AMERICAN HEALTH CONSULTANTS®

Medical Ethics Advisor™

For 16 years, your practical guide to ethics decision making

March 2000 • Vol. 16, No. 3 • Pages 25-36

IN THIS ISSUE

In This Issue **continued on next page**

NOW AVAILABLE ON-LINE! www.ahcpub.com/online.html

American Health Consultants® is A Medical Economics Company

End-of-life care makes inroads in adult patients, so why do children suffer?

Study reveals disparity in pediatric palliative care

Pediatric oncology teams should take a closer look at the long tradition of protocol-based management and put greater stake in improving childrens' quality of life during end-of-life care.

That's the recommendation from a two-year study of children who died of cancer between 1990 and 1997 and received care at Boston's Children's Hospital, Dana-Farber Cancer Institute, or both.[1] Parents of 103 children who died were interviewed during 1997 and 1998, and additional data were obtained from medical records review.

"This is one of the first studies to highlight the fact that palliative care is less adequate than needed in children with cancer. Without asking, we may have assumed that care was as best as could be expected, given the circumstances and given that we made such great strides in curing pediatric cancers," says **Joanne Wolfe**, MD, lead author of the study. Wolfe is an instructor in pediatric oncology at Harvard University, the Dana-Farber Cancer Institute, and Children's Hospital.

Researchers found that children who die of cancer receive aggressive treatment at the end of life, but many experience pain in the last month of life because many caregivers focus on treating the disease rather than the pain. Cancer is the leading cause of non-accidental death in childhood,[2] but little research has been conducted into the overall experience of children in end-of-life care or into their symptoms, the authors point out.

Parents surveyed reported that 89% of the children

In This Issue **continued from page 25**

Special Report:
Ethics and Patient Confidentiality

In Brief

COMING IN FUTURE ISSUES

■ **An in-depth look at the ethics of teaching hospitals:** How far is too far when it comes to teaching?

■ **Gene therapy in the new millennium:** What your ethics committee needs to know

■ **Research at what cost?** Many community hospitals cannot offer emergency angioplasty, but is that ethical for the patient?

■ **Eagerly awaited:** An analysis of the Institute of Medicine's anticipated report on nonheart-beating organ donation policies

■ **Keeping a secret:** The Centers for Disease Control and Prevention strong-arms states that protect the privacy of individuals with HIV

had suffered "a great deal" or "a lot" at the end of life from at least one symptom. More than half (57%) reported suffering significantly from at least three symptoms. The most common complaints parents reported were fatigue, pain, dyspnea, and poor appetite. Of those treated for pain, only 27% reported feeling better following treatment.

The preliminary results prompted Wolfe and colleagues at both Children's Hospital and Dana-Farber to develop a multidisciplinary palliative care program, which she recommends for ethics committees looking to revise existing pediatric programs. **(For more on the multidisciplinary palliative care program, see story, p. 27.)**

The results weren't surprising for palliative care advocates. **Suzanne Mintz**, co-founder and president of the National Family Caregivers Association in Kensington, MD, says other studies point to the conclusion that many people die in pain.

Caring for children is a different matter

Caring for children with cancer at the end of life poses different problems than caring for adults, Wolfe and her team of researchers point out in the article. First, the providers' goal of treatment is to achieve a cure. That often leads to the physicians' inability to change their focus, even when there is little hope of a cure, they write. In fact, considerations such as toxicity of therapy, the quality of life, and growth and development usually are secondary to that goal.

A second problem is that parents and patients usually have little or no time to participate in decisions about end-of-life care or address emotions, such as anticipatory grieving, because they are reluctant to abandon treatment.

Additionally, more training and education on the part of caregivers is needed in pain management and spiritual care to improve palliative care among children. Physicians should take an active role in the child's care, even if that involves frank discussions of death with family members.

"We did find that when the parent reported that the primary oncologist remained actively involved in the child's end-of-life care, the child experienced less suffering from pain. This suggests that one can effectively manage symptoms when we pay close attention to them and integrate palliative care more comprehensively into the treatment plan," explains Wolfe.

The ethics committee can play an integral role in educating not only caregivers and parents on palliative care with children. Wolfe suggests

SOURCES

- **Dana-Farber Cancer Institute**, 44 Binney St., Boston, MA 02115. Telephone: (617) 632-3000. World Wide Web: http://www.dfci.harvard.edu.
- **National Family Caregivers Association**, 10400 Connecticut Ave., # 500, Kensington, MD 20895-3944. Telephone toll-free: (800) 896 3650. Fax: (301) 942 2302. E-mail: info@nfcacares.org. World Wide Web: http://www.nfcacares.org.

ethics committees help in communicating with parents about decision making for end-of-life care issues. "Ethics committee members are trained to elicit and respect the values of patients, families, and parents. This is critical to developing an appropriate personalized, palliative care plan," says Wolfe.

References

1. Wolfe J, Grier HE, Klar N, et al. Symptoms and suffering at the end of life in children with cancer. *N Engl J Med* 2000; 342:326-333.
2. Landis SH, Murray T, Bolden S, Wingo PA. Cancer statistics 1999. *CA Cancer J Clin* 1999; 49:8-31. ■

Study prompts gains in pediatric palliative care

Multidisciplinary approach boosts quality of life

Early results from a two-year study on end-of-life care in children with cancer prompted improvement efforts in palliative care at Children's Hospital and Dana-Farber Cancer Institute, both in Boston.

"Based on early results, we developed a palliative care service called PACT, which stands for pediatric advanced care team. It is a multidisciplinary consult service available to children cared for at Dana-Farber and Children's Hospital," says **Joanne Wolfe**, MD, an instructor in pediatric oncology at Harvard University and at the Dana-Farber Cancer Institute and Children's Hospital. Wolfe led research on a two-year study of palliative care for children with cancer; the results were published in the Feb. 3, 2000, issue of *The New England Journal of Medicine*.

The PACT team, implemented in 1997, is a multidisciplinary group consisting of:

CME questions

1. According to **Joanne Wolfe**, MD, lead author of a study and instructor in pediatric oncology at Harvard University, the results point to the need(s) for:
A. Better transition between hospice and intensive care unit care
B. Improvement in quality of life during end-of-life care
C. Legislative changes allowing for the use of stronger medications
D. All of the above

2. The most common complaint(s) parents cited in the study "Symptoms and Suffering at the End of Life in Children with Cancer" were:
A. Fatigue
B. Pain
C. Poor appetite
D. All of the above

3. One of the most disturbing findings comparing caucasian and African-American women with breast cancer, according to **James J. Dignam,** PhD, research assistant professor at the University of Pittsburgh's Department of Biostatistics, is:
A. Treatment was delayed or postponed
B. Treatment was not necessarily optimum
C. Patients were told the cancer was in remission
D. All of the above

4. The problem with ethnic bias, according to **Barbara Ross-Lee,** DO, dean of The Ohio University College of Osteopathic Medicine, is that:
A. All minority Americans have problems getting equal health care treatment
B. Physician attitudes can never be changed
C. Hospital accreditation is jeopardized
D. All of the above

- physicians;
- nurses;
- psychosocial clinicians;
- ethicists;
- chaplains;
- pain team consultants.

"We provide consults, educational efforts, and are developing interventions to improve the quality of life in children with advanced disease," notes Wolfe.

Patients can be referred to PACT at any time. Early involvement with children is encouraged, she says. Providers are asked, "Would you be surprised if the child died in the next year?" If their answer is "no," the child is eligible for PACT.

The team also developed a medication worksheet to guide clinicians on recommending medications that would help patients at home should their conditions change. Generally, the same PACT members follow the patient in both inpatient and outpatient settings.

Having an ethicist on the team proves invaluable, adds Wolfe. "Our ethicist has been critical in developing a comprehensive palliative care plan during [ethics] consults. He has been helpful in educating the PACT about the ethics of end-of-life decision making," she says. Decisions may be needed, for example, regarding withholding fluids and nutrition and determining resuscitation status.

A recent addition to the program is a patient diary, which is still being evaluated in terms of effectiveness. The diary, which the patient shares with PACT members, is designed to improve physician-patient communication around symptoms and quality of life. "For the individual children and families we have served so far, we have seen wonderful improvements in the child's experience," Wolfe says. ■

Minorities need better access to breast screening

Ensuring fair treatments is ethical responsibility

Health care institutions need to do more to ensure minority patients receive equal access to breast cancer screening and aggressive therapies, according to information collected by a researcher at the University of Pittsburgh Graduate School of Public Health.

The good news is that the ethics committee can take a leading role in ensuring fairness in treatments and procedures among all patients in the hospital.

According to his recent analysis of several national research studies, black and white women experience similar outcomes when they are diagnosed at the same stage of disease and given similar treatment. Nationwide, however, mortality rates for black women meet or exceed those of white women, even though the incidence of breast cancer is lower among African-Americans.

"I did an overview article, combining a lot of research on this topic," explains **James J. Dignam,** PhD, research assistant professor at the school's department of biostatistics. Dignam is author of a study published in the January issue of *CA: A Cancer Journal for Clinicians*.[1] "It seemed that [in] the studies that take into account early detection, similar stage of diagnosis, and then treatment for disease stage — when those factors are comparable — the outcomes are more similar."

The findings indicate that the disparity in outcomes is largely due to environmental and social factors rather than physiological differences in disease progression among the two groups.

Although some of the studies reviewed indicated differences in tumor size, tumor resistance to therapy, and age at diagnosis (which may indicate a small propensity to poorer prognosis for black women), those factors were not enough to justify the significant disparity in outcomes, Dignam adds.

Differences in receiving appropriate therapy

Most disturbing among the findings were indications that black and elderly women at some institutions were less likely to receive diagnostic and therapeutic options in accordance with nationally accepted guidelines for breast cancer treatment. "With a lot of studies, what we saw was that the treatment that was given at a particular stage was not necessarily the optimum," he says.

For example, when studies compared women with the same stage of disease, black women more often showed characteristics associated with poorer prognosis, which would call for more aggressive therapies, such as chemotherapy in addition to or instead of tamoxifen therapy. But, many of the studies reviewed showed that black women were not undergoing those therapies.

In addition, many of the studies indicated that

black women were much more likely to receive total mastectomy rather than lumpectomy with radiation therapy in cases where either procedure would be appropriate.

Dignam attributes that to a knowledge gap at certain institutions of the latest evidence-based recommendations for treating those conditions.

"The National Institutes of Health [NIH] frequently convenes consensus panels of experts, and sometimes experts from other areas do the same," he says. "They form guidelines on when certain diagnostic tests should be ordered and — based on the result — which treatments are indicated. Because we are at an institution [University of Pittsburgh] that performs clinical research, we are aware of these recommendations when they are being made. But we tend to forget how long it can take for that information to get out and become part of the common practice."

Dignam also attributes the disparity to economic factors. More black women may seek treatment at financially strained urban hospitals with fewer resources available for diagnostic testing and early detection screening. "If the early diagnosis isn't there, then often the other treatment options are not going to be possible," he adds.

Additionally, there's the issue of insurance. Patients with inadequate or no insurance may be given treatment options that are less expensive.

The problem isn't limited to women with breast cancer, experts say. Minority Americans have problems getting equal treatment from the health care system across the board, not just for breast cancer, and the reasons are complex, advises **Barbara Ross-Lee,** DO, dean of The Ohio University College of Osteopathic Medicine and the first African-American woman to head a U.S. medical school.

"There is an institutional bias against minorities in the system, which is compounded by access issues," says Lee. "One of the largest barriers is poverty, then whether the patients are uninsured or underinsured. But it is not that simple to think that changing poverty, specifically, would solve everything. There are other social and cultural factors as well."

For example, a Department of Veterans Affairs retrospective review of cardiac patients[2] found that the only significant difference in whether some patients received catheterization or revascularization procedures while others did not was the patient's race, she continues.

To counter ethnic bias, hospitals need to be aware that the cultural and social biases of their clinicians will be reflected in the overall care their patients receive, says Ross-Lee. Ethics committees play a crucial role in ensuring policies are developed to address the potential for discrimination.

Compounding that problem are issues related to minorities' trust of institutional systems such as hospitals, she adds. "Often, minorities delay and do not seek treatment for a long time. There is a historical culture in the minority community that avoids use of the health care system. Because they tend to come in isolated from the large institutional system . . . there has never been any effort to build their trust."

In many of the trials Dignam studied, black women were more likely to be diagnosed with a more advanced stage of breast cancer, indicating they may have waited longer before seeking treatment, he says. That can have the most significant impact on the patient's survival.

"The stage of the primary breast cancer at diagnosis remains the foremost determinant of ultimate outcome," he writes in the research paper. "The benefit obtained from effective treatments is modest compared with the predictive effect that disease stage has on prognosis."

What hospitals should be doing

Hospitals first should strive to ensure they are following the latest treatment recommendations from the NIH and other consensus panels, says Dignam. Standard treatment guidelines will reduce the possibility of patients with the same disease characteristics receiving unequal treatment. Hospitals also must communicate the need for early diagnosis and preventive screening to all patients more effectively, he adds.

Those changes are not likely, however, until health systems are held accountable for the health of their communities at large, Ross-Lee says.

"In my opinion, we need to start looking at ways to hold institutions and providers accountable for overall health," she says. "Right now, we hold them accountable through our legal system for errors related to disease, but we need to also hold them accountable for health status. If you are in a community, by virtue of the fact that you are the health system in that community, the health status of that community is your responsibility."

For example, hospitals that discover they are diagnosing a number of black women with late-stage breast cancer should feel it is their responsibility to facilitate preventive screening and breast cancer awareness in that community, Ross-Lee

SOURCES

- **James J. Dignam**, University of Pittsburgh, Graduate School of Public Health, Department of Biostatistics, 403 Professional Building/GSPH, Pittsburgh, PA 15261.
- **Barbara Ross-Lee**, DO, The Ohio University, College of Osteopathic Medicine. Contact: Carl Denbow, Director of Communications, OU-COM 330 TEB, The Ridges, Athens, OH 45701.

says. "We need to put that level of accountability for health into the health system."

Both Dignam and Ross-Lee say minorities also are underrepresented in clinical research, and recruiting more minority participation is needed to help discover the reasons for the disparity in health outcomes and determine the remedies.

"We don't get the recruitment we would like, even in our trials," Dignam says. "We have a percentage of minority participation that is relative to their presence in the population, but the overall studies are not large enough that we have a significant number of African-American, Asian, and other minorities represented."

Research only means to treat

The numbers of minority participants are not high enough to determine the impact of different treatments in those specific populations, Ross-Lee agrees. However, she expresses concern that some medical policy-makers see more minority participation in research as a direct means of providing at-risk populations with access to new and/or costly treatments.

"There is an ethical question for me in that it seems that some people are saying that the only way women can achieve the appropriate treatment, or the full range of options of treatment, is by engaging in research or by becoming a research subject," she says. "It is very scary. I do hear people propose that the way to improve the access of minorities to care is that they should go into research projects.

"At the same time, you hate to oppose this when you know that there are women out there dying because they don't have all of the options or the cutting-edge treatments, but I think that is our default position. If we did the job we are supposed to do [in providing equal access to screening and treatment], then this issue would have never come up."

References

1. Dignam, JJ. Differences in breast cancer prognosis among African-American and Caucasian women. *CA Cancer J Clin* 2000; 50:50-64.
2. Peterson ED, Wright SM, Daley J, et al. Racial variation in cardiac procedure use and survival following acute myocardial infarction in the Department of Veterans Affairs. *JAMA* 1994; 271:1,175-1,180.

Additional reading

Kahn KL, Pearson ML, Harrison ER, et al. Health care for black and poor hospitalized Medicare patients. *JAMA* 1994; 271:1,169-1,174. ■

Medical record portability may erode patients' rights

Some pending legislation limits patients' choices

As the deadline nears for government adoption of regulations that will protect the confidentiality of patient medical information, some experts fear that the rush to make health information accessible will erode patients' rights to privacy and leave ethics committees making difficult decisions for hospitals.

"We are very concerned that some of the bills on Capitol Hill and even the President's privacy regulations eliminate the choice and control citizens now have over their medical information," says **James Pyles**, a privacy expert and health care attorney who lobbies Congress on behalf of the Chicago-based American Psychoanalytic Association. "It is ironic that the new regulations are designed to increase public control, when, in fact, they decrease or eliminate it in most cases."

Special Report: Ethics and Patient Confidentiality

The Health Insurance Portability and Accountability Act of 1996 required Congress to pass regulations protecting the confidentiality of individually identifiable patient medical information by Aug. 21, 1999. In the event Congress failed to do so, the Department of Health and Human Services (HHS) would be required to implement its own confidentiality regulations by Feb. 21, 2000.

Although four separate legislative measures were introduced last year, none passed, and HHS Secretary Donna Shalala proposed departmental regulations on Oct. 29, 1999.

As this issue of *Medical Ethics Advisor* went to press, HHS announced it was delaying implementation of the regulations due to an overwhelming number of comments on the proposed rule. The comment period was extended, and a date for final implementation of the rule has not been set.

The main sticking point for Pyles is that the proposed regulations do not specifically require obtaining the patient's consent for releasing identifiable medical information.

"As the regulations are currently written, the patient would not have the choice to not give out the information," he says. "and they don't require any record to be kept of the disclosure. So the patient would not only not know when and where the information went out, they would have no way of finding out."

Although the regulations state that the patient's right to privacy should not be violated and that agencies and people who obtain individually identifiable information through "false pretenses" should be subject to punishment, the regulations do not provide for enforcement of those protections and, essentially, remove the individual patient's ability to protect himself, says Pyles.

"The rules state the individually identifiable information can be given out if the purpose is for one of three things: medical treatment, payment, or for health care operations. There is no requirement that the patient consent," Pyles explains. "The terms are so broad that almost any organization could make an argument to obtain that information, and the patient would not only have no power to keep the information private, he or she would not even be informed that the disclosure was made."

Although the regulations were designed with the intent of facilitating the sharing of medical information among providers and throughout the health care system, the end result will be a massive violation of patient-provider trust, says Pyles.

Once identifiable patient information is disclosed to one source, it can be disclosed again and again without the patient's consent or even knowledge, notes Pyles.

"I don't think this proposal was thoroughly thought out," he says. "If the public cannot trust that their private medical information can be kept confidential, then they will decide to seek treatment underground, outside the system."

The Chicago-based American Health Information Management Association (AHIMA), a professional organization representing 40,000 health information management professionals, submitted comments on the proposed rule Jan. 20. In general, AHIMA supports the HHS effort to form a "clear and consistent set of privacy standards" for the entire country.

"The current legal obligation of health care providers to maintain the confidentiality of health information is based on what the Office of Technology Assessment found to be a patchwork quilt of federal and state laws," wrote AHIMA executive vice president/CEO **Linda L. Kloss**, MA, RHIA.

"We commend HHS for proposing standards consistent with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996," she wrote.

Regulations don't go far enough

However, the association did make several recommendations to strengthen the privacy protections in the proposal, including the following:

- add language that would require agencies obtaining information to only acquire the minimum amount of identifiable information necessary for the performance of their specific treatment or health care task and to destroy the record of the information afterward;
- establish a standard for "de-identifying" health information so the patient's identity is not discernible and outline penalties for agencies that receive de-identified information and then "re-identify" it or reinsert information linking the information to a specific patient;
- add language that would offer more protection for the patient against unauthorized re-disclosure of identifiable information from the covered agency to a third party.

Interestingly, AHIMA did not object to the removal of the patient's right to restrict the release of identifiable information to third parties.

"While we believe individuals should have the right to access, copy, amend, and correct their information, giving them the right to request restricting its uses and disclosures is in contrast with the intent of the proposed rule," AHIMA's comments state. "Permitting patients to dictate the flow of their health information for treatment, payment, and health care operations will seriously hamper the ability to achieve the intentions stated above."

Pyles considers that opinion to be dangerous. "The regulations propose to substitute security

measures to protect the information [in place of requiring patient consent for release]," he says. "But the regulations also concede that they don't have authority under the statute to institute effective enforcement of these protections. They are rendering the patient incapable of protecting themselves, and then the government cannot provide substitute protection. The bottom line is the right to privacy is eliminated."

In the event the regulations are put into effect, hospitals will be placed in the uncomfortable situation of deciding when it is appropriate to release identifiable medical information. Most likely, those decisions will be brought to the ethics committee for resolution.

"Right now, if a physician or hospital receives a request for a patient's medical record, the only thing they can do is ask for the patient's consent," Pyles says. "If the patient does not consent, that is the end of it."

Under the proposal, however, the provider can be placed in the position of deciding whether the purpose of the request for the information is for "treatment, payment, or health care operations."

"It could be an employer, a health plan, or insurer or any other individual or agency making the request," Pyles says. "As long as they convince the provider that they have a valid reason for giving the information, it would be legal. And what if the provider makes the decision to release that information and, at a later date, a court decides the disclosure violated the patient's privacy?"

Implications not well-understood

The damage release of confidential medical information can have is not well-understood by many Americans, including some of our country's leaders, says **Claire Dixon-Lee,** PhD, RHIA, immediate past president of AHIMA.

During her tenure, AHIMA sent a letter to Sen. John McCain (R-AZ) asking the presidential candidate to reconsider his decision to release his entire medical record to the media.

"We as the public are, essentially, hiring the president," she says. "Are we going to require all applicants for that job to turn over their medical information? What does that say about other employers' ability to demand this information?"

The American public needs to become more savvy about what that might mean, she says. "We need to do more education with the public about what information is contained in the medical record." For example, a given patient's medical history will contain not only information about the patient himself or herself, but about his parents and possibly siblings, she notes. Clinicians use the medical record to document their decision-making process in deciding for or against certain treatments or therapies.

"When you consider allowing the public to have access to this information, you are really releasing information about more than just your own personal medical history," she advises.

If physicians feel the documentation of the process they go through to make decisions will be shared with multiple third and fourth parties, they may become reluctant to put that information in there, she adds.

"What we don't want to see happen is physicians creating 'shadow' records, where they have the official medical record and then another record detailing the process that they go through to make a treatment decision."

Currently, the medical record is designed to include information about the patient that is shared with other providers who care for that patient, not for anyone who just might be interested in knowing, she says.

The Washington, DC-based American Association of Health Plans also opposes the HHS proposal, but on the grounds that the privacy requirements are so broad that they afford patients *too much* power to restrict access to their medical information.

Pyles argues that health plans and other agencies wanting health information for the purposes of statistical analysis or quality control should be able to use the information without the patients' identifying information attached.

"We have no objection to the release of information if it is stripped of all identifying factors," Pyles notes. "Then it does not violate a person's right to privacy." ■

SOURCES

- For the AHIMA comments on the proposed regulations, go to the organization's Web site: http://www.ahima.org/privacy.comments.html.
- For a copy of the proposed regulations from the Department of Health and Human Services, see the Nov. 3, 1999, *Federal Register*, p. 59,917.
- **James Pyles**, American Psychoanalytic Association, 222 N. LaSalle St., Suite 400, Chicago, IL 60601.
- **Claire Dixon-Lee**, P.O. Box 285, Oshtemo, MI 49077.

What the privacy legislation says

What you might encounter under new regulations

Here is more detail about the "Standards for Privacy of Individually Identifiable Health Information," issued by the U.S. Department of Health and Human Services (HHS) on Nov. 3.[1]

❑ **Information protected:**

• Information that relates to an individual's health, health care treatment, or payment for health care and that identifies the individual is protected from time it becomes electronic. That protection continues as long as the data are in the hands of a covered entity, such as a health care provider who transmits data electronically, a health plan, or a health care clearinghouse. Paper versions of the information, such as computer printouts, also are protected.

❑ **Individual rights:**

• the right to receive a written notice of information practices from health plans and providers;

• the right to access one's own health information, including the right to inspect and obtain a copy of the information;

• the right to request amendment or correction of protected health information that is inaccurate or incomplete;

• the right to receive an accounting (audit trail) of instances when protected health information has been disclosed for purposes other than treatment, payment, or health care operations.

❑ **Obligations of health care providers/plans:**

• Develop a notice of information practices. Providers would provide the notice to each patient at the first service after the effective date of the rule and post a copy of the notice.

• Allow individuals to inspect and copy their protected health information.

• Develop a mechanism for accounting for all disclosures of protected health information for purposes other than treatment, payment, or health care operations.

• Allow individuals to request amendments or corrections to their protected health information.

• Designate a privacy officer who will be responsible for all necessary activities.

• Provide privacy training through the facility's policies and procedures to all staff and any others who would have access to protected health information.

• Establish administrative, technical, and physical safeguards to protect identifiable health information from unauthorized access or use.

• Establish policies and procedures to allow individuals to complain about possible violations of privacy.

• Develop and apply sanctions, ranging from re-training to reprimand to termination, for employee violation of entity privacy policies.

• Have available documentation on compliance with the requirements of the regulation.

• Develop methods for disclosing only the minimum amount of protected information necessary to accomplish any intended purpose.

• Develop and use contracts that will ensure that business partners also protect the privacy of identifiable health information.

• Be prepared to respond to requests for protected health information that do not require consent, such as for public health, health oversight, or judicial activities.

❑ **Disclosures without patient authorization:**

• Covered entities could use and disclose protected health information without patient authorization for purposes of effecting treatment, payment, or health care operations. Individuals must be informed of the right to request restrictions concerning the use of protected health information for treatment, payment, or health care operations.

• Under specific conditions, covered entities are permitted to disclose protected health information for federal, state, and other health oversight activities; public health activities and emergencies; judicial and administrative proceedings; to a law enforcement official with a warrant or subpoena; to next-of-kin; to coroners and medical examiners; for government health data systems; for purposes of hospital and other facility directory listings; for certain banking and payment processes; and for health research.

❑ **Uses and disclosures with patient authorization:**

• Covered entities could use or disclose protected health information with the individual's consent for lawful purposes. If an authorization would allow the covered entity to sell or barter information, that fact would have to be disclosed on the authorization form.

• Authorizations must specify the information to be disclosed, who would receive the information, and when the authorization would expire.

Individuals could revoke an authorization at any time.

• Covered entities would be prohibited from conditioning treatment or payment upon an individual's agreeing to authorize disclosure of information for other purposes.

❑ **Scalability:**

HHS intends that these new privacy standards be flexible and scalable, taking into account each covered entity's size and resources.

❑ **Preemption:**

The regulation establishes a "floor" of privacy protections. State laws that are "less protective" of privacy are preempted, but states are free to enact "more stringent" statutes or regulations.

❑ **Enforcement:**

• Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the HHS Secretary has the authority to impose civil monetary penalties against those covered entities that fail to comply with the requirements of the regulation.

• HIPAA also established criminal penalties for certain wrongful disclosures of protected health information. Those penalties are graduated, increasing if the offense is committed under false pretenses or with intent to sell the information or reap other personal gain.

• Civil monetary penalties are capped at $25,000 for each calendar year for each standard that is violated.

Reference

1. 99 *Fed Reg* 59,917 (Nov. 3, 1999). ■

Americans concerned about Web site ethics

Internet users suspicious of health-related sites

An on-line survey reveals that Internet-savvy Americans are concerned about the privacy of health information, but more importantly, suspicious of the ethics of health-related World Wide Web sites.

The on-line poll, with 1,009 responses, was commissioned by the Oakland-based California HealthCare Foundation and the Internet Healthcare Coalition, an international nonprofit organization. Titled "Ethics Survey of Consumer Attitudes about Health Web Sites," the survey found the average American Internet user is:

• concerned about the privacy of on-line health information;

• suspicious of the ethics of many Internet health Web sites;

• uncertain whether personal health data are protected by law;

• confused about who should regulate Internet health information or if it should be regulated.

When asked about general privacy issues, 61% said they were "concerned" or "very concerned." Respondents indicated they were more concerned, however, with on-line privacy issues than with non-Internet issues. Three main fears regarding privacy cited by respondents (with percentages) include:

1. sites sharing information with a third party without permission (75%);

2. individuals other than the addressee reading e-mail (65%);

3. unauthorized hacking into personal health information (59%).

The most cited turn-offs for consumers were sites that share profiles with advertising and marketing partners.

The issue of who should regulate the use of personal health information on the Internet is still divided. The government, according to 35% of on-line users, should take the lead in regulating health information. But 20% said industry associations should develop regulations, and 8% said no regulation should occur.

Top honors for the most trusted sites went to government-sponsored institutions such as the Centers for Disease Control and Prevention in Atlanta and the National Institutes of Health in Bethesda, MD. Medical groups, including the American Medical Association, received high honors as well. Ranking at the bottom were on-line pharmacy outlets and portals such as Yahoo!

Patients are more likely to visit or share information with a site if their physician recommends it. In fact, 80% said a recommendation from their physician would increase their willingness to share.

(Editor's note: To see the survey in its entirety, visit the California Healthcare Foundation on the World Wide Web: http://www.chcf.org.) ■

NEWS BRIEFS

ACS endorses stem-cell research proposals

Society cites 'extraordinary promise'

Dependent upon appropriate restrictions and oversight, the Atlanta-based American Cancer Society (ACS) decided to endorse and support research proposals involving stem-cell research. The 80-year-old organization announced its decision in late 1999. Acknowledging that stem-cell research holds "extraordinary promise in eradicating cancer," the organization states the decision to endorse such funding was not made lightly or with disregard for the concerns of others. Stem-cell research, officials at the ACS say, has the potential of unraveling the mystery of how cancer cells develop.

Opens vast field of research

Additional areas where stem cell research could provide insight include these:

1. developing and testing new cancer drugs;

2. treating chemotherapy side effects in cancer patients;

3. repairing damaged tissue;

4. improving the odds against rejection following organ transplantation;

5. assisting in gene therapy studies.

To be considered by the ACS for funding, however, grant proposals must meet existing ACS review standards. Additionally, the proposal will have to comply with proposed guidelines by the National Institutes of Health, which guarantee federal oversight of stem-cell research. The guidelines also provide informed consent standards for donors and prohibit payments or incentives for the creation of human embryos for specific research purposes. ▼

New institute formed to distribute stem cells

The Wisconsin Alumni Research Foundation in Madison (WARF) announced in February it has established a private, nonprofit subsidiary with the main goal of distributing stem cells to qualified scientists. Embryonic stem cell research was first conducted in 1998 by a team of scientists from University of Wisconsin at Madison. The patents used to govern the use and technology of the cells are held by WARF.

The primary mission of the new WiCell Research Institute is to supply cells for academic and non-academic research. The institute's director will be James Thomson, the biologist whose lab first isolated human embryonic stem cells. The lab has received more than 100 requests for cells, and

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 AHC) 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.)

Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Managing Editor: **Kevin New**, (404) 262-5467, (kevin.new@medec.com)
Contributing Writer: **Cathi Harris**.
Production Editor: **Terri McIntosh**.

Editorial Questions

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

at least a dozen companies have approached WARF about stem-cell technology.

The National Institutes of Health guidelines on stem-cell research, when implemented, likely will accelerate the demand for cells because they will permit the use of federal money for the first time to conduct human stem-cell research. ▼

Suicide how-to video aired in Oregon

A how-to video on drugs to take to commit suicide was broadcast in Oregon last month, angering assisted-suicide foes and right-to-die advocates alike.

The video was created by Derek Humphry, the British journalist who wrote a book on suicide for terminally ill patients, *Final Exit*. The video, he says, can be shown to terminally ill patients and their families. It is available for purchase at Amazon.com, he says.

The decision to air the video on a local cable program was intended to serve the public's needs, but critics call it reckless. "There is undoubtedly a hunger for this type of information," counters Humphry, who lives in Oregon. "This is something 60% to 70% of the public supports."

Advocates of the state's Death with Dignity Act fear the video will cause people to act irresponsibly. "It can give people the means to act on impulsiveness," says **Barbara Coombs Lee**, executive director of the Portland-based Compassion in Dying Federation. Humphry does not support a medical model of assisted suicide like her group does, she adds.

The video includes instructions on buying items in hardware stores, getting prescription drugs, and mixing the drugs. The cable channels that broadcast the video included warnings about the program's contents. ■