



Barely beating. Patient privacy laws could shut down a heart study led by Minnesota epidemiologist Russell Luepker.

PATIENT PRIVACY

Rule to Protect Records May Doom Long-Term Heart Study

Researchers are still grappling with how to conduct medical studies while complying with federal and state laws to keep patient data private

For 25 years, heart disease researchers have tapped the medical records of more than 40,000 Minnesotans for findings on everything from sex differences in heart attack survival to the role of cholesterol-lowering drugs in saving lives. But the well may be drying up: State and federal privacy laws could make it impossible for epidemiologists at the University of Minnesota, Twin Cities, to continue to collect the hospital data they need.

The problem stems from a federal privacy rule that took effect 3 years ago and that affects biomedical researchers around the country. The rule “still is slowing down or substantially discouraging researchers from certain studies,” says Susan Ehringhaus, associate general counsel for regulatory affairs of the Association of American Medical Colleges (AAMC). Prominent on that list is the Minnesota Heart Survey, which periodically reviews patient records from hospitals around Minneapolis to analyze factors in heart disease and stroke survival such as ethnicity, procedures, and medications. “They’re leaders on this,” says epidemiologist Steven Shea of Columbia University. “We would lose a very important, very high-quality lens on what’s going on over time.”

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA) to make it easier for people to retain or switch their health insurance coverage. In April 2003, the Department of Health and Human Services (HHS) began to implement one provision, called the Privacy Rule, that gives patients access to their medical records and restricts how health care providers use them (*Science*, 9 July 2004, p. 168).

One key change from existing practices requires researchers outside the provider organization to obtain written consent from each patient in order to use the patient’s records or, if that is impractical, to get a waiver from their institutional review board (IRB). Researchers can also receive a data set stripped of identifying information. The onus is on health care providers, who can be fined or jailed for violating the rules.

A National Institutes of Health (NIH) spokesperson says most researchers have received waivers and managed to continue their studies. But the law continues to lead to delays, say some researchers, and a review of HIPAA in the February 2006 *Annual Review of Medicine* suggests that the higher costs—the government has estimated \$600 million over 10 years—is causing researchers to revise or scrap some studies out of concern the work will become prohibitively expensive.

The Minnesota Heart Survey is one example of a study that has been hit particularly hard by the double whammy of federal and state laws. Investigators need identifiers such as Social Security number and birth date to match the medical data with death records, says principal investigator Russell Luepker. Although hospitals once allowed his team to view patient files, he paid a research foundation affiliated with the hospitals to collect the data after Minnesota implemented a new privacy rule in 1997. Last summer, however, the foundation folded, and Luepker hasn’t found a replacement.

Luepker can’t simply get an IRB waiver to HIPAA because Minnesota’s privacy law requires

each patient to give consent. The hospitals ask patients to sign a general consent for use of their records, but it’s not easy to get written consent from a sick person admitted to a hospital for a heart attack or stroke, notes Luepker. Not everyone returns mailed consent forms, he adds, and some hospitals are even reluctant to send them.

So Luepker has been talking to lawyers from each of the 22 hospitals to work out a way to obtain the identifiers even for patients who haven’t signed a form. If that approach fails, Luepker says he won’t apply for a renewal of two large NIH grants that expire in June. “I’m quite frankly very worried,” Luepker says about a situation first reported by *The Minneapolis Star Tribune*. “For us it’s quite bad. This long-running study may stop running, and we’re vain enough to think it’s produced some very good information.” Luepker says a related telephone population survey will continue.

Other studies face new limitations as institutions interpret their responsibilities under HIPAA. For example, at the University of Michigan, Ann Arbor, researchers who once recruited subjects for a survey of acute coronary disease care by telephone had to get their written permission first. In a 23 May 2005 paper in the *Archives of Internal Medicine*, Kim Eagle and others reported that consent rates dropped from 96% to 34% when they switched from phone calls to mail. Subjects also tended to be older, healthier, and married. Roberta Ness of the University of Pittsburgh in Pennsylvania says she must now rely on patients’ doctors to recruit prospective patients for preeclampsia and cancer studies.

Studies that pool data from many centers are also feeling the impact of HIPAA. An Alzheimer’s disease consortium’s database of clinical data on patients that’s used to develop better diagnostics and treatments has been delayed while contributing researchers obtain

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IRB waivers to record the ages of subjects over 90, says one investigator who asked not to be named. An international trial of a drug for brain injury was hamstrung by the refusal of many U.S. hospitals to divulge ages, the exact time of injury, and other data on patients screened for the trial, reported a Dutch team in the February 2006 issue of *Intensive Care Medicine*.

Efforts to ease the load on researchers have so far been unsuccessful. For example, in 2004 a panel that advises the HHS Office for Human

Research Protections recommended nine changes, including eliminating a requirement that hospitals account for each use of a patient's data for research; shortening the list of identifiers; and allowing patients in a study approved under the federal Common Rule, which protects human subjects, to authorize use of their data for future, unspecified research. "There is still a need to bring some sense to these regulations," says former panelist attorney Mark Barnes of Ropes & Gray in New York City. AAMC has

gone further, urging that any research already approved under the Common Rule should be exempt. The HHS Office of Civil Rights says its staff "continues to listen to the concerns of the research community" and is working with researchers "to enable important research to move forward."

Meanwhile, researchers are doing their best to get by. The University of Michigan's IRB, for example, eventually allowed Eagle's team to send prospective patients a letter saying their

records could be part of the survey unless they mailed back a postcard to opt out. Only 5% have objected, says Eagle, and many "are delighted that we're doing the study." New York University's Douglas Morse, who's had trouble finding patients for an oral cancer study in Puerto Rico through pathology labs, says that life under HIPAA is like coexisting with an infected toe. "You might be able to get around, ... but the result might not be everything you hoped for."

—JOCELYN KAISER

RESEARCH FUNDING

China Bets Big on Big Science

For a few lucky research fields, a new government road map for science is like winning the lottery

BEIJING—He Fuchu, a major general in the People's Liberation Army, is combat ready. "Advanced countries compete fiercely to control the high ground in protein research," says He, using military jargon to describe his primary objective as director of the Beijing Protein Research Center. Now He, a vice president of the Chinese Academy of Military Medical Sciences, is about to get a substantial war chest to fund his center's research in proteomics, a big winner in China's new 15-year plan for science and technology (S&T).

The long-awaited S&T plan, a set of marching orders handed down to scientists last month, may set the tone of science in China for years to come. It specifies 16 major engineering projects, including design of large aircraft, moon exploration, and drug development. Four major basic research programs are highlighted: protein science, topics in quantum

physics, nanotechnology, and developmental and reproductive science. Although not stated in the plan, R&D spending by all sources, industry included, will rise from 236 billion yuan (\$30 billion) in 2005 to 900 billion yuan (\$113 billion) in 2020, Chinese officials announced last month. Basic research is slated to climb from 6% of R&D expenditure in 2004 to as much as 15% in 15 years.

With government coffers flush, Chinese scientists had hoped the new plan would give a bigger boost for basic research. However, "basic science is still not playing a central role in the government's mind," asserts Shing-Tung Yau, a mathematician at Harvard University. As in the past, scientific activity will be yoked tightly to economic development. "New scientific knowledge and inventions need to be industrialized and transformed," says Lu Yongxiang, president of the Chinese Academy of Sciences

(CAS). A buzzword permeating the document and on the lips of science officials is "innovation": the key, the plan states, to reducing China's reliance on imported technology and intellectual property. Industry is expected to shoulder a heavier load than it currently does. For encouragement, the plan offers companies tax incentives to spend more on R&D.

Although the details have not been filled in, the plan has been hailed as a noble attempt to reshape a landscape of patchy scientific talent into a cohesive community churning out innovations, rivaling the West. The plan is "an important platform for China to transform from the largest developing country to a world powerhouse," says Duan Yibing, a science policy expert at the CAS's Institute of Policy and Management.

Others are hesitant to jump on the bandwagon. They worry that a heavy emphasis on applied science and megaprojects will stifle creativity. "The most innovative ideas come from very few creative scientists at rare moments, whereas planning of large-scale projects requires the consensus of many scientists," says Yi Rao, a neurobiologist at Northwestern University in Evanston, Illinois, and deputy director for academic affairs of China's National Institute of Biological Sciences (NIBS). "It is unrealistic to expect very innovative science projects to come out of planning."

Muffled criticism

Drafting the S&T plan was not straightforward. Twenty working groups involving 2000 scientists and officials wrangled over the document for close to 3 years, revising it a dozen times at a cost of \$10 million. The buck stopped with Prime Minister Wen Jiabao, who chaired a ministerial committee over the working groups. Since becoming China's prime minister in March 2003, Wen has made a "scientific approach to development" a theme of his administration, backed by steady increases in R&D funding. "I believe that Prime Minister Wen had the best intentions when he decided to increase funding and, at the same time, required scientists and engineers to come up with visionary plans on how to use the funds," says Rao.

A Few of China's Billion-Dollar Babies

Major science programs

Protein science

Quantum research

Nanotechnology

Development and reproductive biology

Engineering programs

Next-generation broadband

Large-scale oil and gas exploitation

Transgenic plant breeding

Drug development

Manned moon exploration

Raising the Ante

	R&D spending (All sources, \$ billions)	Percent of GDP	Central government R&D appropriation (\$ billions)	Central government R&D appropriation (% of overall)
2004	\$24.60	1.23%	\$8.70	35%
2010	\$45.00	2.00%	\$18.00	40%
2020	\$113.00	2.50%	NA	NA

Ready for liftoff. A large share of China's R&D spending will be funneled to a favored few projects.