

Patient Privacy and Journals: The Challenges of HIPAA and Other Privacy Laws

Panelists:

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Two questions permeated the session on patient privacy and journals:

- What is the duty of a journal with regard to privacy of patients?
- How do patient-privacy laws (for example, the Health Insurance Portability and Accountability Act of 1996, HIPAA) affect the workings of a journal?

How journals address patient privacy has evolved substantially over nearly 200 years, said Faith McLellan. McLellan displayed historical examples of journal articles that highlight a trend from full and complete patient identification (1823), to partial obscurity (a 1917 article that identifies the patient by initials and employment information), to the current standard of a full effort at preservation of anonymity. The effort at preservation of anonymity is best exemplified by the phrase “nothing

about me, without me”, McLellan said. In other words, journals must take the patient’s point of view when obtaining consent and preserving privacy. The presentation concluded with a question about the potentially changing role of medical journals: possibly to serve as an educational and informational resource to authors and researchers about patient-privacy concerns and to fulfill an obligation to patients to maintain existing privacy standards.

Harold Sox followed with a detailed explanation of HIPAA. The privacy rules of HIPAA, which took effect in 2003, may have implications for scientific publishing. Data in a medical chart, test results, and billing information all constitute federally identified “personal health information (PHI)”, Sox said. HIPAA restricts the disclosure of PHI between covered entities, specifically including doctor’s offices and insurance companies, without the patient’s authorization. Medical journals are not covered entities and therefore may not be subject to HIPAA disclosure regulations when they publish potentially identifiable PHI.

An important implication of HIPAA for journals is the distinction between informed consent and authorization to disclose PHI, Sox said. Informed consent may contain elements of agreement to participate in research and permission to disclose results; a problem may result in the case of research activities in which consent is not required. For example, publishing billing-claim studies, quality-of-life research, and patient-registry information may provide useful information to physicians. Yet in these forms of research, patients may not be required to provide informed consent

and therefore may not be authorizing anyone to transfer PHI under HIPAA; this could pose problems for the research community, including reduced availability of research results and a less representative pool of research subjects, Sox said.

Virginia Barbour began her presentation by succinctly outlining the challenges facing patient privacy in light of technology’s having made medical information readily available to physicians, patients, journalists, and commercial organizations. Barbour focused on global responses to those challenges. The UK General Medical Council, the International Committee of Medical Journal Editors, and the World Medical Association (WMA) have each developed statements calling for the requirement of patient consent in the disclosure of identifiable patient information. A 2002 follow-up statement from WMA extends the statement to cover identifiable patient information residing in databases.

What, then, constitutes consent for a journal? Barbour provided examples of consent forms from the *Journal of the American Medical Association*, *The Lancet*, *PloS Medicine*, and the *BMJ*. The common elements of a high-quality consent form are that the patient has read the paper, understands that complete anonymity is impossible to guarantee, and has received an explanation of how the data are to be disseminated; and that the author has signed the form. Barbour concluded that the legal environment in which journals operate for consent has not changed, although journals have a moral duty to ensure that consent is obtained. 