AMERICAN HEALTH CONSULTANTS®

Medical Ethics Advisor®

For 16 years, your practical guide to ethics decision making

July 2000 • Vol. 16, No. 7 • Pages 73-84

IN THIS ISSUE

In This Issue **continued on next page**

Human subjects bill could supercede newly created protections office in HHS

Government tightens reins on human research

Ethics committees likely will play a larger role in monitoring the education of institutional review board (IRB) members and investigators if Congress has anything to say about it.

Last month, legislation was introduced in Congress to ensure human subjects are protected in research studies. U.S. Reps. Donna DeGette (D-CO), Henry Waxman (D-CA), and John Mica (R-FL) introduced the Human Research Subject Protections Act of 2000, which would establish standards for research institutions and increase funding for a new Office for Protection of Human Subjects (OPHS). The goal of the legislation, according to DeGette, is improved training of members of hospital IRBs and better informed consent processes. **(For a summary of the bill, see p. 75.)**

Days before the bill was introduced, Health and Human Services Secretary Donna Shalala announced that the newly created Office for Human Research Protections (OHRP) would have more control and independent authority to ensure human research subjects are protected. Details regarding the new office were published in the June 13 *Federal Register*. **(See *Medical Ethics Advisor*, February 2000, pp. 13-17.)**

The OHRP will be headed by **E. Greg Koski**, MD, a Harvard Medical School anesthesia professor. Koski currently oversees the protection of research subjects at a consortium of Boston-area hospitals, including Massachusetts General Hospital and Brigham and Women's Hospital.

In This Issue **continued from page 73**

COMING IN FUTURE ISSUES

■ Award-winning end-of-life care programs: What works and what doesn't

■ Establishing ethical standards for pharmaceutical advertising to consumers

■ Did Iceland go too far in selling its health care database?

■ Does prayer heal patients? A look at the Anglican Working Group in Bioethics

■ Inspector General begins looking at self-policing policies of the tissue bank industry

Two major announcements in such a short amount of time can be confusing, says Koski. "The bill recently introduced by Representatives DeGette, Mica, and Waxman has been in the pipeline for some time, as I understand it, and does reflect the recent initiatives of the Secretary to create the new office and strengthen protections for human subjects," adds Koski.

One of the key features of the bill is to bring all human research under the common rule, he notes. "That's a step that I believe would be very valuable."

Education will be critical

"Regardless which office — the OHRP or the OPHS — will eventually be responsible for the oversight and control of human research protection, one of the overriding responsibilities between the two is the oversight of the education of IRB members and investigators on human research subjects protections," says **Tom Tollison**, assistant director of compliance and research contracts attorney for Banner Health System in Phoenix.

Tollison predicts that the ethics committee will be a critical element in the educational process. "I foresee a concerted effort between the research department and the ethics committee of the institution, whereby the research department will be responsible for the implementation of the educational programs, and the ethics committee will be responsible in an active advisory role for those programs," he explains.

While the legislation is not law yet and there's no word from the new OHRP, the issue of educating IRB members will be critical, adds Tollison. The National Institutes of Health (NIH) is emphasizing education as well.

Beginning Oct. 1, 2000, the NIH will require investigators to provide a description of education completed for individuals identified as "key personnel" in the proposed research. Key personnel are defined as individuals responsible for designing and conducting the study.

All investigators need education in the basics of human subjects research, according to an NIH press release, but some institutions may elect to require more intensive study, especially in difficult topic areas or special patient groups. The NIH does not plan to issue a list of endorsed programs.

The NIH does offer a free curriculum for its own staff, however, that can be adapted and

used in other institutions, and it offers an on-line tutorial for its investigators and researchers called *Protection of Human Research Subjects: Computer-Based Training for Researchers.* **(See editor's note below for more information.)**

(Editor's note: The NIH on-line tutorial can be downloaded from the NIH's Web site: http://helix.nih.gov:8001/ohsr/newcbt. A bioethics education and curriculum development resource also is available from NIH. The site contains resources for a broad range of topics and provides links to additional resources. Visit the site at: http://www.nih.gov/sigs/bioethics.) ■

Human Research Subject Protections Act of 2000

SECTION SUMMARY

Section 1 – Short title
This act may be cited as the Human Research Subjects Protections Act of 2000

Section 2 – Findings and purposes
The purposes of this act are:

1. To apply common rule and vulnerable-population protections to all human research subjects independent of setting and funding source.
2. Require classified research to be approved by an Institutional Review Board (IRB) and compliant with other human research subject protections.
3. Establish an Office for Protection of Research Subjects in the HHS Office of the Secretary.

Title I – Human Subject Protections

Section 101: Protection of Human Subjects in Research; Uniform National Applicability of Common Rule and Provisions Protecting Vulnerable Populations.
Applies common rule and vulnerable-population protections to all human research subjects independent of setting and funding source.

Section 102: Scope of Authority of Secretary
Establishes the Secretary's authority to modify the common rule and vulnerable-population protections. Permits federal agencies to establish protections above and in addition to the common rule and vulnerable-population protections. Authorizes the Secretary to suspend or revoke the registration, impose restrictions

CME questions

1. A key feature of the Human Research Subject Protections Act of 2000, according to **E. Greg Koski**, MD, an anesthesia professor at Harvard Medical School in Boston who oversees the protection of research subjects at a consortium of Boston-area hospitals, is:
A. Increased oversight from the Department of Justice
B. Criminal penalties for breach of conduct
C. All research is under the common rule
D. All of the above

2. The ethics committee, according to **Tom Tollison**, assistant director of compliance and research contracts attorney at Banner Health System in Phoenix, will be a critical element of new policies by:
A. Policing the researchers
B. Collaborating with IRB members on education
C. Creating a compliance subcommittee
D. All of the above

3. **Kenneth Brummel-Smith**, MD, Bain Chair at the Providence Center on Aging in Portland, OR, says older Americans often are:
A. Rarely given follow-up tests to confirm a diagnosis
B. Swept under the rug
C. Given levels of care considered unthinkable for younger patients
D. All of the above

4. Obstacles to pain management, according to **Perry Fine**, MD, professor of anesthesiology and associate medical director at the University of Utah Pain Management Center in Salt Lake City, include:
A. Biases in caregiver attitudes
B. Misalignments in reimbursement and payment structures
C. Patient attitudes
D. All of the above

on, or withhold federal funding from an IRB.

Section 103: Enhanced Human Subject Protections

Instructs the Secretary to promulgate new standards to protect research subjects with diminished decision-making capacity within 180 days of the date of enactment.

Title II – Informed Consent

Section 201: Right of Informed Consent

Establishes a research subject's legal right of informed consent. Requires the provision of "full and complete information" to research subjects necessary to "make an informed decision, free of coercion, regarding their participation in research." Also specifies the minimum elements of an informed consent form.

Section 202: Written Attestation and Disclosure

Requires investigators to file a written attestation of familiarity and agreement to comply with human subject research protections. Requires investigators to disclose to research subjects their financial interests in the research and any other conflicts of interest deemed necessary by the IRB.

Title III – Institutional Review Boards

Section 301: Requirements for Board

Requires IRB approval before human subject research can proceed. Establishes IRB membership requirements consistent with current common rule regulations. Establishes procedural requirements, including adequate funding, quorums for decision making, orientation and continuing education programs, and registration with the Secretary.

Section 302: Notification of Institutional Review Board

Requires sponsors and investigators to notify IRBs of prior IRB review and findings on a research proposal, as well as the regulatory disqualification or restriction of the sponsor, investigator, or research institution by a federal agency.

Section 303: Activities

Requires IRBs to compile and report summary annual data on the number of proposals reviewed, number of human subjects involved, and other subjects. Requires the Secretary to promulgate regulations on improved clinical trial monitoring and the conduct of research at multiple research sites.

Section 304: Disclosure of Interests

Requires investigators to disclose to IRBs their financial interests and conflicts of interest in the research. Requires all IRB members to disclose their conflicts of interest in the research, including ownership of financial relationships with the sponsors. Prohibits participation of IRB members in decisions on research in which they have conflicts of interest.

Section 305: Accreditation

Effective two years after the date of enactment, IRBs shall be accredited by a nonprofit private entity approved by the Secretary. Specifies that accreditation shall be to standards established by the Secretary.

Section 306: Cost Recovery

Authorizes institutions to recover the costs of compliance with human subject protections from government research sponsors as direct costs.

Section 307: Applicability of Requirements

Requirements of the Act shall apply on the date of enactment.

Title IV – Federal Oversight

Section 401: Establishment of Office for Protection of Research Subjects

Establishes an Office for Protection of Research Subjects in the Office of the Secretary of Health and Human Services. Calls for an Office Director to be appointed by the Secretary.

Section 402: Authorization of Appropriateness

Authorizes $20 million for the Office in fiscal year 2001 and such sums as may be necessary in subsequent years.

Section 403: Institutional Programs for Providing Education on Protection of Human Subjects in Research

Requires a "comprehensive and ongoing program" to educate investigators and IRB members on human subject protections as a condition of federal grants, cooperative agreements, or contracts with public or private entities for the conduct of research.

Section 404: Certain Classified Human Subject Research

Prohibits federal funding of secret, classified research if an IRB has waived the requirement of informed consent or the research is exempt under the common rule from IRB review. Fulfills the recommendations of the 1995 Report of the National Advisory Committee on Human Radiation Experiments.

Section 405: Rule of Construction Regarding Individual Agency Offices

Provides for transferring duties from any existing office, such as the HHS Office of Human Research Protections, to the newly authorized Office for Protection of Research Subjects.

Section 406: National Bioethics Advisory Commission

Authorizes the National Bioethics Advisory Commission as the successor body to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1979-1986). ■

Does your facility provide proper care for the elderly?

Experts claim lack of training hinders care

A man comes to your facility's primary care clinic suffering from unexplained incontinence. No work-up is performed because the physician assumes the problem is caused by an enlarged prostate gland and prescribes a medication for prostate problems.

The medication significantly lowers the patient's blood pressure, and he experiences an adverse reaction due to the interaction between the prostate medication and other medications prescribed by a neurologist the patient is seeing for a separate problem.

On seeing the patient's decline in blood pressure, the neurologist prescribes another drug to increase the patient's blood pressure. The patient begins having unexplained fainting spells and episodes of losing balance and falling down.

Does this represent an appropriate standard of care for your health system? Would your answer change if you knew the patient was 80 years old?

Older Americans often are asked to accept a level of care that would be considered unthinkable for younger patients, says **Kenneth Brummel-Smith**, MD, a board-certified geriatrician and president-elect of the New York City-based American Geriatrics Society (AGS). Brummel-Smith also is Bain Chair at the Providence Center on Aging in Portland, OR.

"For example," he explains, "it is very common in normal practices for incontinence to be seen as a normal part of aging, especially in women. Confusion is another good example. If a 25-year-old is confused, people assume the person is taking drugs or has some sort of mental disorder. If the person is 85, they say, 'Oh, it is probably Alzheimer's — get a nursing home placement. No work-up is done to find out if, No. 1, it really is dementia, or, No. 2, if it is treatable."

The problem is threefold, says Brummel-Smith: First, clinicians, like the rest of our society, harbor biases against the elderly. Second, there is insufficient available medical training in the specific needs and unique presentations of elderly patients. Third, elderly patients frequently require longer visits and hospital stays, which is discouraged by the current managed care reimbursement environment.

"The AGS has begun to expand geriatric training to other specialties: cardiology, pulmonology, general surgery, orthopedics, urology, and rehabilitation," he says. "We have been doing lots of training with physicians."

It is essential for health care systems to emphasize the importance of knowing how to provide good care to older patients instead of allowing those patients to be swept under the rug, he says.

"We have found, with the physicians, that the big thing is to test them," he says. "We have been working with other specialty societies and their boards to incorporate more geriatric questions into the certification examinations. If you have geriatric questions, people believe geriatrics is important."

Situation is becoming critical

According to the AGS, there are 9,116 geriatric-certified allopathic physicians, approximately half of the estimated 20,000 to 25,000 needed to properly care for today's population of older Americans. The society frequently gets calls from families seeking a certified geriatrician, says Brummel-Smith. By the year 2030, according to AGS estimates, more than 36,000 physicians with geriatrics training will be needed to care for a projected 76 million older adults.

According to a survey by the Association of American Medical Colleges, 122 out of 125 surveyed medical colleges require geriatrics as part of regular course work, but recent medical school graduates perceived their instruction in care of seniors to be inadequate.

"Another big initiative of the AGS and the Foundation for Health in Aging is to say that medical schools should be held accountable for

their geriatric training," he adds. "Sixty percent of our hospital patients are elderly people, and we mostly train doctors in hospitals, so we ought to make sure the training is there. Every medical school in the U.S. requires a pediatric rotation, but not everyone requires a geriatric rotation. We have to do something to change that. Pediatric patients make up only 11% of the patient population, as opposed to 60%."

The first thing that needs to change is the negative attitude many clinicians have toward older patients, Brummel-Smith says. "Surveys have shown that medical students enter school with about the same level of negative attitudes about elderly people as the rest of society, but their attitudes get worse in medicine. One of the reasons, we believe, is that all of their exposure to geriatric patients is negative, they see the worst of the worst."

As a result, clinicians inexperienced in dealing with geriatric patients tend to discount physical complaints as age-related, he says. Many heart surgeons, for example, tend to consider postoperative delirium and disorientation as a normal part of an elder person's response to surgery, whereas delirium and disorientation would be treated in a younger person, Brummel-Smith illustrates.

"The classic geriatric story is a doctor who examines an older man complaining of pain in his hip, and the doctor says, 'Well, you're 90. What do you expect?' And, the man replies, 'My other hip is 90 also, and it doesn't hurt.'"

Elderly present with unusual symptoms

Aside from negative attitudes, many clinicians are simply unfamiliar with unusual signs and symptoms that occur in the elderly population, he says.

"Many physicians lack knowledge of geriatric-specific issues, which we are trying to remedy now," he says. "Certain drugs have side effects in the elderly patient. An elderly patient who has suffered a heart attack may only present with confusion and mild discomfort, as opposed to the 'crushing chest pain' a younger patient would have had."

At the other end of the spectrum, many physicians tend to ignore the fact that the patient is significantly older and that very invasive or risky procedures may do more harm than good.

"The flip side of undertreatment is that when the medical ball gets rolling, often nobody stops to think whether it is appropriate care or not," he says. "The fact is, all older people die, and they all eventually die of some medical condition. It is very easy sometimes to frame that normal dying process as a pathologic kind of issue. Instead of paying attention to the real needs of that person, ever-widening and intensive medical interventions are offered."

Coordinating with other caregivers

Not all elderly persons require the services of a geriatrician, notes Brummel-Smith. About 80% of seniors are healthy and independent, he says. Patients with more than one chronic medical problem and those who are very ill cause the greatest worry.

General practice physicians often are reluctant to coordinate with other caregivers to develop a plan of care for a severely ill patient, says **Mary Moorhead,** MS, MFCC, a Berkeley, CA-based geriatric care manager, certified social worker, and licensed family counselor who specializes in coordinating medical care for elderly patients.

"Let's say you have a son and daughter who are concerned about their father and take him to see a general internist," Moorhead explains. "The physician establishes a diagnosis of Alzheimer's or Parkinson's. Really, that physician's expertise ends there. At that point, the patient and family are going to be faced with a number of challenges: Does the father need a nursing home placement? Can they afford home health care if he requires it? A trained geriatric case manager is experienced in handling these issues and should be consulted."

Geriatric case managers, who most often are licensed social workers specializing in this area, can sit down with the family, make a home visit and assessment, and help the patient's caregivers come up with a plan for continuing care of the person, she says. "The physician, if he is seeing 20 to 26 people a day, is not going to have the time to do that."

The National Association of Professional Geriatric Case Managers in Tucson, AZ, is a good source of information about geriatric care management and resources. Its Web site (www.caremanager.org) has a searchable member directory for physicians who need to locate one, she says.

Although not all seniors will require this level of care, many will. AGS data show that seniors (those 65 years and older) are hospitalized more than three times as often as younger people, and their

hospital stays are 50% longer. They use twice as many prescription drugs as the general population, and almost three-fourths report at least one disability. "Doctors are not trained in coordinating this type of care and do not know what is available in the community," she says. "It is a whole other world of expertise."

Geriatric care managers often know of valuable community resources available to the patient to meet some of their medical needs and cost issues. For example, most areas have a designated, federally funded agency on aging that coordinates programs like Meals on Wheels, adult day care, and transportation services for the elderly.

"If you put the patient or patient's family in touch with this agency, it can go a long way to filling in what otherwise would need to be handled through home health or a visiting nurse," she says.

Create a commitment

First and foremost, however, institutions need a firm organizational commitment to 1) providing health care to the elderly that meets the same standards as that of other patients and 2) to providing education for clinicians about geriatric-specific needs, say both Moorhead and Brummel-Smith.

"Again, we have to deal with the public and with misconceptions," says Brummel-Smith. "In our society, we have TV telling older women they ought to be wearing the wonderful [incontinence] pads that make life beautiful, rather than go get a work-up and find out whether the problem could be treated."

Pain, incontinence, and medical problems should not be overlooked or discounted based upon the person's age. ■

SOURCES

- **Kenneth Brummel-Smith**, American Geriatrics Society, The Empire State Building, 350 Fifth Ave., Suite 801, New York, NY 10118. Telephone: (212) 308-1414. Fax: (212) 832-8646. E-mail: info@americangeriatrics.org.
- **Mary Moorhead**, 1664 Solano Ave., Berkeley, CA 94707.
- **National Association of Professional Geriatric Care Managers**, 1604 N. Country Club Road, Tucson, AZ 85716-3102. Telephone: (520) 881-8008. Fax: (520) 325-7925.

National summit tackles 'institutional' obstacles to pain management

Ethics committees must meet requirements

No one — no matter how ill — should suffer needlessly from pain, and treating pain is as much a health care provider's responsibility as treating the patient's underlying medical condition. That's the ethic driving the Joint Commission on Accreditation of Healthcare Organizations' new pain management standards.

Released to the public in August 1999, the standards set specific benchmarks for evaluating and treating pain. According to the standards, health care facilities must:

- recognize the right of patients to appropriate assessment and management of pain;
- identify pain in patients during their initial assessment and, where required, during ongoing periodic reassessments;
- educate patients and their families about pain management.

The standards are not a separate document, but new requirements incorporated into each of the Joint Commission's accreditation manuals. Health care organizations accredited by the Joint Commission will be scored on the new standards beginning in 2001. **(See *Medical Ethics Advisor,* September 1999, p. 101.)**

Hospital administrators, physicians, nurses, and ethics committees, however, are just beginning to realize that putting those standards into practice is not as easy as simply following the rules. Implementing the standards will mean a sea change in clinical attitudes, education, and practice.

"I view the institution of these standards as a seminal event in the history of health care. They establish, for the first time, that evaluating and treating pain is no longer an option, but this is really the first step. Now comes the real work," says **Perry G. Fine,** MD, professor of anesthesiology and associate medical director at the University of Utah Pain Management Center in Salt Lake City.

Fine and other pain management experts recently spoke at a national summit, co-sponsored by the Joint Commission and the American Pain Society, designed to educate providers about the

new standards. The summit's goal was to prepare providers for the difficult task of implementing the requirements at their institutions. More than 400 providers from across the country attended the Leadership Summit on Pain Management: New Expectations for Pain Assessment and Treatment, held May 22 in Chicago. A second summit will be held July 31 in Los Angeles.

Complex biases in the form of caregiver attitudes, patient attitudes, and misalignments in the structure of reimbursement and payment systems present significant obstacles to adequate pain management, and they will have to be addressed, says Fine. "We have to have the attitude that pain management is essential, just like taking vital signs and treating infection and trauma. And, there are now very good means of evaluating and treating pain, that patients and even many providers are not fully aware of.

"If only we had the same approach to other areas of patient care that we traditionally have to the management of pain. The analogy would be a patient coming in with bacterial pneumonia, and the physician — instead of doing culture sensitivities and treating with the appropriate antibiotics — goes back to, 'Well, we'll do some cupping and postural drainage and give you some antifever medication and just hope for the best.' It's archaic," Fine explains.

Patient education is essential

Although much of the blame for undertreatment of pain is laid at the feet of physicians and nurses, patient attitudes about pain present one of the biggest barriers to appropriate pain management, says **June L. Dahl**, PhD, professor of pharmacology at the University of Wisconsin Medical School, which helped develop the Joint Commission standards, and a speaker at the summits.

"One of the critical standards is in the education chapter," says Dahl. "It states, 'The patient will be taught that pain management is an essential part of their care.' Facilities will have to address the issue of patient education because consumers are one part of the equation."

Many patients do not report pain or underreport their pain for a variety of reasons, she adds. "Within our culture there are a variety of factors. We have the macho culture, where there is a feeling among some people that they should just put up with pain," she says. "We also have stoicism, which is different than the macho behavior, but with a similar effect. We also have some people who believe that suffering is necessary for redemption, that pain can be 'purifying' in a way."

Other patients are simply afraid of the medications involved in treating pain, Dahl continues. "They are afraid of side effects and do not know that side effects can be controlled, or they are worried about dependence or addiction."

It doesn't help that terms like *addiction, dependence,* and *narcotics* are frequently misused in public discourse and in the media, she says. "I don't even like to use the word *narcotic* anymore because it has been misused so often to mean drugs that are illegal," Dahl says. "I have even seen newspaper articles that referred to cocaine as a narcotic. I use the term opioids instead."

She has encountered patients who considered themselves addicts because they need to keep taking the medication in order to prevent or treat the pain.

"One patient said to me, 'I am addicted,' and when I asked her why she thought she was addicted, she said, 'If I don't take the medicine, the pain comes back,'" Dahl relates. "That was the most interesting definition of addiction that I had ever heard of. But, if you look in the literature, even recent textbooks, you will see a confusion about withdrawal symptoms and addiction, when almost everyone would go through a withdrawal in that situation. We can't withdraw suddenly from tons of drugs, but that is not addiction, it is a physical dependence."

Many physicians may not have the appropriate education to adequately assess and treat severe acute or chronic pain, which may explain why they are unable to dispel some of the myths surrounding pain medication, say Dahl and Fine. Many clinicians may have their own incorrect beliefs.

"Sadly, these issues are not taught well in medical school and postgraduate training," Fine says. "There are no requirements along the line for physicians to have to demonstrate competency in the basic elements of pain assessment and pain management. You cannot get hospital privileges if you cannot demonstrate competency in CPR, but there is no equivalent standard for being able to assess and treat the far more universal and debilitating complication of pain that is out of control."

A basic competency, suggests Fine, would be to include an understanding of basic approaches to pain control, know processes to evaluate pain in ways that are pertinent to the clinical situation,

use standardized approaches to treatment, and document the approaches.

"So, basically, the physician would have a standard evaluation for anyone who is at-risk or of an identified risk population for having pain. It would be a default to evaluate the intensity and etiology of the pain, then that would trigger a care plan to treat the pain. There is no departure in this from what is considered a good standard of care in any other domain of medicine."

However, evaluating pain is different and understandably difficult for many physicians who have not had training and education in this area, argues Dahl.

"Pain is a subjective concept," she explains. "There are not many objective measures of pain. The only way you can know if patients are experiencing pain is to ask them. You don't ask someone if they have hypertension, you take their blood pressure and you know. You don't ask someone if he or she has diabetes, you take the blood sugar."

Physicians must learn how and when to appropriately do a pain assessment. "Determine what is the intensity of the pain. What is the quality? What makes it better? What make it worse? What medicines have you taken and how do they work?" she says. "Then you should screen for anxiety and depression because these things can exacerbate pain."

Many physicians end up undertreating simply because they don't know what to do to treat chronic pain.

Nurses are part of the equation

It's also a common misconception that the way to improve pain management is getting physicians to do a better job of prescribing pain medication, says Dahl. "This is an important issue because there are physicians who underprescribe pain medication. But lots of times nurses will say to me, 'If only the physician would prescribe appropriately, pain management would not be a problem.' But, I have found that, even when the doctors do prescribe appropriately, the nurses will not administer as much as the doctor has ordered."

Surveys in the nursing literature indicate that many nurses simply do not believe patients who say they are experiencing unexplained severe pain, she says. "There is this disconnect. I also hear from nurses who are doing a pretty good job of pain management that many of their colleagues have the attitude that, 'I just don't believe that person is in that much pain.'"

There also are forces outside the hospital and provider environment that present obstacles to pain management, such as scrutiny of the drugs used to alleviate pain and low reimbursement of pain treatment.

"There is this whole regulatory environment surrounding the appropriate use of opioids," says Fine. "There is a huge mythology around this, where people are very misinformed and physicians are anxious and running scared. Medical boards are not adequately informed, and there needs to be a lot of social adjustment to ensure that there is adequate prescribing."

Lack of adequate reimbursement is another obstacle, says Fine. Most third-party payers do not properly reimburse visits for the evaluation of uncontrolled pain, and many will only cover the cost of a limited number of pain medications.

"For chronic pain patients, especially, there is nothing efficient and easy about treating the problem," he says. "These are complex, time-consuming problems. In the same manner that you cannot do good coronary artery disease care and you cannot do a revascularization procedure in a 7.5-minute visit, you cannot value and manage over time chronic pain patients in seven to 15 minutes a visit and get paid $18 to do it, when it costs that much just to have a medial assistant escort the patient to the room."

Though they can do little about the regulatory or reimbursement environment, hospital ethics committees will be challenged to ensure their facilities meet the new requirements despite myriad obstacles.

Families of patients frequently come to her expressing frustration at the lack of attention and effective intervention given to a loved one's pain, says Dahl. "That is why it is so critical that we have the standard in the organization and ethics chapter that patients have a right to adequate pain management," she reiterates. "So, when people call me, totally frustrated with the care a loved one has received — often that loved one may have died — I can say, 'Please go see the ethics committee. That is what they are for.'"

And, she notes, it would be wise for facilities to consider such complaints within the context of an ethics committee meeting because the alternative is often a courtroom. "These people are usually not trying to create a lot of problems for the hospital or for the doctor. They are trying to reach someone within the organization who can

SOURCES

- **June Dahl**, University of Wisconsin Medical School, 1300 University Ave., Madison, WI 53706. Telephone: (608) 263-4900.
- **Perry Fine**, University of Utah Pain Management Center, Salt Lake City. Telephone: (801) 585-7690.
- **The Wisconsin Cancer Pain Initiative** has published a resource manual, *Building an Institutional Commitment to Pain Management, the Wisconsin Resource for Improvement.* The manual outlines the key elements of institutionalizing pain management and contains sample documents shared by pain management groups around the country. For more information, visit the American Alliance of Cancer Pain Initiatives Web site: http://www.aacpi.org.
- The new **Joint Commission** standards are available on-line at the organization's Web site: http://www.jcaho.org/standard/pm_mpfrm.html.

address this issue and make sure that other people do not suffer the way their loved one did."

When these families are rebuffed, they may seek a remedy through the court system, she adds. "People need to be aware of how important ethics committees are, and ethics committees need to take these issues very seriously." ■

Palliative Care News

Study: Nonwhite areas less likely to have opioids

More than 50% of New York City pharmacies do not have adequate medication in stock to treat people in severe pain, a study reported in the April 6 *New England Journal of Medicine.*

New York researchers surveyed pharmacies throughout the five boroughs of New York City to examine the availability of commonly prescribed opioids in the city's pharmacies. They discovered that pharmacies in predominantly nonwhite neighborhoods are significantly less likely to stock opioids than pharmacies in predominantly white neighborhoods. Two-thirds of pharmacies that did not carry any opioids were in neighborhoods where the majority of the residents were nonwhites, according to the study.

"Previous research has shown that members of racial and ethnic minority groups are at substantial risk for the undertreatment of pain," said **R. Sean Morrison**, MD, lead author of the study and assistant professor at The Lilian and Benjamin Hertzberg Palliative Care Institute of the department of geriatrics and adult development at Mount Sinai School of Medicine in New York City.

"Our research identifies a barrier to treating the pain of these groups effectively. When patients are prescribed opioid analgesics by their physicians but do not have access to these pain medications at their neighborhood pharmacies, they are needlessly suffering," says Morrison.

Pharmacies are ill-prepared

Of the 347 pharmacies in the five boroughs — 81% of all pharmacies contacted — that responded:

- 176 (51%) did not have opioid supplies that were sufficient to provide adequate treatment for a patient with severe pain.
- 54 (16%) had no opioids in stock.
- Although 116 (95%) of the pharmacies with incomplete supplies had a combination of products in stock that could be used for the treatment of moderate pain, only 55 (45%) carried a strong opioid preparation that could be used for the treatment of severe pain.

According to surveyed pharmacists, the three major reasons for not having adequate supplies of opioids were:

- regulation with regard to disposal, illicit use, and fraud;
- low demand;
- fear of theft.

Other reasons pharmacists gave included:

- additional paperwork required by state and federal drug-enforcement agencies;
- regulatory oversight and monitoring of those medications;
- fear of penalties imposed by state and federal agencies.

Pharmacists who reported a low demand for opioids or expressed concern about their disposal were most likely to be in predominantly nonwhite neighborhoods.

"The movement to educate health care professionals on providing appropriate pain and palliative care for patients has made tremendous strides over the past few years," said Morrison. "However, our efforts are thwarted when access to and availability of the services and therapies we prescribe are denied." ▼

Mt. Sinai starts national pain management center

The Mount Sinai School of Medicine in New York City has created a new national center to promote pain management. The Center to Advance Palliative Care was established thanks in large part to a four-year, $4.7-million grant from The Robert Wood Johnson Foundation in Princeton, NJ.

"People are learning to expect more from the care they get at the end of life. Young doctors are learning that technical medical care isn't enough, that pain and suffering have to be addressed, too," says **Rosemary Gibson**, senior program officer at the foundation. "We need hospital environments that support these changes, and I can easily see the day when providing good palliative care [will] become the standard of care for every hospital in our country. Today, a hospital wouldn't dream of not having an infection control program. In a few years, they won't imagine not providing good, palliative care of the seriously ill, as well as the dying."

The center will offer a how-to manual on establishing a hospital-based palliative care program, a national directory of palliative care programs, case studies on ways to institutionalize palliative care programs, a comprehensive Web site at www.capcmssm.org, a speakers' bureau, policy papers on financing and other issues affecting palliative care, referral to fellowship and other training opportunities for physicians and nurses, and a national educational conference. ▼

Increase in opioid use is not prescription for abuse

Conventional wisdom that drugs used for relief of severe pain — such as morphine — are widely abused was challenged by a recent study published in the *Journal of the American Medical Association.*

The study looked at the use of opioids in the early 1990s and their rate of abuse. It also compared the rate of abuse of opioids to the abuse of illicit drugs. The study, published in the April 5 issue, was done by the Pain & Policy Studies Group (PPSG) of the University of Wisconsin Comprehensive Cancer Center. Researchers examined data from two government-sponsored sources: the Drug Enforcement Agency's medical use data from the Automation of Reports and Consolidated Orders System, which collects information on the national distribution of selected drugs to pharmacies and hospitals, and abuse data from the Drug Abuse Warning Network, which collects data about drug overdoses from a nationally representative sample of general hospital emergency departments.

The study found that from 1990 to 1996, U.S. physicians prescribed significantly more opioids. "Although there are many ways to treat pain, the increased medical use of opioids is a strong indicator that we are making progress to improve pain management," said **David E. Joranson**, lead author and PPSG director.

The study also found that abuse of opioids was low and stable, accounting for a small part (less

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Medical Ethics Advisor®**, P.O. Box 740059, Atlanta, GA 30374.

American Health Consultants® designates this continuing medical education activity for up to 15 credit hours in category 1 toward the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

American Health Consultants® is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). Hours of operation: 8:30 a.m. -6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $399. With CME: $399. Outside U.S., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $319 per year; 10 to 20 additional copies, $239 per year. Call for more details. **Back issues**, when available, are $67 each. (GST registration number R128870672.)

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Leslie Coplin**, (404) 262-5534, (leslie.coplin@ahcpub.com).
Managing Editor: **Kevin New**, (404) 262-5467, (kevin.new@ahcpub.com).
Contributing Writer: **Cathi Harris**.
Senior Production Editor: **Terri McIntosh**.

Editorial Questions

Questions or comments? Call **Kevin New** at (404) 262-5467.

than 5%) of the national drug abuse problem, as measured by drug overdoses. From 1990 to 1996, abuse of opioids increased 6.6%, in contrast with the abuse of the category "illicit drugs," including cocaine and heroin, which increased by 109%.

"These results indicate that the United States could be a model for how to achieve a balanced controlled substances policy; that is, one which can improve the availability of opioids for medical purposes while limiting abuse," said co-author **Karen Ryan**, chief policy analyst for the PPSG.

Joranson added that the danger for abuse should not be taken lightly. "We must continue to exercise caution with opioids, since there is an illicit demand for these drugs. Health care professionals and patients should continue to exercise appropriate care to avoid diversion and abuse of pain medications." ▼

'Old' narcotics may fight pain, reduce side effects

Researchers at the University of California at San Francisco have found that a certain combination of kappa-opioids — once thought ineffective — have fewer side effects and less potential for abuse in relieving moderate to severe pain. Current narcotics used to treat pain, such as morphine and fentanyl, are associated with side effects, and patients have a risk of becoming addicted.

Researchers led by **Jon D. Levine**, MD, found that nalbuphine and naloxone given in combination relieved pain in both men and women. Nalbuphine given in low doses actually increased pain in men and had no effect on pain in women. The study, involving 56 patients undergoing dental surgery, was published in the June 14, 2000, issue of the journal *Pain*.

The research adds to previous research into gender differences in pain and response to medication, notes Levine. "I think the kappa-opioid analgesics currently available have two mechanisms of action, one that decreases pain, and one that makes it worse," he says.

Researchers will next find out who can benefit the most from the drug combination. "There are a lot of other pain syndromes in which we would like to test this therapy. We want to figure out the exact mechanism for the pain enhancing component of the effect of kappa-opiates that appears to be much greater in males," explains Levine. ▼

Hawaii pioneers medical marijuana legislation

Hawaii became the first state to enact a medical marijuana law crafted by its state legislature. The law, SB 862, signed by Gov. Ben Cayetano in June, protects seriously ill patients who grow, possess, and use marijuana from arrest and originally cleared both houses of the state legislature last April.

While seven other states and the District of Columbia have similar legislation, Hawaii is the first to pass a bill without a ballot initiative. Patients who use marijuana in Hawaii will be subject to federal law and could be arrested by a Drug Enforcement Agency agent, but Federal Bureau of Investigation statistics show that 99% of all such arrests are made by state and local officials, says **Chuck Thomas**, director of communications for the Marijuana Policy Project in Washington, DC, a national organization dedicated to passage of medical marijuana laws at the federal level. ■