Family Caregiver Research and the HIPAA Factor

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Research in family caregiving recently has become more challenging because of the strict protection of privacy mandated in the Health Insurance Portability and Accountability Act (HIPAA) of 1996. We ask when should Institutional Review Boards (IRBs) follow HIPAA rules to the letter and when might they use the waiver option? What is the appropriate balance between the goals of protecting the privacy of patients’ personal health information and facilitating family-caregiver research that may benefit them and others? More particularly, should patients be gatekeepers for caregiver participation in minimal-risk research? We describe one approach that successfully met HIPAA criteria and also allowed high-quality research. In developing protocols and applying for IRB approval, researchers must be as familiar with HIPAA regulations as they are with IRB standards. Finally, we recommend changes in the review process that may facilitate research efforts with family caregivers while protecting important privacy interests.

Key Words: Family caregiving, HIPAA, IRB, Home-care agencies, Research ethics

In the past 25 years family caregiving for elderly people who are frail, ill, demented, or disabled has become a major gerontological research area, with more than 8,000 articles in the National Library of Medicine’s PubMed database. The advent of this field of study coincided with the establishment in 1981 of a major revision of federal regulations governing research review by Institutional Review Boards (IRBs; 45 CFR 46). With some subsequent changes, these regulations, well known to gerontological researchers, are still in place.

Established in hospitals, health care facilities, educational institutions, and other organizations, IRBs review protocols for studies involving human participants in terms of ethical standards, questions primarily, but not exclusively, dealing with risk-benefit ratios, informed consent, and protection of confidentiality. IRBs have been established in institutions that do research and receive federal funds for any purpose, and many of those that have only private funding have chosen to follow the same rules.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which went into effect April 13, 2003, added another layer of review. HIPAA was designed to permit employees to retain their health insurance if they changed jobs and to protect individuals’ identifiable health information, such as diagnosis or the content of mental health counseling services, from unauthorized disclosures. Most individuals do not want employers, marketers, or the media to use private medical information for their own purposes. Preventing this kind of unwanted and unwarranted disclosure was the original intent of the law. Its ramifications, however, are far broader.

While a complete analysis of HIPAA’s provisions is beyond the scope of this article, some basic facts are important to understand our primary concern—the relationship among these new rules, IRB review, and family-caregiver research. HIPAA applies to “covered
entities,” such as hospitals, doctors’ offices, home-care agencies, and other health care providers. The Privacy Rule (45 CFR 160, 164), which is the regulatory framework for HIPAA, sets out specific requirements for the release of “protected health information,” defined broadly as information about an individual’s physical or mental health that either identifies or can reasonably be used to identify that person.

The Privacy Rule provides two basic ways in which such information can be released. An individual may, indeed must, consent to its release for general purposes of treatment, payment, or health care coordination. An individual also may authorize the release of more detailed information for specific, time-limited purposes, including research. Both consent and authorization, however, must meet rigorous standards, and in practice, the line between them has become blurred (Gunter, 2002). Given the legalistic language in which these releases generally are written, many individuals do not understand the distinction, or even their rights under the Privacy Rule (U.S. Government Accountability Office, 2004).

The applicability of the Privacy Rule to research has created considerable concern and confusion, especially since the federal rules cited above governing biomedical and behavioral research also contain confidentiality protections (Gerlach, 2002; Maloney, 2003; Annas, 2002; Kulynych & Korn, 2002; Olsen, 2003; Gunn et al., 2004). The Privacy Rule does not apply directly to researchers, except those who also treat patients. However, researchers are significantly affected in their procedures for recruiting participants, working on collaborative projects, and monitoring data.

Within the federal regulatory parameters, local IRBs have significant flexibility to determine if and how research will be conducted in their institutions. IRBs and new entities called privacy boards have the authority to approve a waiver or an alteration of the Privacy Rule’s authorization requirement (45 CFR 164.508). Eight criteria must be met, including a determination that the individual’s “privacy rights and welfare” will not be adversely affected and that the risks to privacy are “reasonable.” In the current risk-averse regulatory environment, however, IRBs may take a more restrictive path. IRBs are keenly aware that research at several well-known institutions was shut down temporarily because of ethics violations. While these shutdowns were totally unrelated to privacy issues, they do contribute to the general atmosphere of anxiety among researchers about legal repercussions. Furthermore, violations of the Privacy Rule carry heavy financial and even criminal penalties.

Very few articles in the literature bring the dual concerns of family caregiving and research review together. While one can find articles about the appropriateness of family members serving as surrogates in consent processes for dementia patients, there are scant references to the ethical and procedural questions that arise when family members themselves are recruited as research participants. If published research reports on family caregiving mention IRB review, it is with uninformative statements such as “This study was approved by the ______ IRB” or “Informed consent was obtained.” Part of the reason may be that journal editors impose strict word limits and want only an assurance that the study was appropriately reviewed and approved. Another possible reason is that many investigators consider IRB review a necessary but burdensome hurdle and do not want to dwell on the compromises in research strategy they may have had to make to get approval.

We believe, however, that it is important for researchers and IRB members to discuss the dilemmas they have encountered so that they can recognize elements of future protocols that may create problems and resolve them before submitting the protocol to the IRB. In that spirit, we present our experience in one study of family caregivers, which raised several procedural and ethical questions. When should IRBs follow HIPAA rules to the letter and when might they use the waiver option? What is the appropriate balance between the goals of protecting the privacy of patients’ personal health information and facilitating family-caregiver research that may benefit them and others? Should patients be gatekeepers for caregiver participation in minimal-risk research?

“‘This Case Is Closed’: A Study of Transitions When Formal Home Care Ends

Since 1996 the Families and Health Care Project of the United Hospital Fund, an independent nonprofit health care research and policy organization, has worked to improve the relationships between family caregivers and the health care system. Transitions between health care settings were identified early as key points at which caregivers had to make adjustments and also at which they were in contact with health care providers who could offer assistance and guidance (Levine, 2000). After focusing on discharges from hospital to home, we realized that another caregiver transition—from formal home-care services provided by agency staff to reliance on the family’s own resources—was an almost completely unexplored area. We found only a few older articles that relate to this transition from the point of view of its impact on caregivers (e.g., Agazio, 1997; Hooyman, Gonyea, & Montgomery, 1985).

For the study “‘This Case Is Closed: How Family Caregivers Manage the Transition When Home Care Services Are Terminated,” we focused on caregivers whose family member had suffered a stroke or a brain injury. These conditions typically require long periods of rehabilitation, present cognitive and emotional as well as physical challenges for patients and caregivers, and often fit into the category of “custodial” care, which is not covered by Medicare or private insurance. We had pilot data from a study at Peninsula Hospital in Far Rockaway, NY, funded by the United Hospital Fund (Albert, Im, Brenner, Smith, & Waxman, 2002), which showed a decline in formal home care even while an agency was involved and caregivers’ isolation after it ended.

We proposed to follow a sample of 100 caregivers after they brought their family members home from the hospital, rehabilitation facility, or nursing home,
through the end of formal home care, however long it lasted, and for up to 12 months thereafter. Our goal was to document how case closings are handled from the clinicians’ and caregivers’ perspectives and how caregivers managed or failed to cope on their own. We also planned to recruit a retrospective sample of comparable caregivers whose home-care experience had occurred a year earlier and to conduct a series of focus groups with clinical home-care staff and home-care aides.

Three certified home health agencies (CHHAs) in the New York City area agreed to cooperate; they too wanted more information on how better to serve family caregivers in these vulnerable situations. Their initial responsibility was to identify patients with involved family caregivers who fit the study’s clinical and other requirements: discharged with stroke or traumatic brain injury as the primary International Classification of Diseases 9 (ICD9) diagnosis; discharged home; name of family or friend caregiver in electronic record; both patient and caregiver aged 18+; residence in metropolitan New York City area; nonhospice care; caregiver able to speak English. The agencies also agreed to recruit clinical staff and home-care aides for the focus groups and to supply administrative data on the types and duration of services provided.

From these different perspectives, we hoped to draw a comprehensive picture of the challenges both agencies and caregivers encounter when cases are closed. Our cohort would be more representative than a convenience sample of identified caregivers or those already enrolled in a supportive program. Furthermore, we would follow caregivers for months, unlike a one-time population-based survey.

Before we could recruit participants, of course, we had to obtain IRB approval. Each CHHA in this study has its own IRB. Rather naively, it turned out, we believed that our combined experiences—Dr. Albert’s as a seasoned researcher, and Ms. Levine’s as a well-known writer on ethics in human research—would make this process relatively simple. In our view the study met the federal standards for “expedited” review (45 CFR 46.110), that is, it involved “no more than minimal risk.” Under expedited review the IRB’s chair or designee can review a protocol without sending it to the entire board, saving time and effort. This was not the case.

Negotiating Approvals

After receiving funding for the study in January 2002, we spent several months obtaining the cooperation of agency administrators and, with ongoing consultation with their operations and data-management staff, developing the questionnaire and research procedures. We specified protections for confidentiality of the data and promised that participants would not be identified or identifiable when the results were published. Participants in both the prospective and retrospective arms of the study and focus-group members would receive a stipend, and the agencies would be compensated for their time.

The study was submitted to the first of the three CHHA IRBs in June, and we finally obtained IRB approval in November. The second agency’s approval was obtained the same month and the third in June 2003—18 months after the project began and 9 months after the protocol was first submitted to that agency’s IRB. This agency’s delay was partly a result of its IRB’s staffing problems, which necessitated resubmission of the protocol and several interventions with each new person assigned to the job. Time between submission of the IRB protocol and approval ranged from 2 to 9 months, with an average of two revisions before approval.

The involvement of agency representatives throughout the preparatory period was critical because the protocol called for agency staff to identify eligible families and make initial contact. It also gave the agencies a stake in the project. Indeed, without such involvement, approval would likely have been delayed much longer or not obtained at all. (For one agency, this involvement saved the project a $1,000 charge for IRB review of a protocol from outside researchers.)

Despite this high level of agency cooperation, the project was nearly derailed. We initially proposed that the agencies and the United Hospital Fund would simply mail a letter to eligible family caregivers describing the study and inviting them to participate. This letter would provide an agency phone number and postcard for families to decline participation before any personal contact was made. Fund researchers would then make an initial telephone contact with all those caregivers who had not refused, giving them still another opportunity to decline participation. This “opt-out” process had been standard social science research practice.

However, the IRBs would not approve this method. They did not identify any particular risk to patients or caregivers, but they worried that this method would violate HIPAA rules. Technically our direct approach failed HIPAA’s “covered entity” regulations in two ways. First, as outside researchers, we could not have access to the name of someone receiving services and his or her family caregiver unless agency staff first contacted the person, explained the risks and benefits of the study, and obtained an authorization or preconsent for study personnel to contact them. Second, we could not approach caregivers unless patients first allowed family caregivers to share health information with the research team. Even though in our view the study met the criteria for a waiver and IRBs had the authority to approve one, they were not willing to do so.

As an alternative, the first IRB suggested that the agency mail a letter to patients inviting caregiver participation, limiting recruitment to patients and caregivers who responded positively to the inquiry. This “opt-in” approach, while HIPAA-compliant, was unacceptable as a research strategy. It would almost certainly result in a heavily biased sample, as it would likely exclude caregivers to demented patients, the most burdened caregivers, low-income and low-educated families (hence the Medicaid and minority families absent from most studies), and people with changed addresses. It also would lengthen the recruitment period un acceptably.

Given this potential study-breaker, we called other national researchers in the field and asked for their
advice. Only a few had encountered this problem before, either because their research population was identifiable without patient consent, or because they had not yet dealt with IRBs who interpreted HIPAA requirements in this way. They did, however, agree with our assessment of the research drawbacks of the opt-in strategy.

The only acceptable alternative within HIPAA stipulations was for agencies to call eligible patients and obtain authorization for the research team to contact their caregivers. This is the procedure we agreed to and that was ultimately approved. It worked this way: An agency representative called the patient at home to obtain permission to contact the caregiver; if the patient agreed, the agency representative made a second telephone call to the caregiver to obtain permission for the research team to make the initial direct contact by telephone. Patients or caregivers could refuse at the outset; in those cases, agencies did not forward names to the research team.

This procedure by itself was not overly onerous, given that the majority of patients and caregivers lived in the same household. Complications arose in the case of patients who were demented or too impaired to answer the telephone. In these cases, we had to adopt a more circuitous procedure. If the caregiver had power of attorney for the patient or was the patient’s health care proxy, agency staff explained the study to the caregiver directly and sought participation. About a third (36%) of caregivers did have power of attorney or served as health care proxies. To our knowledge, none of the care recipients had court-appointed guardians or conservators, which would have created yet another level of permission. (It is unclear to us if a power of attorney, which relates to financial matters, or a health care proxy, which gives surrogate decision-making authority for an incompetent patient’s medical treatment, are also valid in research contexts. It is likely that at least in New York State they are not. Possession of these instruments, however, did reassure the IRB that the patient had some level of trust in the caregiver.)

If the caregiver did not have power of attorney or a health care proxy, and someone else did, the agency sought the name and telephone number of this person from the caregiver, called, and attempted to obtain authorization from this person. If no one had these instruments, caregivers were asked to rely on their understanding of patient preferences—a sort of “substituted judgment”—to determine if their participation in the study was appropriate. Throughout this procedure the main burden fell on agency staff but potentially could delay recruitment and use up the forbearance of potential participants with extra phone calls.

Thus, while only one consent form was used for caregivers in the study, we submitted three different telephone scripts to IRBs, all of which might be necessary to enroll caregivers: (a) “Call to patient to explain study and to identify primary caregiver and/or power of attorney”; (b) “Call to patient’s power of attorney (if not the caregiver) when patient is ‘decisionally incapacitated’”; and (c) “Call to caregiver to set up research call for consent and first interview.”

All three agencies eventually approved this procedure. We enrolled our first caregiver in January 2003, a year after we began discussions with the agencies.

For the retrospective arm, we sought to enroll 100 caregivers whose family members had received home-care services for stroke or traumatic brain injury within the previous 12 months and whose cases were now closed. The CHHAs identified large numbers of potential participants, from 500 to 1,400 across the three agencies. Because the potential pool was so large, the agencies mailed letters inviting participation or, in one case, the questionnaire itself. In this component of the study we were limited to caregivers who “opted in.”

Recruitment in Practice

Our target was 100 participants in the prospective component of the project. In 19 months (January 2003–July 2004), we enrolled 99. The agencies differed in the degree to which they kept track of initial calls. The agency with the most complete records provides a good guide to the challenge of this recruitment protocol. In 12 weeks of monitoring, agency staff identified 164 clients who had been discharged with stroke or traumatic brain injury and seemed to meet the other eligibility criteria. In 7 cases, patients refused participation, and in 18 cases caregivers refused. Thus, a total of about 15% refused. Forty-nine (about 30%) gave authorization to be contacted by the research team. The remainder turned out to be ineligible for a variety of reasons.

Of the 49 from this agency who agreed to be contacted by the research team, we successfully enrolled 39, about 80%. We were never able to reach two of the families, and eight refused upon hearing further details of the project. In this agency, 10% of the enrolled caregivers reported that the patients were “totally dependent cognitively” or “not always alert or oriented,” suggesting moderate to severe dementia.

Our experience with the other two agencies was quite similar: For every caregiver enrolled, agencies had to screen four patients. Once agencies obtained authorization, participation rates ranged from 78–82% across the three agencies.

Though labor-intensive, the recruitment procedure yielded a diverse sample on the indicators most critical to the study. About 10–20% of patients were reported to have moderate to severe dementia. Minority caregivers ranged from 55–81% of the sample across sites, and Medicaid enrollment similarly ranged from 10–47%.

Despite the challenges of this recruitment procedure, we were able to meet the strict time framework specified in the protocol. We sought a first interview while caregivers were still receiving service from the home-care agency, which in our sample was a mean of 32 days. All three agency data-management departments were able to identify potentially eligible families within 10 days of the start of service. The internal agency telephone contact and forwarding of names to the research team took another 7–10 days. The research team took another 7–10 days, in turn, to contact participants, and more time was required in many cases to
set up interviews. Despite this lag of up to 30 or more days, by persistent follow-up we were able to obtain first interviews during the home-care-service period for two thirds of the sample.

For the retrospective component, the yield from the mailed letters or questionnaire was predictably poor: 2–3% of potential respondents were enrolled for a total of 64 of the 100 target. The true participation rate is probably higher, since many of the mailings were returned because the address was wrong, the patient had died, and other reasons. The poor response, however, confirmed our doubts about this recruitment strategy, since the caregiver sample we obtained was less likely to be minority and more likely to be highly educated.

The Ethical Questions

Acknowledging the critical role played by our agency partners, and the diligence of the IRBs in moving into unfamiliar regulatory territory, we still have to ask: Did this process actually protect patients and their caregivers? And if so, from what? Or did it subordinate caregivers’ autonomy to other interests?

The most innovative aspect of our study—recruiting participants from a group of caregivers who were not themselves clients of the service provider—turned out to be the major IRB stumbling block. Most caregiver studies recruit from people identifiable because they are physically present when the patient/client is receiving services, whether in a hospital, outpatient clinic, or community agency, or because the caregiver is involved in some educational or supportive activity. We wanted to recruit caregivers who probably did not even know that they were caregivers or were still in shock after their relatives’ recent stroke or brain injury. Because our first contact with the potential participants to explain the study would occur only after the patient had been determined to be eligible for home-care services, a decision that is made after a nurse’s in-home evaluation, we had no possibility of prior contact.

Patients clearly have an interest in protecting their health information from unauthorized scrutiny; we recognized this by establishing strict protections for safeguarding all data about patients and their caregivers. Most of the patient-specific information we obtained from the agencies related to diagnosis and use of home-care services. We also asked family caregivers about the patient’s emotional state and functional capacities.

Because of their stroke or brain injury, these patients were likely to have cognitive deficits even if they were not “incompetent” by legal standards. Just released from the hospital or nursing home, they were unlikely to be opening their mail or answering the phone. These tasks were probably being taken over by the caregiver, who in the strict “patient privacy” view was not even supposed to know about the possibility of participating in the research.

Patients who could answer their telephone and read their mail could refuse to allow the agency to contact the caregiver, creating an arguably unethical situation in which patient autonomy was allowed to trump the autonomy of a family member for a selfish, well-meaning, mistaken, or no reason at all. Patients were not potential participants but were gatekeepers to potential participants.

Paradoxically, home-care agencies do not provide services for patients who require extensive care unless there is an involved family member. Under Medicare and most private insurance plans, agencies offer part-time and short-term services. They are understandably concerned both about patient safety and their own financial and legal liability if the patient needs more care than the payer will authorize.

The family member who provides most of the care, however, is not an agency client or even a semi-official treatment-team member. The caregiver is given responsibility for the patient’s care but has no status or rights. It is conceivable that some patients would not authorize the release of their diagnosis and other health information even to family members responsible for their care, and under HIPAA, that refusal would have to be honored.

CHAA IRBs are charged with protecting the welfare of patients in the conduct of research, and they are concerned with protecting the agency’s interests and facilitating ethical research. But they have no fiduciary or regulatory obligations to third parties, whether they are outside researchers or family members.

Even without HIPAA, however, it is possible that our study would have raised concerns in some IRBs about potential obligations to “secondary subjects.” Studies that obtain family genetic histories, which may uncover health or other information about individuals who have not consented, are the primary example (Botkin, 2001; Cook-Deegan, 2001). Typically the primary subject is the person with the condition, such as Alzheimer’s disease or breast cancer. These studies present risks to unconsenting family members. In our study the primary subject was not the person with the condition but the person who takes care of that person. We considered our primary obligations to the secondary subject to be avoiding harm (none was contemplated) and ensuring the confidentiality of the data.

Our study went forward and has produced solid results, which will be reported separately. But without adequate funding (and patience from our funders, who expected a faster project completion), and our commitment to the project, it might well have foundered or produced a skewed sample with predictably skewed results.

Recommendations

Is there a better way to recruit caregivers while protecting the privacy of patients’ personal health information? Gerontological researchers need to become as familiar with HIPAA rules as they are with IRB procedures. (A good starting point is the National Institute of Health’s web site on HIPAA [http://privacyruleandresearch.nih.gov/].) Researchers should determine whether identifiable information is needed and what steps will be taken to ensure HIPAA and IRB compliance for protection of identifiable data. If a waiver
or alteration of HIPAA rules is requested, compliance with the Privacy Rule’s criteria should be detailed.

But this approach can take researchers and IRBs only so far. Some reconsideration of the regulations is warranted. In reviewing the first-year’s experiences under the Privacy Rule, the U.S. Government Accountability Office (2004, p. 16) concluded that while the overall introduction of the Rule went more smoothly than expected, research groups reported “unnecessary delays and less access to health data” and that smaller providers with more limited resources are “reluctant to facilitate research studies because of misunderstanding of the rule and the added burden of contacting patients.” This was exactly our experience.

In our view, the Privacy Rule in its current form unnecessarily complicates caregiver research without protecting patient privacy. Caregiver research typically falls within the realm of minimal-risk studies. For such studies, the requirement that patients provide formal authorization may be an unjustifiable deterrent to ever reaching their caregivers, much less obtaining their participation.

We propose the following alternatives to current HIPAA guidelines. One approach is to replace explicit patient authorization with a general “informed assent” procedure. As part of the information provided to clients of home-care-agency services (or indeed other services for which this problem might arise), agencies might say, “From time to time we cooperate with researchers on aspects of your care and your family caregiver’s experiences. We consider research a vital aspect of improving the care we provide. Each study we endorse has been reviewed and approved by a special committee called an Institutional Review Board, which is devoted to protecting your rights and welfare. In each case the primary participant—whether that is you or your family caregiver—will be advised of the study purpose and procedures and of your or your caregiver’s right not to participate. The decision to participate is completely separate from the agency’s provision of services, and your care will not be affected by your decision not to participate.” In this way the patient and the caregiver would be recognized as separate individuals, and the patient would not be placed in the unrealistic and ethically dubious role of gatekeeper for caregiver research.

A second alternative would be to codify relationships between external researchers and service providers. For the purposes of HIPAA-compliant research, it may be necessary for researchers to become quasi-staff at clinics or health care agencies. Perhaps some kind of “allied researcher” status could be developed, with researchers receiving appropriate training and signing agreements to protect patient confidentiality.

Finally, it should be possible to obtain a combined review when several IRBs in the same locale are presented with the same minimum-risk protocol. While IRBs are understandably reluctant to cede their authority to another body, a cooperative arrangement in which all questions were raised at the same time would not only facilitate the research but also would give each IRB the added benefit of other opinions on the same issues. Regional IRBs have been suggested for many purposes; even without going this far, some local collaboration would be extremely helpful.

In order to better inform the research and IRB communities, and ultimately policy makers, we recommend developing a consensus among gerontological researchers and IRB leaders about when it may be appropriate to use the HIPAA waiver and when more stringent rules should be followed. Interpretation of the rules now varies widely depending, it appears, on the local level of risk avoidance rather than any question of principle or practicality.

Our experience may be unusual but it is probably not unique. It is important to conduct gerontological research that is based on sound science, ethical principles, and efficient procedures. Protection of private medical information in research and care is a critical priority, but its implementation should not create roadblocks where no danger exists.

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