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OIG issues follow-up report on human subjects: More work needed

Legislative change is most likely catalyst, OIG says

Recent deaths of gene therapy patients have brought human subject research under greater public scrutiny. Now the government wants to know why its recommended reforms issued in June 1998 largely have been ignored by the research community.

In April, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued a follow-up report to its June 1998 report, "Institutional Review Boards: A Time for Reform." Last month, HHS Secretary **Donna Shalala** warned researchers that while the Clinton administration still supports biomedical research, more protections need to be in place for the use of human subjects. Shalala said she soon will announce who will oversee the recently moved Office for Protection from Research Risks (OPRR). "I will select the person personally with the advice of Surgeon General and Assistant Secretary for Health, David Satcher," she said in a statement.

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(For more on moving the OPRR out of National Institutes of Health [NIH], see *Medical Ethics Advisor*, February 2000, pp. 13-17. To see how each agency affects institutional review boards [IRBs], see chart, p. 64.)

The OIG report, "Protecting Human Research Subjects: Status of Recommendations" (OEI-01-97-00197, April 2000), concludes that overall, few of the

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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
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- The ethics of reimbursement: Is it OK to lie to get treatments covered?

office's previous recommendations have been enacted.

The follow-up report was published on the heels of an open letter sent to the health care community in March urging providers to self-disclose improper conduct. Inspector General **June Gibbs Brown** stated that providers who promptly self-disclose improper conduct may be eligible for "favorable treatment in the resolution of their case, including less rigorous corporate integrity agreements."

"We want to encourage providers to come forward and disclose conduct that threatens the federal health care programs, including Medicare and Medicaid," Brown wrote. "A provider's good-faith self-disclosure and continued cooperation go a long way in convincing the Office of Inspector General that less rigorous integrity requirements are needed to protect the federal programs."

Events contribute to controversy

Since the OIG's original report was published in June 1998, the following actions and events have received attention from the HHS and national media:

- Congress held two hearings addressing improving the effectiveness of IRBs.
- The National Bioethics Advisory Commission continued deliberations on what reforms should be undertaken.
- Shalala relocated the OPRR from the NIH to the Office of the Secretary and established an advisory committee to provide scientific and ethical guidance to OPRR.
- A participant died in a gene therapy study conducted at the University of Pennsylvania in September 1999, the first death directly linked to an experimental gene therapy procedure.
- A joint project between the FDA and NIH to enhance human subject protections resulted in a new government clinical trial Web site: www.clinicaltrials.gov.

The OIG reports that while there's been an increase in enforcement of requirements such as on-site investigations and suspension of funding at seven institutions, there's room for improvement. In fact, the report lists six areas where reforms have not been enacted. **(For a list of recommendations and actions taken, see p. 63.)** Here is a summary of the six areas and an explanation of the deficiencies:

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Current Status of FDA and NIH/OPRR Response to Recommendations

***Institutional Review Boards: A Time for Reform* (OEI-01-97-00193), June 1998**

Recommendation		Status
1. Recast Federal Requirements	**1a Eliminate or lessen some of the procedural requirements**	➤ FDA and OPRR issued more expedited review categories (11/98) ➤ OPRR/NCI proposed demonstration project using a central IRB to streamline processes
	1b Require IRBs undergo regular performance-based evaluations	➤ No action ➤ Private accreditation movement initiated
2. Strengthen Continuing Protections	**2a Require Data Safety Monitoring Boards (DSMBs) for certain trials**	➤ NIH reasserts policy on appropriate monitoring of its trials (5/98) ➤ No other action
	2b Require DSMBs to provide summary information to IRBs	➤ NIH requires its DSMBs to share summary info with IRBs (6/99) ➤ No other action
	2c Alert IRBs to corrective actions taken against investigators under their purview	➤ FDA now notifies IRBs and sponsors of actual and potential misconduct by clinical investigators
	2d Require sponsors and investigators to notify IRBs of any prior review	➤ No action
	2e Call for increased IRB awareness of on-site research practices	➤ No action
3. Enact Educational Requirements	**3a Require institutions to establish an education program for investigators in human-subject protections**	➤ NIH has launched a number of initiatives and OPRR has required the establishment of education programs as a result of investigations ➤ No action toward a requirement
	3b Require investigators provide a written attestation to uphold human-subject protections	➤ No action
	3c Require IRBs to educate their members about human-subject protections	➤ No action ➤ FDA and NIH/OPRR have required the establishment of educational programs as a result of investigations and are active in outreach
4. Help Insulate IRBs from Conflicts That Threaten Their Independence	**4a Require more extensive representation of nonscientific and noninstitutional members**	➤ No action
	4b Reinforce the importance of IRBs maintaining sufficient independence	➤ No action
	4c Prohibit equity owners from participating in the IRB review process	➤ No action
5. Recognize Workload Pressures	**5 Require that IRBs have the resources to adequately carry out their duties**	➤ No action
6. Re-engineer Federal Oversight Process	**6a Revamp NIH/OPRR assurance process**	➤ NIH has initiated a proposal to streamline the assurance process
	6b Revamp FDA on-site inspection process	➤ FDA has increased its on-site presence, but no other action
	6c Require IRBs register with the federal government	➤ FDA has set working group for registration process, but no action yet

Delineation of HHS Authority and Activity

Agency	Purview	Primary Body for Protections	Oversight Conducted
NIH/OPRR	research supported or otherwise subject to regulation by HHS	IRBs	assurance, inspections of IRBs
FDA	research conducted on products subject to FDA approval	IRBs	inspections of investigators, IRBs, and research sponsors

Source: Charts above and on p. 63 are from "Protecting Human Research Subjects: Status of Recommendations," Office of the Inspector General.

1. **Flexibility and accountability:** Minimal progress has been made in recasting federal IRB requirements so they grant IRBs greater flexibility and hold them more accountable for results. Too much IRB attention now focuses on review responsibilities of questionable protective value.

2. **Oversight and protections:** Minimal progress has been made in strengthening continuing protections for human subjects participating in research. Continuing IRB review of research after it initially has been reviewed is a low priority at many IRBs. IRBs know little of what actually occurs during the consent and research processes.

3. **Education:** No educational requirements have been enacted for investigators or IRB members. The most important continuing protection for human subjects is the presence of well-trained and sensitized investigators and IRB members.

4. **Conflicts of interest:** There has been no progress in insulating IRBs from conflicts that can compromise their mission in protecting human subjects. The increased commercialization of research and the growing importance of research revenues for institutions heighten the potential for conflicts of interest in clinical research.

5. **Workload:** Minimal progress has been made in moderating workload pressures of IRBs. IRBs are inundated with protocols and adverse event reports. With limited personnel and few resources, many IRBs are hard-pressed to give each review sufficient attention.

6. **Federal oversight:** Minimal progress has been made in re-engineering the federal oversight process. Federal oversight of IRBs is not equipped to respond effectively to the changing pressures and needs of the current system of protections.

The NIH cannot implement many of the recommendations, the OIG says, because of a 1991 policy known as the Common Rule. Core HHS regulations concerning IRBs and human subject protections were incorporated into a federal policy for HHS and 16 other federal agencies.

Changes to the rule must concur at all 17 agencies. The OIG agrees with the NIH's claims that changing its policy would require a lengthy complex process of obtaining consent from other agencies. The OIG concludes in its report the likely catalyst for a timely change in policy would come from legislative changes.

One health provider isn't waiting for legislative changes to improve protections for its

Group sets ethical framework for trials

A policy of ethical standards for hospitals involved in gene therapy clinical trials is now available.

The American Society of Gene Therapy (ASGT) in Milwaukee approved the policy, developed by its ethics committee to ensure the safety of patients in gene transfer studies. The policy also ensures researchers are free from financial conflicts of interest.

"This policy is a significant step forward in addressing the safety and interests of the many patients who volunteer in such trials. Patients should know that investigators have their best interest in mind and are practicing in an objective manner and are not in any way influenced by financial incentives," says ASGT president **Savio L.C. Woo**, PhD.

ASGT members have been notified of the policy. ■

research participants. The twist is that the provider is a government entity that was stripped of federal research funds for violating protections last year.

The Department of Veterans Affairs announced that starting this past May, the National Committee for Quality Assurance will implement an accreditation program for biomedical research at 150 VA medical centers nationwide. The $5.8 million contract will last five years.

Independent survey teams will conduct accreditation visits every three years at medical centers conducting human research. The teams will certify that the medical center is effectively managing research risk and identify improvements needed. ■

'Selling' clinical trials goes too far, ethicists say

Corporations hold strings on recruiting methods

Type the phrase "clinical trials" into any Internet search engine, and the responses leap out at you: CenterWatch Clinical Trials Listing Service, Clinical Research Studies Database, AIDS Clinical Trials Information Service — the list goes on.

Increasingly, people with life-threatening conditions do not have to rely on their physicians to inform them about available research studies of new drug regimens or procedures. They can research available studies on their own. In the latest example of this shift, the National Institutes of Health (NIH) and the U.S. Food and Drug Administration have launched their own public Web site, ClinicalTrials.gov, that allows people to search a database of all federally funded clinical trials.

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Although this has the potential to open access to the latest therapies to a wider range of people, some ethicists are concerned that such Web sites eventually may function more to recruit study subjects for trials than to inform the public.

"This creates a single outlet, endorsed by the highest authority in the research community. Unlike advertisements in the newspaper or on the radio, which people understand to be true commercials, ClinicalTrials.gov could give people the impression that the trials listed there are somehow endorsed or otherwise better, safer, or, in effect, given the government's seal of approval," states **Jeffrey Kahn**, PhD, MPH**,** director of the Center for Bioethics at the University of Minnesota in Minneapolis. Kahn is author of the "Ethics Matters" column for CNN.com.

Currently, ClinicalTrials.gov, which was created in response to a 1997 congressional law mandating better public information on clinical trials, has several confidentiality protections to guard against misrepresentation. There is no site registration and no requirement for personal identification. People who search the site are not contacted by sponsors of listed studies, although contact information for the studies is listed, and people can call for more information about a particular trial.

Kahn is more concerned about how studies are listed on ClinicalTrials.gov and other informational Web sites, and whether the public understands what clinical trials involve.

"[There should be] clear statements about how research projects get listed on the site, and that the listing carries no endorsement by the listing entity," he says. "There should also be a list of questions potential subjects should always ask about a prospective trial, [as well as] what privacy protections are in place if there are on-line mechanisms for asking for more information about a trial."

Many research studies already advertise in newspapers and on the radio. As long as researchers have adequate informed consent procedures in place before enrolling a subject, does advertising have a harmful effect?

Informed consent is only part of what determines whether a study is conducted in ethical ways, Kahn contends. "Recruitment of subjects is a separate issue, and we need to ask whether recruitment techniques or approaches undermine voluntariness by pressuring potential subjects, or as is more likely in a case like this [the Web site], over-promises benefits or offers undue enticement," he explains.

Actual advertising (not just listing) of research studies is already done in the conventional media, and such ads often pose ethical dilemmas for many institutional review boards (IRBs), explains **Gary Chiodo,** DMD, director of the Center for Bioethics in Health Care at Oregon Health Sciences University (OHSU) in Portland and chairman of the university's IRB.

"One of the things we see is advertisements that, rather than couch the approach as 'We are seeking research subjects for study,' it is, 'We are

seeking patients for treatment,'" he notes. "There is a very thick line between the investigational study-subject relationship and the doctor-patient relationship that I am not sure is drawn."

Also, advertisements often do not mention the presence of a control group or the chances that a subject participating in the trial will be placed in a group that will not receive the experimental drug or procedure, he adds.

"And one of the things that really drives me crazy is having one centralized phone number to call for more information and having initial screening performed over the telephone," Chiodo states. "When the person calls, the representative on the other end of the line asks them a number of very private, personal questions, and then gets their contact information."

The person calling is then told they will be contacted if they meet the inclusion criteria in the study, he says. "So this other person has all of this sensitive information on an individual — plus the person's name, telephone number, and address — for further use," Chiodo says.

Initial contact through telephone

For local clinical trials performed at OHSU, potential subjects call a phone number for information, receive a number, and schedule an appointment to come in for initial screening. If the patient is not selected, his or her information is destroyed.

For multicenter trials, which usually offer one centralized telephone number for information and initial screening, the OHSU IRB asks that sponsors either not ask particular questions and/or agree not to ask for identifying information from the person who undergoes the telephone screening. Instead they allow the caller to remain anonymous but call back to find out whether he or she has been accepted.

The OHSU IRB frequently rejects advertisements that do not meet its ethical criteria for informing the public about a study. Those criteria include informing the public of both the possible risks and benefits.

IRBs often face a difficult dilemma when reviewing large multicenter trials that are sponsored by private companies and pharmaceutical corporations, Chiodo says. "For local research studies seeking approval, if we have a problem with the ad, we say, 'This is not acceptable. Change this, change that.' The researchers make the changes, and it goes on from there. But in many cases with larger studies, the advertisements are done by the sponsor, and they don't want to change [them] for one IRB," he says.

In that situation, the IRB at the local center that has investigators wishing to participate in the study must decide not to allow the study to be conducted at the center or allow it to be conducted, but without advertisement.

"This puts the local center at a disadvantage because the other centers with the advertising are going to recruit more participants," he says.

However, the recruiting procedure for a research study should almost be seen as part of the informed consent process, Kahn and Chiodo say. "On the question of informed consent, advertising a clinical trial, either in the newspaper or on a government-sponsored Web site, can create misimpressions or misunderstandings that no amount of informing will undo," Kahn argues. "So, do such potential subjects give adequate informed consent? It's a question worth asking."

As a result of increased information on the Internet and increased advertising by privately sponsored trials, physicians will face even more pressure from patients who learn about studies themselves.

"The first thing physicians should do [when a patient asks about an unfamiliar clinical study] is research the trial for themselves, then counsel patients accordingly," says Kahn. "This is similar to other information available on the Web to patients, which has created a new task for physicians — reviewing the information brought in by their patients and working to separate wheat from chaff." ■

SOURCES

- **Jeffrey Kahn**, PhD, MPH, Director, Center for Bioethics, University of Minnesota, N504 Boynton, 410 Church St. S.E., Minneapolis, MN 55455-0346. Also, see Kahn's "Ethics Matters" column, Shopping for clinical trials: New Web site raises ethical issues. March 6, 2000. http://www.cnn.com/2000/HEALTH/03/06/ethics.matters/index.html.
- **Gary Chiodo**, DMD, Director, Center for Bioethics in Health Care, Oregon Health Sciences University, 3181 S.W. Sam Jackson Park Road UHN-86, Portland, OR 97201-3098.
- **Oregon Health Sciences University.** "Research Compliance and Assurance Guidelines on Advertising for Study Subjects" is available on the Web at http://www.ohsu.edu/ra/ad.html.

What to do when patients refuse food and water

Is refusal an alternative to assisted suicide?

Can physicians ethically aid terminally ill patients who seek to hasten their death by refusing food and water? Or is such aid a violation of their obligation to act in the patient's best interests and, in fact, a form of physician-assisted suicide — a practice banned in all but one of the 50 states.

Two authors from the American College of Physicians-American Society of Internal Medicine's (ACP-ASIM) end-of-life-care consensus panel argue that the use of terminal sedation and permitting voluntary refusal of food and hydration are both ethically sound "last resorts" that allow patients to exercise control over their end-of-life care, without requiring physicians to take part in an act that many of them find unacceptable.

"We felt, as a panel, that it was important to make a distinction between these extraordinary measures of palliative care that are appropriately used when the rest of our palliative care efforts and protocols have not been effective in alleviating the patient's suffering, and physician-assisted suicide," says **Ira R. Byock**, MD, a co-author of ACP-ASIM's recent position paper, "Responding to Intractable Terminal Suffering: The Role of Terminal Sedation and Voluntary Refusal of Food and Fluids."[1] Byock is research professor of philosophy at the University of Montana, director of the university's palliative care service, and author of the book, *Dying Well*.

"Our courts have held that people have a right to refuse any treatment that we offer," he continues. "We as clinicians have a responsibility to serve these patients in a manner consistent with their desire and our clinical and ethical standards."

The position paper, written with **Timothy E. Quill**, MD, of The Genesee Hospital in Rochester, NY, involves a case study of a patient with an incurable brain tumor who asks to only receive treatment directed at relieving symptoms, not treatment to reduce the tumor size or prolong his life. He was prescribed medication directed at relieving pain and preventing seizures.

After developing severe right-sided weakness, seizures, and mental confusion, the patient, known as "BG," began to continually express a desire to hasten his death. The authors report the patient feared becoming a burden to his family and the developing loss of mental capacity more than uncontrolled pain. He decided to refuse all food and fluids and asked that his physicians support his decision.

Although BG's physician had moral and legal reservations about hastening his death, the physician wanted to be responsive to BG's wishes and needs.

In response to the patient's decision to refuse food and water, the physician discussed with him the symptoms he would experience and the methods by which they would be treated. During the last stages of illness, the patient was given morphine to control pain and ice chips to keep his mouth moist and alleviate pain, but no other food or water.

After nine days, the patient could be roused but spent most of his time sleeping. After the 10th day, the patient became confused, agitated, distressed, and incapable of informed consent. However, he had previously given permission to be sedated if this situation arose, the paper's authors state.

The physician started the patient on a subcutaneous infusion of midazolam, increasing the amount gradually to achieve sedation. The plan of care was to use whatever dose was necessary to control the seizures and agitation. After six hours, BG appeared to be sleeping comfortably. He died at home, 24 hours after terminal sedation was initiated.

More education needed

The physician's actions in the above case are consistent with the use of standard palliative care measures, although both terminal sedation (the use of high doses of sedatives to relieve extremes of physical distress) and refusal of food and hydration are considered beyond the palliative care procedures normally required, Byock explains.

Physicians need more education about the process of terminal sedation and supporting the voluntary refusal of food and hydration in order to offer the best range of options to patients who are facing unrelieved suffering after all other palliative measures have failed, he says.

"The panel believes that the controversial nature of using sedation in cases of intractable suffering and supporting patients who deliberately refuse food and fluids is out of confusion

about what these acts involve," he explains.

Terminal sedation, in fact, is not solely used in end-of-life care. Frequently, patients in trauma, burn, post-surgical, and intensive care units receive this type of sedation temporarily. However, because those patients are expected to recover, careful attention is paid to maintaining adequate ventilation, hydration, and nutrition.

In an end-of-life scenario, in which the patient has no substantial prospect of recovery, the attention to artificial nutrition, hydration, antibiotics, and other life-prolonging interventions is not the same. The purpose of the sedation, Byock notes, is to render the patient unconscious to relieve suffering, not to end the patient's life.

No food or drink more controversial

Voluntary cessation of eating and drinking is the more controversial topic. When patients choose to stop taking food or water so they will not prolong their lives — and that choice can be distinguished from anorexia and loss of thirst common in the end-stage of a terminal illness — many physicians consider it to be suicide, which they cannot participate in. However, some argue that this decision is part of the patient's right to refuse life-sustaining therapy.

The physician's participation in this act is not technically necessary, says Byock. A patient can choose to refuse food and water without the physician's knowledge, but without the physician's support, a patient who feels he or she is ready for death must go through an excruciating ordeal.

The panel wants to provide guidance for physicians who may face that situation, so patients will not be abandoned and physicians will not be pushed into compromising their ethical standards.

"I think it is important to note that Tim [Quill] and I are on opposite sides of the physician-assisted suicide debate. He supports it, and I am ardently opposed to it," notes Byock. "However, we were both able to come together and attempt to provide some leadership in this area, because we both agree on what constitutes excellence in palliative care for patients suffering at the end of life."

Byock is careful to emphasize that the instances in which a physician would be confronted with the need for these "extraordinary" measures are rare, and careful precautions to protect the patient are necessary.

First, say Byock and Quill, proper informed consent is the cornerstone of beginning the process of considering these procedures. Also, clinicians should be sure to carefully screen terminally ill patients for clinical depression because the condition is extremely prevalent and difficult to diagnose.

Second, the patient must be experiencing severe suffering that cannot be relieved by other available means, the authors state. "If either option is being considered by clinicians, patients, or families when the suffering person is not imminently dying, assessments should always include second opinions from mental health, ethics, and palliative care specialists."

It is also inappropriate to discuss those "last-resort" options with all patients who have a late-stage terminal illness. "Information about terminal sedation and cessation of eating and drinking becomes important when patients express fears about dying badly or explicitly request a hastened death because of unacceptable suffering," the authors state.

Terminal sedation should be considered only in the most difficult cases," Byock emphasizes. "In some ways, the amount of discussion and struggle that the health care team goes through in making this decision indicates that they are on the right track. It is never a decision that should be easy."

Even though the consensus panel agrees there is a place for such measures, some clinicians and ethicists oppose any physician role in hastening a patient's death.

"Those of us who have a principle-based ethic feel that this is demeaning the life of the patient, devaluing the patient, and it is also devaluing the importance of the physician's role in caring for the patient," states **Gregory Hamilton,** MD, a Portland, OR, psychiatrist and president of Physicians for Compassionate Care, an advocacy group opposed to the legalization of physician-assisted suicide.

The only appropriate use of terminal sedation would be to "interrupt the pain cycle" with the intention of waking the patient at a later time, he says.

Even if the sedation would allow the patient to continue with a previous intention to refuse food and hydration, it would require the doctors to perform outside their role, he says. "If you are doing it with the intention of dehydrating them to death it is just a form of slow euthanasia. It should not be allowed. It doesn't give the patient

SOURCES

- **Ira R. Byock**, Palliative Care Service, University of Montana, 341 University Ave., Missoula, MT 59801.
- **Gregory Hamilton**, Physicians for Compassionate Care, P.O. Box 6042, Portland, OR 97228-6042. Telephone: (503) 533-8154.

control, it gives the doctor control. It relieves the doctor's dilemma, and we should not allow it."

Patients who ask physicians to help them end their lives are putting the physicians in an untenable position, he contends.

Byock and Quill acknowledge that many ethicists and physicians see any supportive effort to allow a patient to hasten death as aiding a suicide and find such action unacceptable. Physicians should not feel pressured to consider options they do not consider within their scope of care.

"Physicians who oppose their patient's decision from the outset must decide whether they can provide all forms of indicated palliation," the authors state. "If the physician feels morally unable to do so, transfer of care to another provider should be considered."

Reference

1. Quill TE, Byock IR. Responding to intractable terminal suffering: The role of terminal sedation and voluntary refusal of food and fluids. *Ann Intern Med* 2000; 132:408-414. ■

Study: Physicians who listen make a difference

People who care for terminally ill patients say that they feel less depressed and better able to cope with their lives when they can talk to a doctor who simply listens to their problems and concerns about their loved ones, according to a new study.

Published in the March 21 issue of the *Annals of Internal Medicine,* the study is the first to show that empathetic doctors can help reduce the enormous emotional and psychological burdens shouldered by millions of caregivers — the spouses, children, and siblings who provide an array of services for people dying of illnesses such as emphysema, cancer, Alzheimer's disease, liver disease, and kidney failure.

The study documents the high economic toll that caring for terminally ill patients can take on caregivers, adding to their emotional and physical stress. For the first time, it suggests an effective method for alleviating some of these burdens.

Physicians of terminally ill patients who show compassion and empathy to caregivers can make an important difference in their mental health, the study asserts. Researchers interviewed 893 caregivers of 988 patients. Among the caregivers, 35% said the patients they cared for had high levels of need, including transportation, nursing care, homemaking, and personal care.

The data suggested that caregivers for dying patients with high care needs whose doctors listened to them were less likely than other caregivers to be depressed (28%), compared with those whose doctors did not listen (42%). They also were less likely to report that their caregiving responsibilities interfered with their personal lives (32% vs. 48%).

Nearly half of terminally ill patients with high care needs reported that medical care costs created economic hardships for their families, according to **Ezekiel J. Emanuel**, MD, chair of the National Institutes of Health's department of clinical bioethics at the Warren G. Magnuson Clinical Center and lead author of the study. It is not unusual, Emanuel wrote, for family members to have to sell some of their assets, take out a loan or mortgage, or obtain another job to pay for a dying relative's medical care.

For the study, terminally ill adults and their primary caregivers were interviewed between March 1996 and March 1997. Patients and caregivers in the study came from six randomly selected cities — Birmingham, AL; Brooklyn, NY; Mesa County, CO; St. Louis; Tucson, AZ; and Worcester, MA. Patients were located by referral from their physicians.

The most common illnesses among them were cancer, heart disease, and chronic lung disease. Patients with HIV / AIDS were ineligible for the study. More than 90% of patients were living at home. However, patients who were hospitalized or living in a nursing home or a residential hospice were included in the study.

"These families need help, and doctors can do a lot to provide it," Emanuel wrote, "This study indicates that doctors have a pivotal role to play by listening better to caregivers and providing them with support at a stressful time in their lives."

The study is one in a series of eight papers in the Commonwealth-Cummings Project on the End of Life, an effort to expand the nation's understanding of the dying experience and finding ways to improve it.

Karen Davis, president of the Commonwealth Fund in New York City, says the study also carries important implications for insurance coverage of terminal illness. "The findings of high out-of-pocket costs for medical bills and medications to care for dying patients point to serious gaps in health plan policies," she says. "We need to look at the adequacy of current insurance coverage in the event of serious illness."

Listening has a direct bearing

Listening is challenging for many doctors, but it has a direct bearing on how patients feel about the quality of their care, the authors wrote. Although doctors are starting to become more aware of patients' end-of-life needs, they might not be as cognizant of the needs of caregivers, according to co-author **Linda L. Emanuel**, MD, PhD, vice president of the Institute of Ethics at the American Medical Association.

"Caregivers are critical supports for terminally ill patients," she wrote. "But they are also subject to great stress. Heavy caregiving responsibilities often result in less time with families and friends, conflicts at work, and financial insecurity. Many physicians are not aware of how much they can accomplish by giving family members and other caregivers the opportunity to air their thoughts and feelings about the challenges they face. It can be a huge relief for them, allowing them to pursue their responsibilities with renewed energy. And, in the end, patients benefit when their caregivers feel less stressed."

The researchers said that physicians need more training and education in end-of-life-care, including listening. One effort to provide physicians with the basic knowledge and skills to care for dying patients is an initiative at the AMA's Institute for Ethics called Education for Physicians on End-of-Life Care (EPEC). Linda Emanuel heads the EPEC Project.

"Family caregivers of terminally ill patients are shouldering a huge emotional and financial burdens," says **Charles Halpern**, president of the Nathan Cummings Foundation in New York City. "This study provides needed direction for supporting these people. We have a responsibility to care for those who care." ■

CME questions

1. Which event(s) described below contributed to the decision to move the Office for Protection from Research Risks from the National Institutes of Health to the Department of Health and Human Services?

A. Congress held hearings on improving the effectiveness of institutional review boards.
B. The National Bioethics Advisory Commission deliberated over what reforms should be taken.
C. A gene therapy study participant died in a clinical trial.
D. All of the above.

2. According to **Jeffrey Kahn**, director of the center for Bioethics at the University of Minneapolis, the new Web site established by the government on clinical trials might:

A. Encourage participation.
B. Lead people to believe the listed trials are endorsed or safer.
C. Create longer delays in enrolling new patients.
D. All of the above.

3. According to **Gary Chiodo**, director of the Center for Bioethics in Health Care at Oregon Health Sciences University in Portland, advertising clinical trials to the public fails to:

A. Mention the presence of a control group.
B. Explain that participants may not receive the experimental drug or procedure.
C. Continue the physician-patient relationship.
D. All of the above.

4. **Ira Byock**, director of the palliative care service at the University of Montana, says physicians need what in terms of terminal sedation and refusal of food and hydration?

A. Education about the process.
B. To explain the options to patients.
C. To offer those options after all other palliative measures have failed.
D. All of the above.

Boards urged to improve pain management

Authorities key in bringing about change

The Compassion in Dying Federation has launched a national effort to enlist medical licensing boards in its battle to improve pain management.

According to the organization, which strives improve end-of-life care, too many people suffer unnecessary pain, and medical treatment of pain is often deplorable. Medical licensing authorities are key to achieving necessary changes.

The Portland, OR-based organization wrote a letter to the Federation of State Medical Boards (FSMB) and each state's medical board. That letter follows a 1998 letter to the same recipients detailing significant inadequacies in pain management across the nation and concrete steps FSMB and state boards should take to improve pain management.

"Too often, medical boards close their eyes and fail to make physicians accountable for woeful undertreatment of their patients' pain," says **Kathryn Tucker**, director of legal affairs for Compassion in Dying Federation.

Formal complaints filed

In 1998, medical licensing boards responded by saying they never hear of cases in which patients are inadequately treated for pain in their jurisdictions. In response, Compassion in Dying officials have helped patients and families prepare formal complaints of inadequate pain care and present them, along with expert opinions, to state medical boards.

In March, the organization announced its second complaint presented to the Medical Board of California (MBC). That complaint involves the treatment of a 14-year-old boy hospitalized with excruciating headache pain and treated with placebos instead of real pain medication. The family recently filed complaints with the MBC and the California Board of Registered Nursing.

Compassion in Dying Federation's first complaint to the MBC — involving 85-year-old cancer patient William Bergman, whose terminal cancer pain went untreated — failed to draw a response from the MBC. The case received national attention when it was featured on NBC's news magazine, "Dateline."

Bergman's family filed suit in California state court asserting that the lack of pain treatment constituted elder abuse. On a 10-point scale, Bergman was complaining of pain ranging from 7 to 10 while in the hospital. Another physician later prescribed pain medication, and the patient was discharged to die at home. He died the next day.

The trial was expected to begin in March but has been delayed until November.

"These cases are typical of many we review through our pain management and advocacy efforts," the letter states. "We know there are thousands we never see. We are working hard to increase the tempo of response to the problems reflected in the stories above." ■

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NEWS BRIEFS

Patient guide available for infertility, multiple births

Booklet reviews risks of procedure

Patients undergoing specialized infertility treatment now have a new patient guide published by RESOLVE, the National Infertility Association.

The guide, *Multiple Gestation Pregnancy and Multiple Birth*, provides patients with a review of risks associated with multiple births and information on reducing the risks for people undergoing specialized infertility treatment. The publication is supported by an educational grant from Serono Laboratories, a Norwell, MA-based manufacturer of pharmaceutical products for the treatment of infertility.

RESOLVE is a national nonprofit consumer organization providing education, advocacy, and support to those struggling with infertility. The organization encourages patients seeking infertility therapy with the use of drugs to enhance ovulation to seek care from certified reproductive endocrinologists.

Finding the right doctor is important

Before beginning treatment, patients and physicians should discuss the risks of multiple birth, how to minimize those risks, and the options available should a multiple gestation occur.

"RESOLVE is working to provide education and support to people needing infertility treatment, including referral to certified reproductive specialists. Finding the right doctor and asking the right questions are vitally important," according to **Diane Aronson**, executive director of RESOLVE.

[Editor's note: Multiple Gestation Pregnancy and Multiple Birth *is available on the RESOLVE Web site at www.resolve.org or by telephone at (617) 623-0744.]* ▼

Hawaii legislature passes medical marijuana bill

Seriously ill patients who use marijuana medically will be protected from local and state criminal prosecution in Hawaii.

The state Senate approved SB 862 in late April. A version of the bill with amendments was approved by the House earlier in the month. Governor Ben Cayetano (D) says he will sign the bill into law. The legislation will allow for the medical use of marijuana with a physician's recommendation for patients who suffer from medical conditions such as cancer, glaucoma, HIV / AIDS, multiple sclerosis, or other conditions approved by the department of health. Patients and their primary caregivers will be required to register annually with the Hawaii Department of Public Safety. Registered patients will be allowed possession of no more than three mature marijuana plants, four immature plants, and one ounce of smokeable marijuana per each mature plant. ■