Invited Commentary


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Privacy seems to be of increasing public concern, as evidenced by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, a regulatory framework that appears to hinder access to data and thus to limit population-based research. A 2009 Institute of Medicine (IOM) report urged Congress, via the US Department of Health and Human Services (HHS), to develop a new approach to protecting privacy that would not employ the HIPAA Privacy Rule. In an accompanying article in the Journal, Nattinger et al. (1) employ one of the constructs recommended in the IOM report: use of a centralized honest broker. Unfortunately, Nattinger et al.’s approach would not be acceptable to all institutional review boards. The IOM report also urged the HHS to reduce variability in interpretations of the HIPAA Privacy Rule by privacy boards through revised and expanded guidance and harmonization. HHS Secretary Kathleen Sebelius has not acted upon any of the IOM report recommendations. The need to remove major barriers to human health research cannot be forgotten. At risk is America’s progress in finding solutions to our most pressing health concerns.

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Abbreviations: CMS, Centers for Medicare and Medicaid Services; HHS, Department of Health and Human Services; HIPAA, Health Insurance Portability and Accountability Act; IOM, Institute of Medicine; IRB, institutional review board.

How to conduct population-based health research in the era of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: that is the question addressed by Nattinger et al. (1) in this issue of the Journal. The HIPAA Privacy Rule was intended to strike a balance between protecting the privacy of personal health information and preserving the legitimate use and disclosure of this information for important social goals (2). Yet, since its enactment in 2003, concerns have been raised, and subsequently codified by a report from the Institute of Medicine (IOM) (3), that the Rule has added uncertainty, cost, and delay to health research (4). Even more concerning, the Rule may lead to nonrepresentative participation by research subjects and thereby erode study validity (5).

Against this backdrop, Nattinger et al. (1) tested a strategy involving: 1) identification of patients with likely breast cancer from Medicare claims data; 2) honest broker invitations issued to patients via the Centers for Medicare and Medicaid Services (CMS); and 3) the opportunity for respondents to “opt out” of participation, meaning that persons who did not specifically say no to further contact were contacted by the research team. Nattinger et al.’s approach did not involve the onerous step of obtaining treating physician approval to contact potential subjects. To assess the efficiency and representativeness of this approach, they calculated a response rate and compared participants and nonparticipants. The response rate was a respectable 70%, and the distributions of most demographic variables were similar between participants and nonparticipants, except that participants were younger and more likely to be from California, Florida, or Illinois than from New York State (1).
Review Board (IRB) and the CMS Privacy Board, satisfied the Privacy Rule mandate that patients must consent to the use of their protected health information. They did this by creating an honest broker interface in which only the honest broker knew who actually had breast cancer and who did not. Researchers presumably received a list of names and contact information that was unlinked to medical information.

A similar approach was highlighted in the IOM report Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (3). The IOM’s first recommendation was: “Congress should authorize HHS [the Department of Health and Human Services] and other relevant federal agencies to develop a new approach to protecting privacy that would apply uniformly to all health research. When this new approach is implemented, HHS should exempt health research from the HIPAA Privacy Rule” (3, p. 28). This new approach was proposed with all due concern about enhancing health information privacy. For instance, stipulations of the new approach include that it should require researchers and institutions that store health data to establish strong data security safeguards; require ethical oversight when personally identifiable health information is used; and certify institutions that, using best-practice procedures to protect data privacy and security, can facilitate database-leveraged research without individual consent. The honest broker used by Nattinger et al., the CMS, is an example of the use of an organization with excellent privacy practices that, under a new approach, might be certified to facilitate health research from a major, national database.

Nonetheless, in a much-quoted editorial, Rothstein questions the IOM’s approach, saying, “Besides the myriad ethical and policy issues raised by this proposal… it is impossible to support replacing the current regulatory regime, notwithstanding its flaws, with such a vaguely described successor” (6, p. 508). Rothstein questions the assertion that the HIPAA Privacy Rule mandate to obtain consent prior to the research use of medical records may lead to biased results; posits that database research poses a broad array of psychological and social risks to subjects and that lack of individual consent eliminates subject autonomy; and interprets the report as a move away from ethical oversight when personally identifiable health information is used; and certifies institutions that, using best-practice procedures to protect data privacy and security, can facilitate database-leveraged research without individual consent. The honest broker used by Nattinger et al., the CMS, is an example of the use of an organization with excellent privacy practices that, under a new approach, might be certified to facilitate health research from a major, national database.

A separate component of Nattinger et al.’s recruitment strategy was that subjects were given the choice to opt out of study participation, rather than having to opt in. This approach is not restricted by the Privacy Rule per se but is of concern to many IRBs, which limit “cold calling.” Many, but not all, IRBs consider direct contact in the absence of physician agreement and in the absence of an opt-in approach to be overly intrusive. This raises one of the most concerning issues pertaining to current strategies for conducting human subjects research: All research is local. The rules and requirements imposed by various IRBs are variable. In a study by Ness et al. (4) on the influence of the HIPAA Privacy Rule on health research, epidemiologists from around the country reported wide variation in how their IRBs would have responded to cases involving medical records, registries, tissue banks, deceased subjects, and limited data sets. In multisite studies, a protocol acceptable to one IRB may be unacceptable to another. Specifically, Nattinger et al.’s protocol was acceptable at the Medical College of Wisconsin but may not be acceptable at your institution. Thus, the IOM report recommends that if national policy-makers continue to apply the HIPAA Privacy Rule to research, “HHS should reduce variability in interpretations of the HIPAA Privacy Rule in health research by covered entities, IRBs and privacy boards through revised and expanded guidance and harmonization” (3, p. 28). This would involve education, greater use of limited data sets, clarifying the distinction between research and practice, and simplifying provisions related to the use of personal health information preparatory to research.

Unfortunately, the IOM report has sat on a shelf since its publication in early 2009. A letter written by the Joint Policy Committee of the Societies of Epidemiology requesting that HHS Secretary Kathleen Sebelius seriously consider the IOM’s recommendations (unpublished correspondence) was met with a form letter. No action towards consideration of the recommendations has been taken.

The final line of the Joint Policy Committee letter read, “Our hegemony in science and innovation remains one of our most valued attributes as a nation. We ask that you act on the recommendations of the IOM report in order to protect citizen privacy while promoting our ability to advance the nation’s health.” We can only hope that Secretary Sebelius someday appreciates the risk to America’s progress in research if this country continues to be weighted towards privacy concerns over the legitimate use of health information for important social goals.

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REFERENCES


