Privacy Regulations Have Mixed Impact on Cancer Research Community

Almost 2 years after new federal regulations pertaining to the privacy of health care information went into effect, cancer researchers continue to cite a heavy paperwork burden and pervasive uncertainty regarding the regulatory requirements as potential impediments to cancer research.

After gearing up to meet the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), institutions say that conventional clinical trials generally have continued in a business-as-usual manner. However, uncertainty continues to swirl around other types of research, including studies involving stored specimens, gene array analysis, epidemiologic investigations, and behavioral studies. Additional uncertainty surrounds sharing of information among institutions.

“I think everyone agrees that privacy of patient information is a good thing,” said James Armitage, M.D., the Joe Shapiro Professor of Medicine at the University of Nebraska Medical Center in Omaha. “However, an unanticipated side effect of the privacy rules has been the impact on various aspects of research.”

“Lawyers for universities around the country are scared to death about violating HIPAA because the punishment for doing so can be quite significant,” added Armitage, who also is a member of the National Cancer Advisory Board (NCAB), which has been at the center of discussions regarding the impact of HIPAA on cancer research. “People are not pursuing some things that they would have done in the past as a matter of routine.”

The HIPAA regulations went into effect in April 2003. The privacy rules established procedures for the acquisition, use, storage, and disclosure of individually identifiable health information in paper or electronic form. The rules cover all aspects of health information including diagnoses, tests, treatments, and use of specimens for research purposes. Under most circumstances, disclosure of protected information requires written informed consent of the patient. Patients have the right to request access to their records and to correct inaccuracies. Patients also have the right to know whether their records have been accessed for nonroutine purposes. (See also News, Vol. 94, No. 20, p. 1521.)

Following implementation of the HIPAA regulations, the NCAB ad hoc subcommittee on patient confidentiality sought feedback from the cancer community about the impact of the regulations on cancer research. In its report, the subcommittee said members of the research community who responded to that public comment initiative “expressed a strong overriding concern that the rule and its implementation are wreaking havoc on crucial aspects of cancer research. … In short, respondents reiterated their belief that HIPAA is severely derailing ‘the progress of knowledge.’”

A year after the NCAB subcommittee released its report, investigators give a mixed review to the impact of HIPAA on cancer research.

“When the rules came in, there was an enormous amount of work required to change all of our consent forms so that they became HIPAA compliant,” said Maurie Markman, M.D., vice president for clinical research at the University of Texas M. D. Anderson Cancer Center in Houston. “We had to convert them over a short period of time. Now, we make sure that every protocol and every consent form is HIPAA compliant. It is part of the regular work load.”

Markman also said the privacy regulations have not had obvious impact on recruitment of patients into clinical trials.

“That doesn’t mean there haven’t been any problems, concerns, or frustrations involving individual protocols or patients,” he said. “However, we have the impression that, other than the additional work required to make sure we’re HIPAA compliant and the initial conversion effort, that the regulations have not had a major impact on our ability to conduct trials.”

At Christiana Care Health System in Newark, Del., patient accrual in clinical trials has actually increased since implementation of HIPAA regulations. The proportion of patients participating in clinical trials has increased from 17% to 23% within the past year.

Jerry Castellano, Pharm.D., corporate director of the Christiana institutional review board, credits a proactive approach toward HIPAA and patient privacy issues for the growth in patient accrual to clinical trials. HIPAA regulations added an additional page to the typical adult oncology consent form, which research nurses take directly to community-based physicians who work with Christiana on many of the health system’s protocols. The nurses work closely with community oncologists to identify patients appropriate for clinical trials and then obtain the necessary consent.

“HIPAA requires you to let the individual participating in the clinical trial know exactly what information is going to be collected, what information is to be disclosed, and who has the authority or right to inspect an individual’s medical records and research records,” said Castellano. “In terms of full disclosure, I think that has been a very positive step.”

HIPAA has posed more problems for epidemiologic studies, said Castellano. Investigators working with existing databases have found the HIPAA regulations more cumbersome and restraining in terms of obtaining consent and complying with requirements related to access to data.
At the American Society of Clinical Oncology meeting last June, investigators at Northwestern University Medical Center in Chicago presented findings that indicated HIPAA regulations had tripled the cost and time required for patient recruitment in a behavioral intervention trial. The findings were based on an assessment that occurred during the first months after implementation of HIPAA. A follow-up evaluation after the ASCO presentation showed that patient accrual and imputed costs had returned to near pre-HIPAA levels. The return to the norm occurred after investigators adapted to HIPAA-mandated changes in the way investigators could approach patients about participation in the trial, said Michael Wolf, Ph.D., an assistant professor at Northwestern’s Robert H. Lurie Comprehensive Cancer Center in Chicago.

The Northwestern group has also seen some of the legal confusion suggested by Armitage. “As we’ve done research at other sites that are under other [institutional review boards], we realize that how each institution recognizes and implements HIPAA is dramatically different,” said Wolf. “That’s a real problem.”

Getting institutions to agree on the language for informed consent has been a problem, said Amelie Ramirez, Dr.P.H., who chaired the NCAB ad hoc subcommittee that conducted the public comment after HIPAA was implemented. Additionally, the HIPAA requirements have added to problems related to making consent forms understandable for many patients.

“We’re using language that HIPAA says we have to include, but it has not been developed in a 4th or 5th grade reading level,” said Ramirez, a professor of medicine at Baylor College of Medicine in Houston. “A lot of people are just signing the consent forms without reading them because they find the forms kind of overwhelming.”

The wording mandated by HIPAA also creates unintended problems. For example, the consent form for a tobacco survey for school children mentioned that the study would cause no harm, a statement mandated by the regulations. Ramirez said the reference to lack of harm served no useful purpose but raised concern among some parents and made them reluctant to allow their children to participate in the survey.

HIPAA has caused major headaches for research programs that are based on
banked tissue or specimens, said Kenneth Cowan, M.D., director of the cancer center at the University of Nebraska Medical Center. His own institution has an extensive lymphoma program that includes 25,000 specimens collected from 3,000 patients. When HIPAA went into effect, each patient had to be contacted again to obtain consent to use the tissue for research purposes.

“The lymphoma study network involves a large consortium of doctors, institutions, and community hospitals,” said Cowan, who is the current chair of the NCAB ad hoc subcommittee on patient confidentiality. “We had to go through all the physicians and contacted all the patients and explain that we’re asking them to sign a new consent form. Tracking down all these patients has been a lot of work. I know it has had an adverse impact on research, but it had to be done.”

The NCAB forwarded to Health and Human Services Secretary Tommy Thompson the subcommittee report, which included suggested modifications to the HIPAA privacy rule. The subcommittee members stated that the most urgent need is “the refashioning of authorization, accounting of disclosures, waivers, and recruitment procedures currently faced by researchers under HIPAA.” The subcommittee also asked for clarification of the HIPAA privacy rule to make it more understandable by investigators and patients and to avoid inconsistent interpretation.

In a February 2004 response to NCAB, Thompson referred the members to various informational pieces developed by the department. Thompson wrote, “I believe that the educational materials we have made available, along without efforts to promote voluntary compliance and the continuing experience of covered entities and researchers with the rule, will go a long way to easing overly restrictive policies and reducing potential barriers to the conduct of research.”

According to Cowan and to NCAB Executive Secretary Paulette Gray, Ph.D., further discussion of the HIPAA regulations is not on the agenda for future NCAB meetings.

—Charles Bankhead