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Shalala takes clinical trials oversight away from NIH, but doubts remain

Move will elevate stature and effectiveness, feds say

A move by the U.S. Department of Health and Human Services (HHS) is expected to change a longstanding perception of how human research is regulated by the federal government. By the spring of 2000, HHS will move the Office for Protection from Research Risks (OPRR) from its current location within the National Institutes of Health (NIH) to the HHS Office of the Secretary. The move will give the OPRR — the agency in charge of enforcing federal protections for human and animal research subjects — more autonomy.

"The way it works now is that office resides within NIH. One perspective is that it is the fox guarding the hen house in that the people charged with oversight are essentially answering to the people who do the research. It is a question of perceived — and to some extent real — independence to do the tasks that they are asked to do," notes **Jeffrey P. Kahn**, PhD, MPH, director of the Center for Bioethics at the University of Minnesota. Kahn also is co-author of the books *Ethics of Research with Human Subjects: Selected Policies and Resources* and *Beyond Consent: Seeking Justice in Research.*[1,2]

According to the Nov. 4 HHS statement announcing the move: "The Advisory Committee to the director of NIH has recommended that the OPRR be relocated in the Office of the Secretary to elevate its stature and effectiveness. Secretary Donna E. Shalala has accepted the recommendation and directed that OPRR be relocated to the Office of

COMING IN FUTURE ISSUES

■ **Diversity in dying:** An in-depth look at improving palliative care in a multicultural society

■ **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

■ **Going too far?** How much 'training' in teaching hospitals should be allowed on newly deceased patients?

Public Health and Science within the Office of Secretary."

The relocation essentially moves the office up a level in terms of the chain of authority — the new position is within the office of the Secretary of Health and Human Services. The NIH is a division of HHS.

Track record is troubled

Founded in 1972 by then-NIH director Robert Q. Marston, OPRR is the federal office that develops and implements regulations governing the use of human research subjects in federally funded studies. Institutions seeking to conduct biomedical or behavioral research using federal funds must sign an "assurance" with OPRR that specifies the policies and procedures they will put in place to ensure compliance with all OPRR regulations. **(For more information on research ethics, see *Medical Ethics Advisor*, July 1999, pp. 73-83.)**

In addition, each institution must form an institutional review board (IRB), made up of medical experts, ethicists, and members of the population studied, that approves research protocols and monitors ongoing studies to ensure compliance.

In addition to rule-making, OPRR is charged with monitoring institutional compliance with the assurances as well as the effectiveness of its protocols and IRB oversight.

Last year, well-publicized rule violations at prominent research institutions — notably Duke University Medical Center in Durham, NC, and the University of Colorado Health Sciences Center in Denver — have prompted Congress, medical ethicists, and several patient advocacy groups to call for an overhaul of existing protections for human subjects. **(See *MEA*, July 1999, pp. 73-78.)**

Concerns arise over independence

Following an initial recommendation from the president's National Bioethics Advisory Commission (NABC) last year, the NIH Advisory Committee to the Director convened a seven-member review panel, consisting of legal experts, medical ethicists, and research scientists, to evaluate OPRR's effectiveness. In its report, the review panel indicated that OPRR was perceived to be unduly influenced by the pro-research endeavors at the NIH.

"OPRR's connection to NIH confers status by virtue of association with one of the premier research institutions in the world and provides OPRR, in theory, with immediate access to scientific expertise," the report reads. "While this aspect of the NIH connection enhances the status and reputation of OPRR in the scientific community, the relationship to NIH increases the public perception that OPRR will be biased in the direction of protecting research interests at the expense of protections for human subjects and animals."

The concerns are more than hypothetical, the report continues. Interviews with OPRR staff indicated that, at times, their policy recommendations had been modified before reaching the Office of the Secretary, "thus subsuming their intentions to the agendas of other divisions within the NIH."

According to the HHS statement, the move also will eliminate the concern that location within the NIH diminished the OPRR's contact with other HHS agencies as well as other federal agencies outside HHS.

Top-level changes: The right solution?

However, some experts feel that relocating OPRR will do little to alleviate the real problems involved in protecting human subjects in the rapidly expanding arena of biomedical research.

In 1998, the University of Pennsylvania Center for Bioethics' Human Research Ethics Group published recommendations for improving protections for human research subjects.[3] Significantly, the recommendations called for increased supervision of research by the IRB at each center and for extending the protection of the IRB process beyond just those studies receiving federal funds.

"I am not sure what moving the OPRR from one level to another will do to address the sort of fundamental issues that were raised in the study that came out last year," says **David Magnus,** PhD, director of graduate studies at the Center for Bioethics. "Most of the key issues that were raised are really things that rise at the local level."

Following the study, the group concluded that the existing model for institutional review was inadequate to deal with the increasing number of studies that involve multiple institutions and many different investigators as well as both public and private funding, says Magnus.

"It is not clear whether or not this move will facilitate the things that are going to be necessary for IRBs to effectively do what our study called

CME questions

1. **Jeffrey P. Kahn,** PhD, MPH, director of the Center for Bioethics at the University of Minnesota, says the main advantage of the change in the Office for Protection from Research Risks is that it will:
   - **A.** Create fewer paperwork duplications for researchers
   - **B.** Change the perception that the people charged with oversight are essentially answering to the people who do the research
   - **C.** Decrease the amount of regulatory oversight on researchers
   - **D.** All of the above

2. That announced change, according to **David Magnus,** PhD, director of graduate studies at the Center for Bioethics at the University of Pennsylvania, will have more impact:
   - **A.** At the local level
   - **B.** At the state level
   - **C.** At the regional level
   - **D.** At the national level

3. The main benefit of a new report co-written by **Kathleen M. Foley**, MD, director of the New York-based Project on Death in America for dying patients is that:
   - **A.** Patients with differing diseases will be treated similarly
   - **B.** Caregivers will benefit from care-specific clinical guidelines
   - **C.** All medical specialties can agree on a core set of principles
   - **D.** All of the above

4. According to **Joanne Lynn**, MD, director of the Center to Improve Care of the Dying at George Washington University Medical Center in Washington, DC, ethics committees can take the lead in following the end-of-life care report by:
   - **A.** Improving end-of-life care in hospitals through quality improvement efforts
   - **B.** Establishing hospitalwide policies on end-of-life care
   - **C.** Directing differing specialties to a defined end-of-life care policy
   - **D.** All of the above

Workshops on human subject protection offered

The National Institutes of Health and the Food and Drug Administration are co-sponsoring a series of workshops on the responsibilities of researchers, institutional review boards (IRBs), and institutional officials for the protection of human subjects in research. Although the meetings are open to everyone, they will be of special interest to anyone currently serving or about to serve on an IRB.

The planned upcoming workshops and locations are listed below. For more information, please contact Darlene Marie Ross, Education Coordinator, Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Suite 3B01, MSC-7507, Rockville, MD 20892-7507. Telephone: (301) 435-5648. Fax: (301) 402-0527. E-mail: dr20a@nih.gov.

- **Feb. 9-11, 2000.** Houston. Privacy and Confidentiality in Clinical and Social Science Research: Myth or Reality. Sponsored by University of Texas at Houston and Prairie View A & M University in Prairie View, TX.
- **Spring 2000.** Location TBD. Protection of Human Subjects: Involving Special Populations. Sponsored by Gallaudet University, Howard University and George Washington University, Washington, DC.
- **May 2000.** Tampa, FL. Protection of Human Subjects: The Myth of Privacy and Confidentiality Explored. Sponsored by the University of South Florida in Tampa, the Indian Health Service in Albuquerque, NM, the University of Miami, and Florida A & M University in Tallahassee.
- **June 2000.** Chicago. Protection of Human Subjects: The Myth of Privacy and Confidentiality Explored. Sponsored by Rush-Presbyterian-St. Luke's Medical Center, Chicago.
- **August 2000.** Portland, OR. Protection of Human Subjects: The Myth of Privacy and Confidentiality Explored. Sponsored by: Oregon Health Sciences, Portland; Northwest Portland Area Indian Health Board; Indian Health Service, Albuquerque, NM.

Source: Office for Protection from Research Risks, Rockville, MD.

on them to do: perform all of the follow-up that is necessary, instead of the bureaucratic rule-solving that is taking place now."

Another recommendation of the OPRR review panel indicates that, although the office currently has the authority necessary to conduct the duties assigned to it, the office may not be able to fulfill its mission with the its current resources.

"Critiques of OPRR make clear that OPRR needs to exert more leadership in education and training, and in providing technical assistance to, and evaluation of, IRBs," the report says. "Wherever OPRR is located, more resources will need to be available to enable OPRR to fulfill the promise of even the current statutory and regulatory scheme."

"There is federal oversight in the vast majority of publicly and privately funded research; the question is how much falls between the cracks."

Although research performed without HHS funds is outside OPRR jurisdiction, many in the bioethical and research communities feel that strengthening the office's resources and authority would both improve its supervision of federally funded projects and its position of leadership in developing protections for all research subjects. [4]

"The way the law actually reads is that only research that is federally funded has to follow the common rules," explains Kahn, "But, most institutions that receive federal funding sign a multiple project assurance, in which they agree that all research performed at that institution will be conducted under the same rules.

"So, it is not just federally funded research that has protection, but it is sort of black box. How many institutions don't fall into that category? It is pretty hard to know. Pharmaceutical companies also have to follow federal rules and submit their data to the [U.S. Food and Drug Administration] FDA. So, there is federal oversight in the vast majority of publicly and privately funded research; the question is how much falls between the cracks."

Frankly, he adds, moving OPRR is not going to address that issue. Only comprehensive legislation by Congress can accomplish that. "It is an issue that Congress has talked about, at times, of fixing, by saying that all research performed within the United States will have to follow certain rules. But that has not ever happened."

SOURCES

- **HHS Fact Sheet: Protecting Research Subjects.** Nov. 4, 1999. World Wide Web: http://hhs.gov/news/press/1999/991104c.html. Office for Protection from Research Risks: World Wide Web: http://www.nih.gov/grants/oprr/oprr.htm.
- **David Magnus**, PhD, Director of Graduate Studies, University of Pennsylvania, Center for Bioethics, 3401 Market St., Suite 320, Philadelphia, PA 19104-3308.
- **Jeffrey P. Kahn**, PhD, MPH, Center for Bioethics, University of Minnesota, Suite N504 Boynton, 410 Church St., Minneapolis, MN 55455-0346. Telephone: (612) 624-9440. Fax: (612) 624-9108.
- **U.S. Department of Health and Human Services**, Office of Public Health and Science, Hubert H. Humphrey Building, 200 Independence Ave. SW, Washington, DC 20201. Telephone: (202) 205-1842.

However, the move may provide the opportunity for the office to re-examine its mission and resources, he notes. "How they will maintain their role as an oversight body, and as an educational body, or as a friend of researchers, as well as maintaining their police function . . . is not exactly clear. I think this is a good time for that mission to be clarified," he says.

Funding is a concern

Another major concern expressed in the report from the OPRR review panel regarding the move was the possible interruption or alteration in the funding stream for the office.

"OPRR's current location within the funding stream of the NIH places OPRR among the privileged," the report states. "The Review Panel recognizes that any new organizational arrangement may disrupt what is now a reliable funding situation and exposes OPRR to the risk that it will be more vulnerable to legislative efforts to impose fiscal restraint or achieve other political goals."

Again, Magnus says, moving the office outside the NIH may have real little impact on how IRBs function at the local level. "The real issues have to do with how much time, how much funding is available, and what in terms of resources are we going to have allocated at the local level to make sure that IRBs can truly function in a way that is necessary to offer protections," he explains.

References

1. Sugarman J, Mastroianni A, Kahn J, eds. *Ethics of Research with Human Subjects: Selected Policies and Resources.* Frederick, MD: University Publishing Group; 1998.
2. Kahn JP, Mastroianni AC, Sugarman J, eds. *Beyond Consent: Seeking Justice in Research.* New York City: Oxford University Press; 1998.
3. Moreno J, Caplan A, Wolpe P, et al. Updating protections for human subjects involved in research. *JAMA* 1998; 280:1,951-1,958.
4. Report to the Advisory Committee to the Director, NIH from the Office for Protection from Research Risks Review Panel. June 3, 1999. World Wide Web: http://www.nih.gov/welcome/director/060399b.htm. ■

NIH: Report all adverse events in gene studies

New guidelines follow death of study participant

Under new proposed guidelines from the federal government, research investigators would have to report all adverse events that occur during studies involving gene therapy. Currently, scientists are required to report only those adverse events that are unexpected or related to the experimental strategy.

Federal authorities announced the proposed guidelines in a November 1999 statement by the National Institutes of Health's Office of Recombinant DNA Activities (ORDA).

The new reporting guidelines were proposed in the wake of the death of a gene therapy study participant at the University of Pennsylvania in September 1999 — the first death directly linked to an experimental gene therapy procedure.

The proposed changes were published in a notice in the Nov. 22, 1999, issue of the *Federal Register*, and ORDA's 15-member Recombinant DNA Advisory Committee (RAC) began considering the proposed changes at its mid-December meeting last year.

The new regulations also require that adverse events be reported within 15 calendar days of the occurrence.

A significant change to existing NIH policy is the stipulation that the adverse event reports will be considered public information unless NIH/ORDA permits an exception.

According to the notice in the *Federal Register*, "some investigators and sponsors have begun to

Bill would monitor studies of vulnerable populations

Amendment would require additional reporting

Following the release last year of a National Bioethics Commission Report on biomedical research involving people with diminished capacity to give informed consent, U.S. Rep. **Edolphus Towns** (D-NY) has introduced legislation calling for the creation of a program to collect information on the use of children and individuals with mental disabilities as subjects in biomedical and behavioral research.

Specifically, H.R. 299 calls for an amendment to the Public Health Service Act that would require the Secretary of Health and Human Services to establish a program to gather information about research involving those vulnerable populations.

According to the bill summary filed with the U.S. House of Representatives, the bill stipulates that — for studies that fall under the jurisdiction of the Public Health Service Act or are subject to chapter five of the Food, Drug and Cosmetic Act — the program may require the submission of reports by the institutional review boards at each institution.

Information collected by the program would include a description of the research subjects, the nature of the research, the objective of the research, the reasons for the use of such subjects, and the source of funding for the research.

Although the legislation only calls for the collection of information, it could be an important step in establishing protections for children and the mentally ill or disabled, says **David Magnus**, PhD, director of graduate studies at the University of Pennsylvania Center for Bioethics in Philadelphia.

"There is a set of values that says we ought to be involving children [and the mentally disabled] more in research trials so that we can make sure that things are going to be safe and effective for them," he says.

"But, on the other hand, we should not do research on these populations when there is no clear benefit to them and there is more than minimal risk. So, you have both sets of well-established values, yet they really do conflict.

"In the end, you cannot do research on children of the sort that is really called for unless you do Phase 1 trials. But, Phase 1 trials are not likely to meet the standard that has been established. So, there is going to have to be more thinking about those issues, and maybe this will help." ■

designate human gene transfer protocols or serious adverse events confidential, thereby precluding RAC review."

The proposed guidelines clarify that all adverse events should be immediately reported to ORDA, which is to immediately notify the RAC. The RAC, by definition, conducts its business in the public domain.

Investigator compliance in question

The Associated Press reported in December that the U.S. Food and Drug Administration investigation into the death of a participant in a gene therapy study at the University of Pennsylvania revealed the investigators may not have complied with all NIH safety rules and did not promptly report problems with the study protocol as current guidelines require.

Jesse Gelsinger, an 18-year-old Arizona man, died days after being injected with a drug containing genetically altered adenovirus during a research study. Gelsinger had suffered since birth from a genetic disorder known as ornithine transcarbanylase deficiency, which weakened his body's ability to excrete ammonia.

The injection of the study drug was supposed to deliver genes to the malfunctioning liver cells that would repair the disorder. Instead, a severe immune reaction rapidly destroyed Gelsinger's lungs. Media reports following Gelsinger's death listed other deaths that had occurred during gene therapy experiments but had not been made public for confidentiality reasons.

The proposed guidelines are under consideration by the RAC and another advisory panel, both of which will make recommendations to NIH. The NIH director will decide whether the recommended changes will be made to the NIH guidelines. ■

Medical groups find common ground

Specialties draft, adapt principles for care of dying

A patient dying from lung cancer may have different clinical needs than someone dying from Parkinson's disease, right? There might be more similarities than you think, say representatives from 13 surgical and medical specialty groups. Following a three-year development effort, the representatives created a core set of principles for caring for patients at the end of life.

The achievement is notable considering today's highly specialized health care industry, whereby each specialty may see a distinct aspect of care for a dying patient. Despite the advances and breakthroughs, one characteristic of modern medicine remains — the lack of a palliative medicine specialty to assist and comfort patients and their families when the end of life is near.

In addition to the assembled medical groups, the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations has reported that its standards for care at the end of life are aligned with those core principles. **(For a list of the principles, see p. 21.)**

The report, titled *Principles for Care of Patients at the End of Life: An Emerging Consensus among the Specialties of Medicine,* was published by Milbank Memorial Fund in New York City. The Milbank Memorial Fund is a national foundation contributing to innovations in health and social policy. **(For ordering information, see editor's note.)**

Specific needs are addressed

"Studies show that there are different trajectories of dying, depending on the underlying health status of the patient and the nature of the terminal illness," says **Kathleen M. Foley**, MD, director of the New York-based Project on Death in America.

"A person dying from congestive heart failure or liver disease may have very different clinical needs than someone dying from lung cancer, and some people may need highly specific specialty care. These core principles allow specialists to address the specific needs of individualized patient populations," adds Foley. **(For a list of specialty groups that have adopted the principles in part or full, see p. 20.)**

Ethics committees can take the lead in improving end-of-life care in hospitals through quality improvement efforts, says **Joanne Lynn**, MD, director of the Center to Improve Care of the Dying at George Washington University Medical Center in Washington, DC. Lynn participated in the development of the principles. "Although it's not in the report, ethics committees can take a lead in quality improvement for end-of-life care. Our research work shows that most teams that embark on serious quality improvement make big gains for patients," she explains.

Lynn adds that having different specialties reach common ground on aspects of care for dying patients is an improvement. "It's one of a host of strategies that, taken together, just might work." And there's still work to be done in terms of caring for dying patients, she notes. "Perhaps one of the biggest injustices in today's health care system for dying patients is that Medicare and other payment systems [do] not cover or pay reasonably for medications, continuity, advance planning, family support, housing, symptom management, or almost anything else that is central to the patient's care when they are very sick and likely to die."

"Our research work shows that most teams that embark on serious quality improvement make big gains for patients."

The St. Paul, MN-based American Academy of Neurology and the American Society of Clinical Oncology in Alexandria, VA, drafted their own specific statements on palliative care and end-of-life care that embody the principles developed for the report. The Glenview, IL-based American Society of Bioethics and Humanities agrees that its members will support the principles but adds that the organization does not officially support specific policy statements.

[Editor's note: The report Principles for Care of Patients at the End of Life: An Emerging Consensus among the Specialties of Medicine, *contains policy and summary statements submitted by some of the specialty groups in regard to the core principles for end-of-life care. Copies of the report are available by contacting the Milbank Memorial Fund, 645 Madison Ave., 15th Floor, New York, NY 10022. Telephone: (212) 355-8400. E-mail: mmf@milbank.org. World Wide Web: http://www.milbank.org.]* ■

Support is growing for new core principles

Resources for your committee

The following organizations have formally adopted the core principles for end-of-life care as written:

• **Academy of Psychosomatic Medicine**, 5824 N. Magnolia, Chicago, IL 60660. Telephone: (773) 784-2025. Fax: (773) 784-1304. E-mail: ApsychMed @aol.com. World Wide Web: http://www.apm.org.

• **American Academy of Hospice and Palliative Medicine**, 4700 W. Lake Ave., Glenview, IL 60025-1485. Telephone: (847) 375-4712. Fax: (847) 375-6312. E-mail: aahpm@aahpm.org. World Wide Web: http://www.aahpm.org.

• **American Board of Hospice and Palliative Medicine**, 9200 Daleview Court, Silver Spring, MD 20901. Telephone: (301) 439-8001. Fax: (301) 434-4118. E-mail: mail@abhpm.org. World Wide Web: http://www.abhpm.org.

• **American College of Chest Physicians**, 3300 Dundee Road, Northbrook, IL 60062-2348. Telephone: (847) 498-1400. Fax: (847) 498-5460. E-mail: accp@chestnet.org. World Wide Web: http://www.chestnet.org.

• **American Medical Association**, 515 N. State St., Chicago, IL 60610. Telephone: (312) 464-5000. World Wide Web: http://www.ama-assn.org.

• **American Pain Society**, 4700 W. Lake Ave., Glenview, IL 60025. Telephone: (847) 375-4715. Fax: (847) 375-6315. E-mail: info@ampainsoc.org. World Wide Web: http://www.ampainsoc.org.

• **National Kidney Foundation**, 30 E. 33rd St., Suite 1100, New York, NY 10016. Telephone: (800) 622-9010 or (212) 889-2210. Fax: (212) 689-9261. E-mail: info@kidney.org. World Wide Web: http://www.kidney.org.

Groups adopting principles in part

The following organizations have adopted the core principles for end-of-life care with modifications:

• **American Academy of Pediatrics**, 141 N.W. Point Blvd., Elk Grove Village, IL 60007-1098. Telephone: (847) 228-5005. Fax: (847) 228-5097. E-mail: kidsdocs@aap.org. World Wide Web: http://www.aap.org.

• **American College of Physicians / American Society of Internal Medicine**, 190 N. Independence Mall W., Philadelphia, PA 19106-1572. Telephone: (800) 523-1546. World Wide Web: http://www.acponline.org.

• **American College of Surgeons**, 633 N. Saint Clair St., Chicago, IL 60611-3211. Telephone: (312) 202-5000. Fax: (312) 202-5001. E-mail: Postmaster @facs.org. World Wide Web: http://www.facs.org.

• **American Geriatrics Society**, 350 5th Ave., Suite 801, New York, NY 10118. Telephone: (212) 308-1414. Fax: (212) 832-8646. E-mail: info.amger@americangeriatrics.org. World Wide Web: http://www.americangeriatrics.org. ■

Core principles for end-of-life care

A new report, developed in conjunction and adopted by 13 specialty medical societies and the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations, lists core principles for end-of-life care.

The eleven core principles are:

1. respecting the dignity of both patient and caregivers;

2. being sensitive to and respectful of the patient's and family's wishes;

3. using the most appropriate measures that are consistent with patient choices;

4. encompassing alleviation of pain and other physical symptoms;

5. assessing and managing psychological, social, and spiritual / religious problems;

6. offering continuity — the patient should continue to be cared for, if so desired, by his or her primary care and specialist providers;

7. providing access to any therapy that may realistically be expected to improve the patient's quality of life, including alternative or nontraditional treatments;

8. providing access to palliative care and hospice care;

9. respecting the right to refuse treatment;

10. respecting the physician's professional responsibility to discontinue some treatments when appropriate, with consideration for both patient and family preferences;

11. promoting clinical evidence-based research on providing care at the end of life.

(The information in this article is from Principles for Care of Patients at the End-of-Life: An Emerging Consensus among the Specialties of Medicine, *published by the Milbank Memorial Fund.)* ■

NEWS BRIEFS

Resuscitation likely to be followed if indicated

Seriously ill patients who indicate they want resuscitation are more likely to get physician involvement during cardiac arrest.

The results of a study were published in the Dec. 22 / 29 issue of *The Journal of the American Medical Association*. Further, resuscitation was likely in patients who had more than a two-month survival expectancy, according to the results.

Other factors, including medical practice at a particular facility also play a role in the decision to resuscitate, notes **Sarah J. Goodlin** of LDS Hospital in Salt Lake City, who was the lead researcher for the study.

Get patients involved in decisions

Goodlin and colleagues analyzed the outcomes of 2,505 seriously ill patients whose hearts stopped beating while hospitalized. Of those, 514 patients received cardiopulmonary resuscitation (CPR) in efforts to revive them. Approximately 18% of those who received resuscitation survived for the duration of the hospital stay. "Patients who had CPR were younger, more often African American, and more often male," the researchers observe.

The remaining patients who died without resuscitation attempts had do-not-resuscitate orders in place. At the same time, 9% of the patients who died without CPR gave no indication that CPR should not be attempted, while 42 patients indicated they wanted CPR to be attempted but didn't receive it. Some clinical situations, however, appear to offer little hope of CPR effectiveness and physicians therefore don't attempt it, the researchers note.

Goodlin and colleagues say it's important for patients with serious illnesses to discuss with their physicians the situations in which they would and would not like to have resuscitation attempted. "One thing we found was that two-thirds of the patients died within a day or two of

an attempted CPR, and this may mean they die a less comfortable death than they would have if care were directed at maintaining comfort," states Goodlin. ▼

Cells for cloning don't go stale

Recent media reports of the successful cloning of a Japanese bull disproves the notion that cells become too stale to duplicate. Ear cells were taken from the 17-year-old bull, frozen, then cultured in a lab over several months.

Until now, cells used for cloning have been implanted either fresh or after fewer than 10 passages, which are periods in a culture medium, researchers note. In this study, however, cells from the bull went through up to 15 passages over three months before being used to clone the calves. A total of six calves were cloned, but only two survived.

The experiment was conducted jointly through the University of Connecticut in Storrs and the Kogashima Cattle Breeding Development Institute in Japan. Researchers involved in the experiment suggest that cells eventually could be used to create clones at any time, even after the original animals are dead.

More importantly, however, it means clones could be made from cells that have been kept in labs long enough to manipulate genes, which can be a lengthy and meticulous process. ▼

Most patients not involved in medical decisions

Physicians lack completeness for informed decision making when it comes to involving patients. That's according to research published in the Dec. 22/29 issue of *The Journal of the American Medical Association.*

"We found that only 9% of all clinical decisions met our criteria of completeness for informed decision making," says **Clarence Braddock**, MD, MPH. Braddock is assistant professor of medicine at the University of Washington School of Medicine in Seattle and was the lead author of the study.

Braddock says even when less-stringent criteria was used, only about one in five discussions were complete by the minimum measure.

More than 1,000 audiotapes of interactions between physicians and patients in an outpatient setting were studied. The presence of seven markers were considered part of a completely informed decision process. They are:

- the patient's role in decision making;
- the nature of the decision;
- alternatives;
- pros (benefits) and cons (risks) of the alternatives;
- uncertainties associated with the decision;
- an assessment of the patient's understanding of the decision;
- an exploration of the patient's preferences.

Discussions were rated as basic, intermediate, or complex. Patients often were told about the nature of a problem, but physicians infrequently explored whether patients understood the decision, notes Braddock.

Physicians cite time, according to Braddock, as the major reason they don't involve patients in the process. "There's a perception that it will take too much time, be too onerous, and patients won't understand. It's easier to write a prescription and say, 'Take this.'" ▼

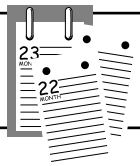
Group wants NIH to correct guidelines

The nation's largest pro-life educational organization wants the National Institutes of Health (NIH) to correct what it calls "misinformation" in the NIH's recent draft guidelines for human stem cell research.

American Life League president **Judie Brown**, in a letter to the NIH, calls for a complete ban on stem cell research and states "anything less would be the intentional promotion of criminal acts by the National Institutes of Health." American Life League comprises more than 375,000 families whose goal is to educate the public on stem cell research.

"It is clear that the guidelines sanction the deliberate destruction of these tiny human beings. The guidelines are based on a utilitarian code of ethics through which the weak are sacrificed for the good of the strong," Brown says. ■

CALENDAR



• **Belief and Bioethics: Religious Faith and Secular Medical Ethics, March 15-16, 2000.** Sponsored by the Center for Biomedical Ethics at the University of Virginia in Charlottesville in cooperation with the Finkelstein Institute of the Jewish Theological Seminary. There is a $100 registration fee for the conference.

For more information, contact: Ann Mills, Center for Biomedical Ethics, Box 348, Health Sciences Center, Charlottesville, VA 22908. Telephone: (804) 982-3978. E-mail: amh2r@virginia.edu.

• **Developing Healthcare Ethics Programs, April 24-29, 2000.** Sponsored by the Center for Biomedical Ethics at the University of Virginia in Charlottesville in cooperation with the office of continuing medical education. Participants can choose to concentrate on clinical ethics, health care organizational ethics, or research ethics.

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For additional information, contact: Kenneth D. Pimple, Poynter Center, Indiana University, 618 E. Third St., Bloomington, IN 47405-3602. Telephone: (812) 855-0261. Fax: (812) 855-3315. E-mail: pimple@indiana.edu. World Wide Web: www.indiana.edu/~poynter/index.html.

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For additional information or to receive a brochure outlining the course, contact: Marilyn Barnard, Manager, Continuing Education Program, University of Washington, Department of Medical History and Ethics, Box 357120, Seattle, WA 98195-7120. Telephone: (206) 616-1864. Fax: (206) 685-7515. E-mail: mbarnard@u.washington.edu.

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For additional information or a course brochure, contact: Marilyn Barnard, Manager, Continuing Education Program, University of Washington, Department of Medical History and Ethics, Box 357120, Seattle, WA 98195-7120. Telephone: (206) 616-1864. Fax: (206) 685-7515. E-mail: mbarnard@u.washington.edu.

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