeting with an investigator who has an industry sponsor, I find out what the sponsor wants and what is required by the IRB," Rightmer explains. "Sometimes the investigator will have to report the AE to the sponsor but won't have to report it to the IRB." ■

CDC report identifies health disparities

Americans' differences in income, race/ethnicity, gender, and other social attributes make a difference in how likely they are to be healthy, sick, or die prematurely, according to a news release issued on a report by the Centers for Disease Control and Prevention (CDC).

The report, titled "CDC Health Disparities and Inequalities Report – United States, 2011" is the first of a series of consolidated assessments and is designed to highlight health disparities by sex, race and ethnicity, income, education, disability status, and other social characteristics, according to the CDC news release.

State-level estimates in 2007, for instance, indicate that low-income residents report five to 11 fewer healthy days per month than do high-income residents, the report says. It also says men are nearly four times more likely than women to commit suicide, that adolescent birth rates for Hispanics and non-Hispanic blacks are three and 2.5 times higher respectively than those of whites, and that the prevalence of binge drinking is higher in people with higher incomes. ■

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 **June** 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

- The ethics of neuroimaging
- Financial incentives for living donors
- Physician responsibilities when the family wants everything
- Rationing of health care

CME QUESTIONS

5. Which government agency issued new rules for Medicare- and Medicaid-participating hospitals to provide patients with the right to choose their own visitors while in the hospital?

A. AHRQ
B. CMS
C. FDA
D. None of the above

6. According to Nancy Berlinger, PhD, MDiv, deputy director and research scholar at The Hastings Center, the movement to push for equality among patients to choose their visitors while in a hospital has been under way for nearly 30 years.

A. True
B. False

7. A study published in the *Journal of the American Medical Association* found that implantable cardioverter defibrillators were implanted based on non-evidence-guidelines in 50% of 111,707 patients analyzed in the National Cardiovascular Data Registry's ICD Registry.

A. True
B. False

8. According to Ralph Brindis, MD, MPH, American College of Cardiology president, one ethical concern raised by the study of variations in non-evidence based use of implantable cardioverter defibrillators (ICDs) is that even if a patient meets the guidelines for implantation, there may still remain the question of whether it is "the right thing to do."

A. True
B. False

CME ANSWERS

Answers: 5. B; 6. A; 7. B; 8. A