NIH Tightens Ethics Rules for Employees

Restrictions bar even uncompensated relationships with organizations affected by NIH decisions.

BY MARY ELLEN SCHNEIDER
Senior Writer

Officials at the National Institutes of Health are tightening restrictions on outside consulting arrangements with industry after more than a year of investigations turned up potential conflicts of interest.

"Nothing is more important to me than preserving the trust of the public in NIH," Elias A. Zerhouni, M.D., NIH director, said in a statement announcing the new ethics rules. "It is unfortunate that the activities of a few employees have tainted the stellar reputation of the many thousands of NIH scientists who have never compromised their integrity and have selflessly served the nation with great distinction through their discoveries."

The new policy bars all NIH employees from engaging in compensated or uncompensated employment, or consulting relationships with those organizations that are substantially affected by NIH decisions.

Such organizations include pharmaceutical manufacturers, biotechnology companies, support research institutions, health care providers and insurers, and related trade and professional associations. The policy also prohibits NIH employees from participating in compensated teaching, speaking, writing, or editing with these affected organizations.

Further, all NIH employees are prohibited from self-employment activities that involve the sale or promotion of services or products from these affected organizations.

However, employees are allowed to teach courses that require multiple presentations and are part of an established curriculum at a university or college. They can also teach, speak, or write as part of a continuing education program.

But if the funding for the program comes from a substantially affected organization, like a drug company, it must be funded by an unrestricted grant.

NIH employees also can author articles, chapters, and textbooks that are subject to peer review, provided that funding from affected organizations is provided in the form of unrestricted contributions.

Under the new policy, NIH employees are also allowed to continue clinical care to individual patients.

The new regulation also takes aim at stock ownership. NIH employees who are required to file financial disclosure statements are prohibited from acquiring or holding financial interests in affected organizations including biotechnology, pharmaceutical, and medical device companies. All other NIH employees are subject to a $15,000 cap on such holdings.

"This new policy is an extension of a profession-wide examination of physicians' relationships to industry," said William E. Golden, M.D., professor of medicine and public health at the University of Arkansas in Little Rock.

Medical schools are likely to be the next major institutions to seek out greater transparency in the relationships between their faculty members and industry, Dr. Golden predicted.

The interim final regulation was developed by the Department of Health and Human Services with the Office of Government Ethics and went into effect immediately. Officials at HHS will continue to review the impact of the regulation and work on developing a comprehensive policy regarding outside consulting activities.

The new policy comes after about a year of internal NIH investigations as well as congressional inquiries into consulting arrangements between NIH employees and outside companies. NIH officials had previously proposed a 1-year moratorium on all outside consulting arrangements.

"Though I believe that some outside activities are in the best interest of the public when designed to accelerate the development of new discoveries, we must first have better oversight systems to ensure transparency and sound ethical practices and procedures," Dr. Zerhouni said.

The new policy was praised by the Association of American Medical Colleges. "The rules are clear and unambiguous and will enhance the public's confidence in the integrity and dedication of NIH employees and scientists," AAMC President Jordan J. Cohen, M.D., said in statement.

"We also firmly support NIH's plan to assess the impact of these new rules within 1 year. Given the sweeping changes being made and the possibility of unintended consequences, it is prudent for the agency to undertake a thorough review after full implementation so that appropriate modifications can be made, if necessary," Dr. Cohen said.

Officials at NIH also announced a new policy aimed at speeding the public's access to scientific articles that result from NIH-funded research. Under the policy, the agency is calling on scientists to voluntarily release manuscripts supported by NIH to the public within a year of peer-reviewed publication.

These articles would then be made available online in an archive to be managed by the National Library of Medicine. ■

Ethnic Health Care Disparities Said to Represent Medical Errors

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — Health care disparities among ethnic groups should be considered a form of medical error, James Gavin, M.D., said at a consensus conference on patient safety and medical system errors in diabetes and endocrinology.

"When we see disparities, that really is a reflection of inadequate patient safety," said Dr. Gavin, who is past president and professor of medicine at Morehouse School of Medicine, Atlanta. "It means that under the same or similar conditions of risk or exposure, the outcomes are sufficiently different that there is some disadvantage conferred on one of the other subject populations."

One example is coronary heart disease, he said at the conference, sponsored by the American Association of Clinical Endocrinologists. "There is a real difference in CHD mortality in black males, compared with whites at every age stratum. It doesn't start to even out until you get to the ninth decade of life."

Results like these are in part a reflection of how medical decisions are made for different patients, and, sometimes, the only way to get at that information is by looking at surrogates for decision making, such as utilization rates, Dr. Gavin said.

For instance, coronary artery bypass graft surgery has proved to be of significant benefit in high-risk patients, and yet "CABG is significantly underutilized in blacks, compared with whites," he said. On the other hand, data on amputation among patients with diabetes "suggest it is significantly more utilized in blacks, compared with whites. Something is driving these outcomes."

Part of the problem may be bad information, he suggested. A report from a commission chartered in the 1980s by Health and Human Services Secretary Margaret Heckler found several myths about heart disease in blacks, including the idea that blacks rarely had MIs or angina, or that they were immune to CHD.

"Because of flaws in the way data were interpreted, they were actually underreporting CHD as a cause of death, when … CHD was actually the leading cause of death in U.S. blacks then just as it is now," he noted.

Now that researchers are looking at disparities more systematically, they are finding that even when minorities have access to health care that is equivalent to that of white patients, there is still an inequity in the services they receive, he said.

"That part of the gap that is attributable to patient needs and patient preferences you have to back out [of the equation] because you can't blame a patient's choice," he said. "But these other issues, the way the system operates, the way individual and group biases and prejudices [affect things], those issues are major drivers."

Medicare data on diabetes care show that something is clearly "amiss," he added. "For example, despite the greater prevalence and risk associated with it, African Americans are less likely to undergo hemoglobin A_{1c} testing, or to have their lipids tested, or to have vaccinations. And this is in the Medicare population, where coverage is not the issue."

In another instance of disparities in diabetes care, "African Americans are 12% of the population, but fully a third or more of the [end-stage renal disease] population," he said. "They also are less likely to receive a kidney transplant and less likely to be referred for a transplant, or to be placed on a transplant waiting list. Those are decisions that someone has to make."

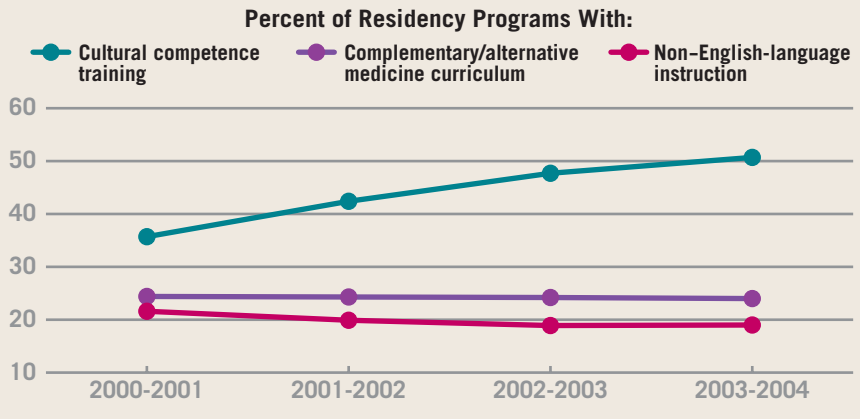
Some of the disparities arise from the clinical encounter itself. "It's at that level we have to begin to pay more attention because it is only to the extent that we improve the quality of this encounter … that we will begin to influence this process," Dr. Gavin said. "There will be less ambiguity, less misunderstanding, and we'll begin to mitigate the influence of prejudices, no matter who brings them to the table."

Dr. Gavin said he didn't agree with the idea of "cultural competency." "It's not something I'm convinced we ever become competent at. It's always a work in progress. But [we] can work to become more self-aware of our own cultural norms and values that will quickly lead us to misjudge or miscommunicate with others."

Cultural competency training can confer a false level of confidence, he noted. "We think we can go to one workshop and come out culturally competent, when in fact it's lifelong learning." ■

DATA WATCH

Cultural Competence Training in Vogue



Note: Based on surveys of about 8,000-9,000 residency directors per academic year.
Source: JAMA 2004;292:1032-7