Other Articles

Medical Records and Privacy: Empirical Effects of Legislation

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Objective. To determine the effects of state legislation requiring patient informed consent prior to medical record abstraction by external researchers for a specific study.

Data Sources/Study Setting. Informed consent responses obtained from November 1997 through April 1998 from members of a Minnesota-based IPA model health plan.

Study Design. Descriptive case study of consent to gain access to medical records for a pharmaco-epidemiologic study of seizures associated with use of a pain medication that was conducted as part of the FDA's post-marketing safety surveillance program to evaluate adverse events associated with approved drugs.

Data Collection. The informed consent process approved by an institutional review board consisted of three phases: (1) a letter from the health plan's medical director requesting participation, (2) a second mailing to nonrespondents, and (3) a follow-up telephone call to nonrespondents.

Principal Findings. Of 140 Minnesota health plan members asked to participate in the medical records study, 52 percent (73) responded and 19 percent (26) returned a signed consent form authorizing access to their records for the study. For 132 study subjects enrolled in five other health plans in states where study-specific consent was not required, health care providers granted access to patient medical records for 93 percent (123) of the members.

Conclusion. Legislation requiring patient informed consent to gain access to medical records for a specific research study was associated with low participation and increased time to complete that observational study. Efforts to protect patient privacy may come into conflict with the ability to produce timely and valid research to safeguard and improve public health.

Key Words. Medical records, privacy, confidentiality, informed consent

Growing public concern about privacy in the computer era is engendering legislative proposals to strengthen existing confidentiality protections for patient medical records. In this policy environment, questions arise about how to balance societal values respecting individual privacy—essential to

ensure patient trust in the care process—while at the same time allowing access to information that is essential for scientific research to improve health and health care (Congressional Research Service [CRS] 1998). There is little empirical evidence to inform these policy considerations.

Proposed individual privacy protections affecting research fall into two general categories: (1) those requiring patient informed consent to gain access to medical records for research generally or for specific studies; and (2) those requiring procedural review before granting access, such as approval by an institutional review board (IRB). Such protections are intended to ensure that access to medical records respects patient autonomy, safeguards patient confidentiality, and serves a socially valued purpose.

The principle of informed consent is a long-standing ethical protection in human subjects research involving an intervention or interaction that risks harm to an individual (Belmont Report 1979). However, the use of existing medical records for observational research poses no risk of physical harm and minimal risk to privacy. For this reason, the current Federal Policy for the Protection of Human Subjects (1991) exempts retrospective medical records research from IRB review when patients are not identified. When research is subject to review, an IRB may waive informed consent requirements under certain circumstances.

Some commentators argue that any use of medical records without consent constitutes a breach of trust (Capron 1991). In support of this argument, a 1993 Harris poll found that 64 percent of the respondents objected to the use of their medical records for research without their consent (Institute of Medicine [IOM] 1994). Other observers argue that obtaining consent to use medical records is not always feasible, especially in epidemiologic studies, and may harm the public if it impedes important health research. Thus, society may decide that the benefits of research access outweigh the intrusion into

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privacy if there are adequate oversight and confidentiality protections (Melton 1997; National Committee on Vital and Health Statistics [NCVHS] 1997).

The State of Minnesota recently passed a law that provides an opportunity to study the effects of requiring patient consent before making access to medical records available for research (see Figure 1). Melton (1997) reported that 96 percent of Mayo Clinic patients who returned consent forms under this law gave general authorization for the use of their medical records in research. It is not known whether Mayo's experience is representative given its unique reputation as a research institution. Moreover, for practical reasons the Minnesota law has been interpreted to require patient consent for a specific study in some noninstitutional settings. This article examines the effect of a study-specific consent requirement on observational research in a health plan environment.

The context for this case study was a pharmaco-epidemiologic study to determine the risk of seizure associated with the use of a newly marketed oral analgesic medication. This research was conducted under a Cooperative Agreement with the U.S. Food and Drug Administration as part of federal postmarketing surveillance efforts to determine the scope and severity of adverse events associated with approved drugs. The FDA requests these studies on an ad hoc basis given a need for fairly rapid, population-based analysis to evaluate spontaneous reports of adverse reactions received from hospitals and health care professionals. The substantive results of these studies help the FDA determine whether additional warnings or restrictions are warranted to help avoid unwanted treatment consequences; thus, such results have potentially significant public health implications for ensuring the safety of the nation's prescription drugs.

METHODS

Data on patient informed consent are from a Minnesota health plan that was one of several plans, located in multiple states, that participated in this study with the Center for Health Care Policy and Evaluation (the "Research Center"). The health plan is a large independent practice association (IPA) health maintenance organization that has under contract numerous physicians and hospitals in the community. Health plan administrative claims used in the first stage of the study consisted of longitudinal pharmacy, medical, and enrollment files that were linked by unique encrypted identifiers. Medical records used in the second stage of the study are maintained by physician offices and hospitals.

Figure 1: Minnesota Law 144.335–Access to Health Records

Subdivision 3–Patient Consent to Release of Records (Effective 1/1/97)*

(d) Health records may be released to a researcher solely for purposes of medical or scientific research only as follows:

(1) health records generated before January 1, 1997, may be released if the patient has not objected or does not elect to object after that date;

(2) for health records generated on or after January 1, 1997, the provider must:

(i) disclose in writing to patients currently being treated by the provider that health records, regardless of when generated, may be released and that the patient may object, in which case the records will not be released; and

(ii) obtain the patient's written general authorization that describes the release of records in item (i), which does not expire but may be revoked or limited in writing at any time by the patient or the patient's authorized representative; and

(3) authorization may be established if an authorization is mailed at least two times to the patient's last known address with a postage prepaid return envelope and a conspicuous notice that the patient's medical records may be released if the patient does not object, and at least 60 days have expired since the second notice was sent; and the provider must advise the patient of the rights specified in clause (4); and

(4) the provider must, at the request of the patient, provide information on how the patient may contact an external researcher to whom the health record was released and the date it was released. In making a release for research purposes the provider shall make a reasonable effort to determine that:

(i) the use or disclosure does not violate any limitations under which the record was collected;

(ii) the use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which the use or disclosure is to be made;

(iii) the recipient has established and maintains adequate safeguards to protect the records from unauthorized disclosure, including a procedure for removal or destruction of information that identifies the patient; and

(iv) further use or release of the records in individually identifiable form to a person other than the patient without the patient's consent is prohibited.

**Note: Clause (d)(3) was amended effective 1/1/98.*

In the first stage of the study, a cohort of 9,377 users and 37,367 nonusers of the oral analgesic (matched at a 4:1 ratio) were identified from the pharmacy claims of 12 health plans. Seizure outcomes were identified from physician and facility claims for each group. In the user group, a medical records study was conducted to verify seizure case and non-case status and to collect information on potential confounding risk factors, such as head injury or stroke, that might account for the occurrence of seizures. The medical record study population included 89 members from six health plans with claims indicating a potential seizure (cases) and 178 members with no seizure claims (non-cases, who were randomly selected at a 2:1 ratio to cases). Of these 267 medication users identified for medical record review, 140 (45 cases and 95 non-cases) were enrolled in the Minnesota health plan and were subject to the state's informed consent requirements.

The health plan's medical director sent a letter to each of the 140 Minnesota plan members in November 1997, requesting their participation. The letter explained that the purpose of the study was to improve the potential safety of pain medication, that participation carried no direct benefits or risks, that records would be kept confidential, and that medical care and insurance would not be affected. Contacts for explanations of the research also were provided. The members were asked to sign and return an enclosed consent form indicating whether or not they wished to authorize access to their medical records for the study. A second letter was sent six weeks later (January 1998) making the same request to those who did not respond to the first letter. Follow-up phone calls were made by health plan personnel between February and April 1998, to those who did not respond to either letter, encouraging them to return the consent form. No monetary incentive was offered at any stage of the consent process. The health system's IRB approved all procedures used to inform and obtain consent from plan members. Data were analyzed in aggregate, and individuals were not identified in the results.

RESULTS

After the first request letter, 43 (31 percent) of the 140 Minnesota health plan members responded with a signed consent form: 19 (14 percent) authorized access to medical records and 24 (17 percent) declined. After the second request letter, 13 additional members responded, with four agreeing to participate and nine declining. (A tally of cumulative responses is shown in Table 1). Ten letters were undeliverable. After follow-up telephone calls to

74 nonresponding members, an additional three members returned consent forms permitting use of medical records and 14 orally declined. Ten members contacted by phone said they would return the consent form; however, no form was received. The remaining 47 members could not be reached directly by phone. Thus, a cumulative total of 73 (53 percent) of the 140 Minnesota plan members responded after two letters and a phone call, with only 26 (19 percent) authorizing the use of medical records and 47 (34 percent) declining. The participation rate varied slightly among seizure cases and non-cases. For the 132 study subjects enrolled in the five other health plans in states where study-specific consent was not required, health care providers granted access to patient medical records for 93 percent (123) of the members based on a general enrollment authorization.

DISCUSSION

Requiring patient informed consent to gain access to medical records for a specific research study was associated with a low participation rate among members of one health plan in this observational study. Low participation is problematic in epidemiologic research because it compromises the ability to generalize from the results. That is, those who declined to respond or to authorize access to medical records may be different in a clinically significant way from those who did authorize the use of their records, in such a way that the results may not be representative of the entire study population. In comparison, other pharmaco-epidemiologic studies done for the FDA have had excellent rates of medical record abstraction completion where study-specific patient consent was not required.

The low rate of agreement to grant access to medical records may reflect various dynamics. Because the benefits of observational research of this nature are necessarily indirect, those who have not experienced an adverse event may not have an interest in the research that justifies returning the consent form. Those who have experienced a seizure may be hesitant to participate if they fear consequences such as a potential loss of driving privileges or insurance should their confidentiality not be respected as promised. Low participation also may reflect, to some degree, the public's general privacy concerns.

In this case study, the extra time (four months) and effort required to complete follow-up consent requests (second mailing and phone calls) did not increase the participation rate appreciably. After this study had been

Table 1: Cumulative Responses to Request for Consent After each Phase of Contact, by Case and Non-case Status, Total and Percent of Grand Total

	Cases	*Non-Cases*	*Cumulative Response Rate* (% of Total)
After First Letter			
Yes	7	12	19 (14%)
No	5	19	24 (17%)
Subtotal	*12*	*31*	*43 (31%)*
After Second Letter			
Yes	7	16	23 (16%)
No	7	26	33 (24%)
Subtotal	*14*	*42*	*56 (40%)*
After Phone Calls			
Yes (written responses only)	9	17	26 (19%)
No (including oral responses)	12	35	47 (34%)
Subtotal	*21*	*52*	*73 (52%)*
No response after phone contact	*5*	*5*	10 (7%)
No direct contact (mail or phone)	19	38	57 (41%)
Grand Total	*45*	*95*	*140 (100%)*

Yes = member authorized access to medical records (written consent only).
No = member declined to authorize access (written and oral responses).
Cases = medication users with a medical claim indicating a seizure outcome.
Non-cases = medication users with no seizure claim.

approved by the IRB and was under way, the Minnesota legislature amended the law to allow implied authorization to be established for the use of medical records if the patient has not responded within 60 days after two good faith attempts to gain consent (see clause (d)(3) in Figure 1). If that provision had been followed in this study design, the participation rate might have been higher, but actual experience is needed to examine such an approach.

This experience provides an example of the tension between protecting the public health and protecting patient privacy. Obtaining informed consent may increase patient trust, but the resulting delay in obtaining research results and the low rate of participation could prove detrimental to timely and informed decision making by public health authorities. Although this article involves only a single case study, it suggests that legislation requiring informed consent for medical records access for specific studies may have unintended consequences on the ability of researchers to conduct observational research

in similar health plan settings. The implications for society are noteworthy, since this health care delivery environment offers important advantages for conducting population-based research of this nature. The health plan's large network and organized database allows for timely evaluation to identify the relatively rare health effects and their associated service utilization that are generally reflective of the community practice of medicine.

Further research in other settings is needed to compare this experience with other methods of requesting patient consent and with different types of research questions and study environments. For example, in this study the health plan's medical director requested participation based on the plan's contractual relationship with the member. Another method would be for the health plan to seek the cooperation of physicians in requesting consent from their patients. Research is needed to determine the effect of this approach on participation rates or on whether physicians are generally willing to perform this role. Researchers may wish to consider publishing secondary analyses of the results of informed consent requirements imposed by IRBs for other medical records studies. Comparing these experiences may help determine whether patients have a consistent philosophy toward giving consent to use medical records in specific cases.

Public discussion is needed regarding the value of including information from medical records in research. It is critical to find the mechanism of accountability that will assure confidence by citizens that research will protect patient confidentiality adequately and will also serve a socially useful purpose that justifies an intrusion into privacy. As this case study shows, the method selected may have important implications on the ability to obtain timely and valid knowledge to safeguard and improve the public's health.

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