It's Not Always Easy to Live Up to One's Medical Ideals

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — Easier said than done. That may be the take-away message from a study that revealed gaps between physicians' attitudes and behavior when it comes to standards of professionalism.

A national survey of 3,500 primary care and specialist physicians found that 95% said physicians should report incompetent or impaired colleagues. However, only 56% of those who had been in a position to do so, in fact, did.

"It's simply not acceptable that bad physicians aren't being reported to the proper authorities," said Dr. James N. Thompson, president and CEO of the Federation of State Medical Boards, at a press briefing to release the findings.

The survey also showed that 92% of physicians thought they should always report medical errors, but 31% admitted to not doing so on at least one occasion.

"Most physicians are trying to do the right thing, under increasingly difficult circumstances," said Dr. David Blumenthal, director of the Institute for Health Policy at the Massachusetts General Hospital, Boston, and senior author of the study (Ann. Intern. Med. 2007;147:795-802).

Those circumstances include not only financial pressures, but also the seemingly constant threat of lawsuits, he said.

"I'm neither surprised nor disheartened by the study's outcome. It just shows that doctors are people," said Dr. Ari Silver-Isenstadt, a pediatrician at Franklin Square Hospital Center in Baltimore

Although 96% of physicians said they should put the patients welfare above their own financial interests, 84% had accepted food or beverages from drug company representatives. Smaller percentages admitted receiving drug samples, admission to CME events, consulting or speaking fees, travel tickets to sporting events, and other industry provided perks.

Physicians may feel they are not influenced by such marketing, but even the appearance of a conflict can undermine patient trust.

"It took me awhile to recognize that I am just as vulnerable as any other Joe to advertising, but given my fiduciary responsibility to my patients, I have to be more vigilant," said Dr. Silver-Isenstadt.

Despite everyday obstacles to professionalism, the authors took it as a hopeful sign that physicians have the right attitude. What is needed next is the ability to bridge that divide between attitude and action in a nonpunitive environment. "We have to create a health care system that is safe for professionalism," said Dr. Blumenthal.

That is borne out by the work of both national groups and more local efforts, said Dr. Peter Cohen, a retired anesthesiologist who chairs the physicians health program for the Medical Society of the District of Columbia, which steps in when physicians are abusing drugs or alcohol.

"We have hospitals reporting, patients reporting, colleagues reporting. They know that … they are doing both the drug-abusing physician and society a favor, because these people do get into treatment and over 90% return to practice," said Dr. Cohen, who also is an adjunct professor of law at Georgetown University, Washington.

"We've got a disconnect. It's important that people look for the reasons behind the disconnect and do something about it. … As more and more knowledge is gathered, the disconnect will begin to disappear," he said. ■

HIPAA Privacy Rule May Impede Research, Fail to Protect Subjects

BY MARY ANN MOON
Contributing Writer

The Health Insurance Portability and Accountability Act's privacy rule has stymied clinical research by making it more expensive and time consuming, according to data from a national survey of more than 1,500 epidemiologists.

The Institute of Medicine commissioned this first-ever, large-scale survey to assess the effect of the privacy rule, which was implemented in 2003 to protect research subjects' privacy while still preserving the legitimate use and disclosure of their health information. The findings confirm those of case reports and smaller or single-institution studies: The privacy rule's overall effect on research has been more negative than positive, said Dr. Roberta B. Ness of the University of Pittsburgh and her associates.

The rule requires researchers to obtain written authorization to access medical records or to obtain a waiver from an institutional review board (IRB). In practice, compliance entails following and documenting complex bureaucratic procedures—particularly patient consent—that complicate the research process.

A total of 1,527 epidemiologists from academia, industry, government, and nongovernment organizations completed the anonymous Web-based survey, which elicited both positive and negative feedback on the privacy rule.

Three major themes emerged from the responses.

First, a solid majority "expressed frustration and concern that the implementation of the privacy rule had added patient burden without substantially enhancing privacy protection." In the words of one respondent, an "already cumbersome patient consent form now has an additional [page and a half] explaining HIPAA restrictions. This detracts from the informed consent process pertaining to the more critical issue: the actual medical risks and benefits of participating."

Nearly 70% of respondents said that complying with the rule made their work much more difficult; an additional 16% said it made their work more difficult. In all, 40% said the rule greatly increased costs, and another 21% said it raised costs moderately. And half said it added considerably to the time needed to complete studies, while an additional 20% said it required extra time. Only 10% said that the rule strengthened public trust, and only 25% said it enhanced patient confidentiality.

Second, research institutions varied widely in their interpretation of privacy rule regulations. This impeded multicenter projects, and left many researchers confused about what research their IRB might or might not sanction. As many as one in nine epidemiologists (11%) had conceived of a study but did not submit it to an IRB because they thought it would not obtain approval under the HIPAA privacy rule, Dr. Ness and her associates said (JAMA 2007;298:2164-70).

Third, compliance with the privacy rule slowed research to such a degree that half of the respondents felt it is "seriously affecting" public health surveillance, which may threaten the ability to combat epidemics and other dangers. As one respondent noted, "I and my staff spend more and more time doing compliance-related things and less and less time doing actual research." ■

Know Your Responsibilities in Handling Vaccine Information

BY SHERRY BOSCHERT
San Francisco Bureau

SAN FRANCISCO — If you're not giving parents a copy of a Vaccine Information Statement every time they accept or reject a child's immunization, you're not meeting your obligations under the National Vaccine Injury Compensation Program and could be increasing your legal liability, Dr. Kristina Bryant advised.

The no-fault civil litigation system known as the National Vaccine Injury Compensation Program (NVICP) has benefited U.S. physicians since 1988 by reducing injury claims against vaccine manufacturers and, the American Academy of Pediatrics (AAP) believes, against health care providers, said Dr. Bryant of the University of Louisville (Ky.).

If an injury that's listed in the program's Vaccine Injury Table occurs within a specified time after immunization, claimants must file for compensation through the NVICP to cover costs for medical care, pain, and suffering before pursuing a civil lawsuit. The program streamlines reimbursement for claimants, and those who get awards cannot file a suit.

"We get some benefit from this, and we have responsibilities" for communication and documentation that are spelled out by the AAP and the Centers for Disease Control and Prevention, Dr. Bryant said at the annual meeting of the AAP.

She suggested providers discuss the benefits and risks of the vaccine being administered, and that they note in the chart that the issues were discussed.

Give parents the current version of the Vaccine Information Statement each time you administer a covered vaccine. Handing it to them once and then making copies available in exam or waiting rooms during subsequent immunization visits is not enough. The most current versions can be found at www.immunize.org or at www.cdc.gov/nip/publications/VIS/default.htm.

Document in the patient's chart the date of vaccine administration, the vaccine manufacturer, the vaccine lot number, your name and business address, the date of the Vaccine Information Statement version, and the date you gave parents the statement. An informal poll of the audience at Dr. Bryant's presentation suggests that perhaps 25% of physicians do not document the version of the statement given to parents, and the date it is given to them.

If a parent refuses a child vaccination, discuss the risk that the child will pose to others and the risk of disease and potential death for the child, and document in the chart that you addressed these topics, Dr. Bryant said. Requirements for obtaining informed consent vary by state, so be familiar with your state's regulations, she added.

Review the risks and benefits of vaccination at each encounter and provide a Vaccine Information Statement. At every refusal, ask the parent to sign the NVICP Refusal to Vaccinate form, which can be obtained at www.cispimmunize.org.

On the second page of the form, parents attest that they have read the Vaccine Information Statement, have had the opportunity to discuss this with the child's doctor or nurse, and recognize that the child could contract the illness that the vaccine is meant to prevent, and could face consequences such as pneumonia, need for hospitalization, brain damage, meningitis, or death.

Some antivaccine Web sites advise parents to cross out portions of the Refusal to Vaccinate form, or to write comments in the margins about points of disagreement. Some parents even refuse to sign the form. Providers should document that they've shown parents the form and discussed risks and benefits, and that the parents refused to sign, Dr. Bryant said.

A physician in the audience said many pediatricians in his area have gone along with insurance carrier demands that patients who don't want to be vaccinated be asked to leave the practice. Dr. Bryant said the AAP urges physicians to avoid discharging vaccine refusers if possible.

Dr. Bryant is associated with several companies that make vaccines. She is on the speakers bureaus of Sanofi Pasteur and Abbott Laboratories, and she has received research funds from Merck & Co., MedImmune Inc., Wyeth Pharmaceuticals, and GlaxoSmithKline Inc. ■