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More attempts — and earlier efforts — needed for advance directives to work

Hospital education often too late

A 22-year-old accountant, just out of college and beginning his first job, applies for health insurance through a plan sponsored by his employer. As part of the process, he is asked to complete an advance directive indicating what lifesaving measures he would like to be used in the event he is seriously ill or injured and unable to communicate with medical personnel.

A 32-year-old new mother files for a change of status with her existing health plan. As part of the routine paperwork, she completes an advance directive form or reviews a prior document to ensure it still reflects her wishes.

Take a proactive approach

If advance directives are going to have the impact on end-of-life care planning that policy experts hope, efforts need to be made to get people to think about such decisions before they are faced with a health crisis, not after they enter a hospital, argues **Arnold Eiser**, MD, professor of general internal medicine in the school of medicine at the University of Illinois at Chicago.

"As a clinician and as a bioethicist, my experience has been that these issues are not considered until the patient is in the hospital, loses his or her decisional capacity, and cannot make decisions about care," he says. "It is then up to the family and the health care provider to try to determine what the person would have wanted."

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Medical Center, raised eyebrows and headlines last month when they announced they were leaving their current positions to set up a much smaller, but more expensive practice — Personal Physicians Healthcare Inc.

In contrast to their practice at Beth Israel, where they are currently responsible for thousands of patients, often seeing 30 a day, their new practice will restrict them to only 300 patients each, with each patient receiving perks such as 24-hour telephone access, house calls, and physician-accompanied visits to specialists.

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The Patient Self-Determination Act, passed by Congress in 1991, requires states to recognize living wills and durable powers of attorney for health care as advance directives and as informed consent for medical care. Among the act's provisions was a mandate that hospitals provide education about advance directives and that patients be given information about advanced directives upon admission.

While well intentioned, the law has not had the intended results, Eiser says. Despite targeted efforts to increase the number of people completing advance directives, the completion rate nationwide remains under 25%. Focusing on hospital admission as the point when a directive should be completed also misses the boat, he adds.

"When people are admitted to the hospital, they are already in a crisis situation," he says. "It's not the best time for them to objectively consider what they want."

Tie directives to health coverage

Amending the law to require insurance companies to offer advance directive forms when initiating or changing a person's coverage is the best way to get more people to take part in the process, Eiser says.

"We are asked to fill out a lot of forms when we get our first job, about things we don't always like to think about, like life insurance. This would be similar to that," he says. "And given that the average person changes coverage about every three years, there would be plenty of opportunities to update the information."

Although such a policy would not cover uninsured Americans, Eiser notes that only 1% of uninsured Americans are over the age of 65. And, the majority of people who die in hospitals are covered by health insurance. Therefore, the people most likely to need advance directives would be reached by such a policy change.

"And people who are uninsured are not prevented from filing out advance directives," he notes. "Anyone can decide to do one."

Asking people to consider completing advance directives at a time when they are healthy and stable has the advantage of forcing people to think about the medical treatments that they do or do not want without the pressure that an immediate medical problem adds. And because most advance directives require a person be designated to implement the document, it ensures that the patient has

involved family members or friends in discussions about his or her wishes.

Incentives might be the answer

Even if opportunities to complete advance directives are improved, policy makers must address the fact that many people just do not want to think about death or serious illness and therefore, don't plan for that eventuality, says **William Lamers**, MD, medical consultant with the Hospice Foundation of America in Washington, DC.

"The first problem is that we as a society don't like to think about death and dying, and we don't want to talk about it. Even physicians don't want to talk about it," he says.

In addition, the current level of specialization in health care, with patients seeing several different specialists for different health conditions, lessens the opportunities for the person to discuss his beliefs and wishes with a single, trusted provider, he adds.

"Even when an advance directive is completed, it is not always respected and adhered to," he says.

Lack of compliance with advance directives is, in part, a result of so few directives being in place, Eiser believes. Unless a significant percentage of patients at the end of life have advance directives in place, physicians and health care systems won't see a need to make their implementation a priority.

Eiser agrees incentives also are needed to induce people to complete an advance directive, even if the forms are made available more often. Even extensive education efforts by the Chicago-based American Medical Association and the American Association of Retired Persons have not resulted in a substantial increase in the number of people completing advance directives, he notes.

"I think it should be some small incentive, possibly involving a free health care service for people who are already ill, or a coupon for an exercise class or program if the person is healthy — something of that sort," he says. "It doesn't necessarily have to be health care-related, but I think, since we are talking about medical care, it makes sense to offer something that would benefit their health."

Model directives

Several different advocacy and professional groups have developed educational materials about advance directives, many of which are available on the Internet, Eiser says. "It's not as if we need a number of new programs."

It would, however, be useful if the National Bioethics Advisory Council or a similar group to develop a model living will that is comprehensive enough to include a wide variety of medical situations that might arise, he says.

"Some advance directives are too vague and some are too specific as to conditions that would trigger implementation," he explains.

For example, failure to list the triggering conditions under which an advance directive becomes operative limits its utility. Conversely, if a living will cites a persistent vegetative state as a triggering condition and the patient presents with advanced dementia, the living will would not be in force.

Benefits of advance directives

It's important to increase the percentage of people completing advance directives for two reasons, Eiser says. One, to remove the unfair burden placed on families forced to make decisions about a patient's care when the patient has become incapacitated and, secondly, to reduce the provision of unwanted medical care.

"While it's true that we might be creating significant record-keeping costs with significantly more people completing advance directives, it is possible that these costs may be offset by a cost-savings from a reduction in performance of unnecessary medical procedures," he explains. "But, the real reason we should do this is to prevent families from being put in the position of deciding what to do, when they haven't discussed these issues with the patient. It is a horrible situation."

Suggested reading

• Eiser AR, Weiss MD. The underachieving advance directive: Recommendations for increasing advance directive completion. *Am J Bioeth.* Available on-line: www.ajobonline.com / in focus / infocuseiser-weiss.htm. ■

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Those most in need are being left behind

Minorities receive inadequate palliative care

Although numerous initiatives have been launched nationwide to improve the care of terminally ill and chronically ill patients, disturbing evidence is emerging that the patients most in need of good palliative care are not getting it.

"We assembled a huge amount of data showing that minorities, African-Americans in particular, have unequal use of a wide variety of medical resources," says **Erik Krakauer**, MD, PhD, associate director of the Palliative Care Service at Massachusetts General Hospital in Boston. "Significant evidence of unequal access also extends to end-of-life care."

Krakauer and colleagues at Massachusetts General published a review of studies of minority access to palliative care services in the January issue of the *Journal of the American Geriatrics Society*.[1]

They conclude that a combination of factors, including poor rates of insurance coverage, lack of sensitivity to differing cultural attitudes about death and dying, and mistrust of the health care system in minority populations present significant barriers to minorities obtaining quality end-of-life care.

In the medical literature, they found numerous examples, he says.

For example, the SUPPORT (Study to Understand Progresses and Preferences for Outcomes and Risks of Treatment) investigators[2,3] demonstrated that in five major medical centers, fewer resources were used in caring for seriously ill African-Americans than for other patients with similar illness severity and sociodemographics.

Cleeland and colleagues[4] studied 281 minority (mostly black and Hispanic) patients and 627 majority patients with cancer. They found that minority patients were significantly less likely to receive guideline-recommended analgesia.

A study of analgesia use in a large Los Angeles emergency department found that Hispanic trauma patients were twice as likely to receive no pain medication as non-Hispanic white patients with similar injuries in spite of the fact that physician assessment of pain severity did not differ between the two groups.[5,6]

Complicating matters is the fact that minorities also face significant barriers to obtaining basic primary care services and to obtaining the more expensive "high-tech" treatments for serious illness, he adds.

Multiple studies document decreased use of cardiac procedures for African Americans with coronary artery disease.[7-11] Other studies found similar disparities in use of renal dialysis for African Americans with end-stage renal disease.[12,13] Ayanian and colleagues found that quality of care was lower for black Medicare beneficiaries than for others hospitalized for congestive heart failure or pneumonia.[14] And Ayanian's group also found substantially lower access to renal transplantation for black than for white patients.[15]

Lack of insurance a culprit

The disparities can be explained, in part, by the higher rates of poverty and lower rates of health coverage among minority populations, says Krakauer. "Minorities are twice as likely to be uninsured as European-Americans."

A 1997 survey found that 14% of European Americans lacked health insurance, compared to 23% of African-Americans and 36% of Hispanic-Americans.

But there are other factors as well.

Different cultural attitudes toward illness and toward health care providers often present challenges for clinicians, and these challenges are more pronounced when the patient is facing a life-threatening illness, he says.

A study by Blackhall and colleagues,[16] of European-American, African-American, and Korean-American senior citizens at a Los Angeles senior citizen center found significant differences of opinions about appropriate health care measures to be taken at the end of life.

"The questions asked were: Who should be told of a diagnosis of cancer? The patient, family, or neither? Who should be told of a terminal prognosis? The patient, the family, or neither? And who should make decisions about life support? The patient, the family, or the doctor?" Krakauer asks. "African-American and European-American respondents were much more likely to believe the patient should be told. Whereas, the Korean respondents were more likely to respond that the family members should be told and should make the decisions."

Ignorance on the behalf of health care providers of such differences of opinion can have devastating consequences for terminally ill patients, he emphasizes.

"If you talk to the son of an elderly Korean woman with gastric cancer and he indicates that he should be the one to make decisions about her health care, and you insist on informing her of her condition and asking her to make the decisions, you may be causing serious distress and confusion," he says. "She may not expect or want to make these decisions."

Clinicians should not assume, however, that just because a patient is of a particular ethnicity or background he or she holds these particular attitudes, Krakauer hastens to add. "You can't assume that because someone is Korean that they don't want to make their own decisions, or that because someone is Muslim, that they don't want certain kinds of care."

Physicians need better training in medical school and beyond how to assess cultural values and attitudes in their individual patients during the individual patient encounters in order to make the best judgments about care, he says.

Issues of trust

Another barrier to obtaining optimal end-of-life care is a certain level of mistrust of the health care system by minorities, particularly in the African-American community.

"There has been a history of broken trust between the health care system in this country and this group, the most egregious example being the Tuskegee experiment, but there have been others," says Krakauer.

Suspicion of the motives of the established health care system has been a significant factor in preventing minorities, particularly African-Americans, from seeking information about palliative care services or formulating advance directives, says **Richard Payne**, MD, chief of the pain and palliative care service at Memorial Sloan-Kettering Cancer Center and consulting attending physician at North General Hospital, both in New York City.

Payne helped establish the Harlem Palliative Care Network, a group of physicians, pharmacies, churches, and community organizations that work to improve medical care for seriously ill Harlem residents by improving access to pain management, respite care, support groups, and transportation assistance.

To establish the network, Payne and others sought the help of local community leaders and clergy.

"One pastor I spoke to asked, 'Why are we talking about this end-of-life stuff and not high-dose chemotherapy treatments or cardiac catheterization?'" he recalls. "'How am I to believe the hospital has our best interests in mind? How many African-American and Latino physicians do you have on staff?'"

To better improve Harlem residents' access to palliative care, the network conducts educational seminars at community organizations and churches and asks community members to refer members of their family with serious medical problems, even if the patients are not terminally ill.

"We want to see these patients and get them services before they present in crisis," he explains.

Increasing the trust of these patients is the challenge and responsibility of the health care community, he adds.

"The break of trust has been on the part of the health system and it is our responsibility to get it back," he says. "What we really need to be talking about is improving care at any stage of illness, access to cancer drugs, certain treatments and, then, quality care if your disease has progressed to the point where no cure is possible."

A variety of solutions exists

There are multiple barriers to access by minorities that have multiple causes, Krakauer argues. And there are a number of actions that need to be taken to find a remedy.

First, health plans must begin offering incentives and not disincentives to health care providers to take care of the most vulnerable patients, the poor and elderly with serious medical conditions, he says.

Second, more efforts must be made to recruit more minority students to medical school and medical programs.

"Studies have shown that minority physicians take care of a larger-than-their-share percentage of poor patients and minority patients," he says. "These are the physicians who are taking care of

SOURCES

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our vulnerable patients, and we see fewer and fewer minority students admitted to medical schools, then, consequently, to fewer minority graduates. It is a pipeline problem."

Medical education should be expanded so that students understand how to ask patients about their cultural beliefs about health care to insure they provide care that is consistent.

"We can never assume we know what a patient will want," he says. "Once you do, you are guaranteed to violate someone."

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House calls are back — for a price

Plush practices on the rise

Boston internists Steven R. Flier, MD and Jordan S. Busch, MD, currently practicing at Beth Israel Deaconess Medical Center, raised eyebrows and headlines last month when they announced they were leaving their current positions to set up a much smaller, but more expensive practice — Personal Physicians Healthcare Inc.

In contrast to their practice at Beth Israel, where they are currently responsible for thousands of patients, often seeing 30 patients a day, their new practice will restrict them to only 300 patients each, with each patient receiving perks such as 24-hour telephone access, house calls, and physician-accompanied visits to specialists.

The catch? Each patient of the practice must pay a premium of $4,000 per year in addition to maintaining existing health insurance coverage.

"They felt that this is what they needed to do to maintain a financially sound practice and provide the kind of quality care for patients that they want to," says **Michael Blau**, JD, partner in charge of the health law department at McDermott Will in Boston, the firm setting up the practice for Flier and Busch. "Physicians in a typical managed care practice see approximately 30 patients a day, with 10-15 minutes for each patient."

Flier and Busch want to see fewer patients, spend more time with each one, and be available in person or on the telephone should the patient need to speak with them unexpectedly, Blau explains.

Premiums up all over the country

Although the doctors' decision spawned articles in the *Boston Globe* and other newspapers nationwide, including an op-ed piece in the *New York Times*, theirs is not the first practice of its kind.

So-called "boutique" or "concierge" practices, those charging patients a retainer fee for services outside of those that can be billed to third-party payers, have been a trend in medicine for a number of years, according to a recent article in *AMA News Briefs*.

Physicians who are members of MDVIP, based in Boca Raton, FL, limit their practices to only those patients who can pay a $1,500 annual fee. In return, the patients can expect to receive same-day or next-day preferred appointments, dedicated support personnel to make follow-up and specialist appointments, mail and home delivery for prescriptions, and a dedicated waiting room.

MD2 (pronounced MD-squared) in Seattle, charges $20,000 per couple, $13,200 for individuals, and an extra $2,000 for a child age 14 to college age. The fee includes all care that is rendered in the physician's office, including some diagnostic tests and medications. Patients can expect to reach their personal physician by phone 24 hours a day and have him or her make house calls and accompany them on visits to specialists. In addition to faster, more personal service, MD2 patients also are treated to amenities such as monogrammed robes and slippers instead of paper or cloth gowns, an office with marble hallways, and the luxury of being the only patient in the office when seen by their physician.

New tier of care created

Critics have accused "boutique" practices of establishing a "third tier" of better health care for the wealthy. Patients with no insurance are the first tier — they often have no health care. Patients with only managed care insurance must still endure long waits to be seen by their primary care physician, who can only give them 10-15 minutes of time.

Though this may strike some as unfair or unethical, it is simply reflective of the current state of our health care system, says Blau. "People tend to react as if physicians are obligated to act on behalf of the entire public good — taking all comers without regard to payment. But that is not the system that we have."

The health care system in the United States is a private enterprise, and physicians are entitled to operate in that system in a way that enables them to establish the practice they want, he says. "They want to be able to cover the overhead of their practice, take home a decent salary, and take care of the patients in the manner that they believe is providing quality care."

Flier and Busch are giving their current patients plenty of notice about the practice change, helping those who wish to not remain in the practice find another provider, and, says Blau, they are waiving their new fees for a limited number of their long-time patients.

"If it comes down to someone who really does not want to change providers, who is really in need of health care, then they have decided to reduce or waive the fee, if they believe that leaving the practice would seriously jeopardize the patient's care," he says.

Practices not unethical

Essentially, the spread of "premium" practices does not represent unethical actions by the physicians themselves, but, arguably, highlights an ethical problem for the system as a whole, says **Richard Roberts**, MD, JD, professor of family medicine at the University of Wisconsin-Madison, and past chairman of the American Association of Family Physicians.

"I don't really see a problem as far as individual ethics, although it does make me rather sad," he says. "A lot of physicians, particularly in primary care, are just very frustrated with the current situation."

Faced with drastic cuts in reimbursement, higher overhead costs, and pressure to see more and more patients, many primary care physicians are frustrated, angry, and overwhelmed, he states. "A number of primary care providers are really struggling."

The main problem with these practices, as he sees it, is that they represent a failure of our health care system.

"We spend $1.4 trillion per year on health care, by far the most of any nation," he says. "Yet our outcomes are way below what they should be."

With more than 30 million people in the U.S. population uninsured or underinsured and challenged to even receive basic primary care, it's difficult to think about practices asking patients to pay additional money for luxuries, he says.

As a physician, Roberts questions the assertion that physicians must drastically reduce their patient load in order to be responsive and provide quality care.

"I have always taken all kinds of insurance, including Medicare and Medicaid; I see 25-30 patients a day, and patients have my home number," he says. "I am able to do that. But I can

appreciate that for some other physicians, it is not possible."

Aaron Katz, CPH, director of the health policy analysis program at the School of Public Health and Community Medicine at the University of Washington in Seattle, agrees that the spread of "concierge" practices is more an overall indicator of the health system's health than an ethical dilemma for providers.

"I don't blame the physician. They are merely playing the game as we have set it up," he says. "But my concern is that we have the most expensive health care system in the world, and it is not clear that the benefits we receive are worth all the extra money that we spend. We spend so much money and, what these practices are saying by their existence, is that that is simply not enough to get what most people say they expect of the system: good access to their primary physician, timely care, answers to their questions."

Limited access not yet an issue

Although some critics have warned that the spread of boutique medicine will mean fewer physicians available to treat the masses of people left out of the loop, Katz doesn't see this as a problem — yet.

"It is not a big-enough phenomenon, in my view, to realize any policy issues in the short term," he says. "Right now, it is mostly in urban areas that have a sufficient number of providers." If we were to see a mass exodus; if we were to see 25% of physicians move to this kind of practice, then, I think we have something very big and troubling to worry about."

If, for example, a number of physicians in a specific geographical area were to form these kinds of practices, limiting the access to care of people unable to afford premiums, then we would probably see some government action, he adds.

"If you had a town of 10,000 people, and three of the four physicians decide to go into one of these practices, OK, now we are talking about potentially causing problems outside of the folks in that practice," he explains. "Then, you would see problems of it driving up the cost of health care."

Lawmakers would react, he says, if large numbers of the middle-class suddenly had difficulty finding care, he says. "That's what happened in the early 1990s when we had the health care reform debate. We were in a recession; middle-class people started feeling like their security was threatened. We may be entering a phase like that; I don't know."

Legal issues examined

Ethicists are not the only ones concerned. Currently, insurance regulators in two states are examining concierge medical practices to determine if their way of doing business violates the terms of their contracts with third-party payers or with federal programs.

But, as long as the practices have established a clear line between what services are paid for by the retainer fees and the clinical services covered by medical insurance, the practices should be OK, says Blau.

Regulators have been most concerned about "balance billing," a practice prohibited by most payer contracts. "Balance billing" is the process of charging the patient the "difference" between what the physician charges for a service and the reimbursement provided by the payer. If physicians sign the contract, they agree to take only what the company reimburses for that service and not bill the "balance" to the covered person.

Some practices may walk a dangerous line by not making abundantly clear in establishing their business structure that the extra fees charged actually pay for extra services and are not just a way for physicians to get the level of charges they feel they deserve vs. what payers want to pay, he says.

Personal Physicians has established two separate business entities for the practice. The first is a business corporation that only handles the non-clinical services provided to patients. That works in conjunction with a separate professional medical practice that provides the actual medical care, he says.

"The corporation is in charge of a range of convenience services offered to our patients, that are not clinical and not covered by insurance," he says. "The practice provides all of the medical care, he says.

As an example, he notes that the pagers, computer systems and other support personnel necessary to maintain direct 24-hour access to the physicians are the purview of the corporate side. But the services the doctor renders when being called in on those pagers or via those computers is either billable to payers (often it is not) or written off by the physician, Blau says.

Establishing such physician practices does

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raise a lot of ethical issues about access to care and about the value of medical care that needs to be examined.

In establishing Personal Physicians Healthcare, Blau has met with representatives and ethics advisory panels from a number of health care organizations and payers that will interact with the practice to address concerns that they have.

"What we have been doing is sort of a didactic examination of different issues; there is not an investigation of a problem," he notes. "But we felt it was important for these issues to be raised and addressed." ■

Detecting conflicts not an easy task

Policy enforcement varies

As both public and private funding of clinical research continues to rapidly increase, federal health officials need to do more to monitor possible financial conflicts of interest in clinical research to ensure that human subjects are adequately protected, say two new reports released in December 2001.

A Government Accounting Office (GAO) study[1] of financial disclosure policies at five major research universities found that while the institutions had disclosure policies in place well before federal law required them to do so, these policies varied greatly from institution to institution with varying degrees of implementation.

And since there is no federal requirement that investigators report possible conflicts directly to the institutional review board (IRB), information about possible conflicts of interest may go undetected by those charged with protecting subjects, according to a report prepared by the Washington, DC-based Association of American Medical Colleges (AAMC).[2]

A key problem, notes **Jennifer Kulynych**, JD, PhD, director of biomedical and health sciences research for the AAMC, is that financial disclosure regulations were not originally designed as measures to protect human research subjects.

"They reflect a concern for ensuring the integrity of the data," she says. "That is the problem that is reflected in those regulations. They didn't really reference the human subjects protection regulations."

Historically, financial disclosure regulations and human subject protections mandates are totally separate areas, she explains.

Rules for financial disclosure vary based on whether the research is federally funded, or whether the research is privately funded but regulated by the U.S. Food and Drug Administration (FDA).

"For federally funded research, the institution is required to appoint an official to oversee financial conflicts of interest," Kulynych explains. "And, that person collects the financial disclosure statements from investigators and then decides if there is a conflict of interest and how the institution will deal with that," she says. "But, that person is not required to give any information to the IRB. Some institutions do, as a matter of practice. But, there is no requirement. That is one of the things we are addressing."

For privately funded research regulated by the FDA, no prior review of possible conflicts is required, she adds. "The financial disclosure regulation that the FDA has only requires the sponsor to keep track of the financial interests of the investigators and the sponsor. The sponsor does not have to give the information to the FDA for review until it submits its marketing application, which is well after all the research is complete."

Funding skyrockets

Funds for biomedical research have skyrocketed over the past two decades, both in the private and public sector. The budget of the National Institutes of Health (NIH), the main federal agency funding biomedical research, jumped from $3 billion in 1980 to more than $20 billion this year. Funding from pharmaceutical companies for drug development research grew even more rapidly, from $1.5 billion in 1980 to $22.4 billion in 2000.

The growing amount of research that is funded

with both public and private dollars, and the increasing number of clinical research initiatives sponsored by private companies, has spurred calls for greater examination of financial incentives that might encourage researchers to overlook risks to subjects.

It is becoming more common for researchers to hold ownership interests in private companies dedicated to developing new medical products and procedures. When these companies fund projects at the institutions where their minority owners conduct research, in some cases funding the research itself, then objectivity is obviously called into question.

However, the potential conflict of interest has to be made known to those in charge of monitoring subject safety in order for objectivity to be evaluated, she explains.

"I think it is partly that these kinds of [public-private] relationships are increasing in number and also that there have been litigation over harm that has occurred to participants in some human trials — the Gelsinger case, the Hutchinson case, for example — in which one of the issues raised by the litigants was the financial interest of the investigators," she says.

Recommendations

In order for potential financial incentives to be out in the open, the AAMC is recommending that research institutions set up a formal committee to review conflict-of-interest issues, rather than relying on a single official.

"We are also recommending that when the committee reviews these interests, if it is human subjects research, there should be a rebuttable presumption against the financial interest," Kulynych says. "In other words, we recognize that in some cases, circumstances might warrant allowing that particular investigator who has financial interest to still conduct the research, but that basically that person should have to make the case to the committee, and the committee should impose conditions that are necessary to oversee the potential conflict."

Possible conditions would include having someone else obtain the informed consent of the subjects, and having a monitoring panel review the research, she says.

Plus, any significant financial interests should be disclosed both to the public and research participants.

"We recommend that whenever the committee would agree to let someone with a financial interest do their research, that this should be communicated to the IRB. And if they still approve the research — if they felt there was any risk that they felt was inappropriate to human subjects, the IRB could still not approve it — the consent forms should mention that there is a financial interest and offer the subject more information if they would like it," she says. "And, we make recommendations that the committee should require disclosure in every publication or presentation of research."

Institutions should also standardize the thresholds at which a financial interest becomes reportable, she adds. The standards used by the U.S. Public Health Service (PHS) are more stringent than those required by the FDA, and the AAMC is recommending use of the PHS thresholds.

"For example, we recommend that for companies that aren't yet publicly traded, any equity interest or any options should be reported to the conflict-of-interest committee and reviewed," she says, not just those interests deemed to be worth more than a specific dollar amount. "Stock options don't hold much current value but they could dramatically increase based on the outcome of the research."

One of the areas in need of much closer examination and regulation is the area of institutional financial conflicts of interest, rather than just the possible conflicts of individual researchers, stated both the AAMC's and GAO's reports.

"It is actually a very complicated situation because there are a number of ways an institution could have a financial interest," says Kulynych. "It could have an equity interest in a private company that was managed by the Office of Technology and Licensing. Or, it could have an equity interest in its general endowment that is managed by a management company at arm's length from the university. So, that is the same interest, but the two situations pose different challenges."

Federal guidance needed

Currently, there is no federal guidance available about evaluating possible institutional conflicts of interest, let alone regulations requiring disclosure, she says.

"That's the thing we have our task force is working on right now — the question of defining what kinds of interests should be the subject of concern," she notes.

In addition to the current regulations, the U.S. Department of Health and Human Services

(HHS) needs to develop more comprehensive guidelines for institutions on how the regulations should be implemented and how institutional issues should be addressed, the GAO report recommends.

"The universities we visited indicated some confusion about what the PHS regulation specifically required them to report to NIH," the authors state. "NIH and FDA have recently taken steps to improve oversight and monitoring, such as conducting site visits, taking an inventory of institutions' financial conflict-of-interest policies, and providing guidance to reviewers of financial conflict-of interest information. In addition, HHS has developed draft guidance on financial relationships in clinical research, which is promising. However, this guidance does not provide detailed advice on managing institutional financial conflicts of interest."

The office recommends that HHS:

• develop and communicate information on best practices for institutions to consider for identifying and managing investigator and institutional financial conflicts of interest in biomedical research;

• develop specific guidance or regulations concerning institutional financial conflicts of interest.

Officials at HHS agree with both recommendations and were moving to develop such resources prior to the report's publication, noted HHS Inspector General **Janet Rehnquist** in a letter drafted in response to the report.

"Best practices evolve from public and private efforts," she noted, referring to the initial recommendation. "The NIH has efforts already under way to collect and develop such information for posting on their web pages, based on their proactive site visits, and their analysis of financial conflict-of-interest policies from the top NIH grantee institutions."

The NIH's draft interim guidance on financial conflicts in clinical research (available on-line at: http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm) touches on both of these issues, and the agency is working to address them further, as are the AAMC and the Association of American Universities, she noted.

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Audio conference replay addresses disaster

On Sept. 11, Saint Vincents hospital in Manhattan, a Level 1 trauma center located two miles from the World Trade Center, found itself at the center of an unthinkable tragedy. A Code Three was called after two hijacked airliners slammed into the twin towers.

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CE/CME *Questions*

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5. One method of increasing the number of people competing advanced directives recommended in the article is:
A. Offering financial incentives to patients on admission.
B. Providing forms for advance directives with other insurance information when health coverage is initiated.
C. Amending the Patient Self-Determination Act to require that advance directives be completed by all Americans applying for health insurance.
D. None of the above

6. Among the barriers to minorities' access to optimal end-of-life care mentioned in the article were:
A. Lack of trust of the health care system.
B. Miscommunication between clinicians and patients due to cultural differences.
C. Low number of minority physicians and other health professionals.
D. All of the above

7. Which of the following is a *legal* issue that must be addressed when establishing a "boutique" physician practice?
A. Ensuring that patients who are not remaining in the practice find another physician.
B. Ensuring that the retainer fees do not violate contractual prohibitions against "balance" billing.
C. Ensuring that residents in a community have equal access to basic health care.
D. None of the above

8. According to the article, current federal regulations on disclosure of possible financial conflicts of interest in clinical research are not sufficient because:
A. There is no requirement that investigators' potential conflicts be reported to the IRB.
B. There are no regulations requiring disclosure or monitoring of institutional conflicts of interest.
C. Universities are often unclear on the manner in which potential conflicts should be reported to federal regulators.
D. All of the above