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same way, creating more targets for HIV. But McElrath's preliminary work found no evidence for this scenario.

Behavioral changes don't seem to provide an explanation: Study co-chair Susan Buchbinder of the San Francisco Department of Public Health said risk behaviors had decreased across the board and more so in the high–Ad5-antibody group. Buchbinder said investigators still are sorting out many variables related to HIV transmission, including circumcision, coinfection with other sexually transmitted diseases, and genetic factors.

One thing is clear: The monkey studies that suggested that the vaccine could thwart the AIDS virus, fueling much excitement, misled Merck researchers. "Mice lie, monkey sometimes lie, and humans never lie," said Peggy Johnston, head of NIH's AIDS vaccine program. "Some monkeys have lied to us this time." Other attendees stressed that Merck relied on a wimpy strain of the AIDS virus to "challenge" vaccinated monkeys and that challenges with stronger strains predicted that the vaccine would fail.

Although the mechanism remains elusive, researchers struggled with whether to tell trial participants if they received the vaccine or the placebo. A more recently launched study of the same vaccine in South Africa was stopped and quickly "unblinded" after learning the Step results, notifying everyone of their vaccine status (*Science*, 2 November, p. 729). After much debate here, Step's scientific steering committee recommended unblinding, and an oversight committee concurred on 13 November.

The specter of enhancement also affects the AIDS vaccine field's next-best hope. This NIH-made vaccine uses a similar Ad5 vector and was slated to enter a $130 million trial this fall without screening people for Ad5 immunity. "Step's results demand that we reexamine and redesign our study," said principal investigator and Step collaborator Scott Hammer of Columbia University.

Merck's Mark Feinberg warned colleagues that "the whole field will come apart at the seams" if it doesn't properly investigate and respond to the Step results. "I've never seen more complicated data to emerge from a study," Feinberg said. "And this one focuses on as important a question as I've ever known."

–JON COCHEN

EPIDEMIOLOGY

Privacy Policies Take a Toll on Research, Survey Finds

A federal rule aimed at protecting patient data is hindering epidemiology research, adding costs and delays without enhancing confidentiality, according to a study this week in the *Journal of the American Medical Association* (*JAMA*). The survey responses from 1500 epidemiologists reflect the first systematic analysis of privacy rules that researchers have complained about for 4 years.

The problems stem from the Health Insurance Portability and Accountability Act (HIPAA), passed by Congress 11 years ago to make it easier for people to transfer their health insurance. A so-called Privacy Rule that took effect in April 2003 requiring health care providers to protect the privacy of medical records also affects research. Investigators must get permission to use a patient's medical data, even to identify potential participants. If that is not possible, the researchers can try to get by with a data set stripped of identifiers, such as name and address, or they can seek a waiver from an institutional ethics board.

These requirements have had a major impact on population-based health research, according to the survey, headed by epidemiologist Roberta Ness of the University of Pittsburgh in Pennsylvania. Survey invitations were e-mailed to more than 10,000 members of 13 epidemiology societies, and 1537 of them completed a Web survey. About 68% said the Privacy Rule has made research a great deal more difficult; half reported major delays; and nearly 40% faced much higher costs (see table). Only one-quarter said the rule has greatly improved confidentiality. Of those who modified a protocol to comply with HIPAA, two-thirds said it was much harder to recruit subjects.

Epidemiologists' Views on the Privacy Rule

	None	Some	A great deal
Made research more difficult	9%	16%	68%
Enhanced confidentiality	47%	20%	26%
Added cost	22%	21%	39%
Delayed time to study completion	21%	19%	51%

Note: Based on 1527 responses.
Results total less than 100% because they do not include responses of "don't know."

SOURCE: R. NESS, *JAMA* **298**, 18 (14 NOVEMBER 2007)

Overprotected? A rule meant to ensure the privacy of medical data is hampering research, according to survey of epidemiologists.

The results support anecdotal evidence that the Privacy Rule has slowed enrollment and threatened some studies, says Ness (*Science*, 9 July 2004, p. 168; 17 March 2006, p. 1547). For example, at the University of Michigan, researchers were required to obtain consent for a survey of patients with heart disease care by mail rather than by phone, resulting in a drop in the response rate from 96% to 34% and a bias toward older, healthier, married participants. Ness's survey also suggests that U.S. surveillance of infectious diseases may be suffering because hospitals aren't sure what they can report.

Three years ago, an advisory panel urged the Department of Health and Human Services (HHS), which administers the Privacy Rule, to ease the burden on researchers by revamping the rule. The agency never formally responded. But HHS and other organizations commissioned the U.S. National Academies' Institute of Medicine (IOM) to examine the issue broadly; one of the results is the *JAMA* survey. Researchers in other disciplines have told the panel of difficulties, too. For instance, clinical oncologist Richard Schilsky of the University of Chicago Medical Center says HIPAA has been "a huge problem" for studies involving tissue samples, among others. Ness says she and her colleagues "really are hoping" that the IOM panel will devise recommendations that produce action. Its report is due by early 2009.

–JOCELYN KAISER

Privacy Policies Take a Toll on Research, Survey Finds

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