Research, Managed Care, and Patient Privacy: Challenges to Successful Collaboration

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Abstract

- **Objective:** To illustrate the impact of increased patient privacy concerns on the conduct of research on managed care patients and to suggest mechanisms for successful collaboration between managed care organizations and academic research organizations.
- **Patients and setting:** Government-funded collaborative research project involving an academic research organization and several managed care organizations. The context is a large coronary artery disease study in which patients were identified using managed care electronic files and then surveyed at 2 different times about their posthospital care.
- **Data collection/extraction methods:** Data for the study included patient surveys as well as electronic claims files. The data relevant to this report are summaries of tracking files that were created for administrative purposes.
- **Results:** The principal observations from this evaluation are: (1) fear of negative publicity for managed care organizations and, more importantly, increased patient privacy concerns create barriers to patient contact; (2) these challenges can have a dramatic effect on duration of a study and the ultimate response rate; (3) response rate can also depend on the mechanism by which the study is introduced to patients.
- **Conclusions:** Managed care research is critical, but managed care organizations perceive significant risks to participation. The process of obtaining funding and executing a successful study would benefit from specific safeguards and sufficient incentives to offset the risks to managed care organizations.

More than 77% of the insured American public obtains health care through membership in managed care organizations (MCOs) [1,2]. To better serve their membership, these organizations frequently incorporate new features into their products, such as preventive services or disease management programs, expecting that these features will lead to improved health for members without escalating health care costs for the MCO. However, MCOs generally do not have adequate time or resources to examine the clinical and economic impact of new product features, particularly over the long-term. One highly effective way to conduct such investigations is through collaboration between the MCO and an academic research organization (ARO), especially if external funding can be secured. The ARO provides study design input, data management capability, and statistical analysis expertise; the MCO provides input regarding the patient population and the care process and supplies access to patients.

It is important for the nation’s health and critical to its economy to understand how managed care patients are affected both by different health plan constructs and by the quality of the care that they receive. Yet, conducting this important research is becoming increasingly difficult as privacy constraints become more restrictive and as MCOs struggle with negative publicity and a volatile health care market. As described in an editorial by Luft and Dudley [3] in a special section of the December 2003 issue of *Health Services Research*, “an integrated set of projects to collect and analyze the necessary data would probably rival that of the Human Genome Project.” This report discusses some of the specific issues that impose challenges on such research in the context of a collaborative research project between several MCOs and an ARO, the Duke Clinical Research Institute (DCRI).

**Methods**

A 3-year study funded by the Agency for Healthcare Research and Quality provided for the Outcomes Research and Assessment Group at the DCRI in collaboration with several MCOs to identify features of managed care products that influence quality of care processes, as well as the short- and long-term health outcomes among individuals with coronary artery disease (CAD). The goal of this CAD study was to discern whether benefit design features such as risk sharing,
capitation, and gatekeepers are associated with higher quality of care for CAD patients.

The study design required the researchers to contact MCO members who had recently experienced a CAD hospitalization and survey them about process and health outcomes measures that reflect quality of care, including health status, risk factor assessment and modification, and medication guidelines adherence. Questionnaires were administered to each patient during 2 periods following the index hospitalization: the transitional phase, approximately 6 months following a cardiac hospitalization, and the longer-term health maintenance phase, approximately 1 year later. During analysis, the patient self reports were combined with MCO administrative data that describe both product features and patient resource utilization to determine which features of MCO products may influence patient outcomes.

In an effort to safeguard the protection of research participants, there has been increasing oversight by local institutional review boards (IRBs) and the federal Office of Human Research Protections (OHRP). Policies governing the protection of human subjects are specified in the Code of Federal Regulations Title 45 Part 46 (45 CFR 46) [4]. In addition, in 2003, the Health Insurance Portability and Accountability Act (HIPAA) regulations were enacted. This federal legislation stipulates that every individual has the right to control access to and the disclosure of their personal health information, thereby tightening access to confidential patient information [5]. Restrictions governing patient identification and the types of information that may be shared between collaborating organizations without the explicit permission of the individual are a central tenet of both human subjects research design and corporate customer relations. However, these constraints can have fiscal, operational, and analytic consequences with respect to research. The sections that follow highlight aspects of the CAD study affected by these privacy concerns:

1. Establishing a protocol that would be acceptable to the MCOs, DCRI, and the Duke IRB
2. Identifying eligible patients from MCO electronic files and sharing data
3. Recruiting patients over multiple sampling cohorts
4. Surveying patients twice in 12 months

**Results**

**Establishing an Acceptable Protocol**

During the grant application process, an MCO provides a letter indicating interest and enthusiasm for the project. True commitment is contingent upon funding and an acceptable operational plan. Because significant MCO input is required to design the details of the project, it is not possible to develop an operational plan until funding has been secured.

During start-up for the CAD study, there was an increase in local oversight of research-related human subject protections. For reasons external to the project, the Office of Protection from Research Risks (OHRP's predecessor) required the Duke University Medical Center IRB to re-review a number of federally funded grants, including the previously approved CAD study protocol. The proposed participant recruitment methodology had relied on passive consent, whereby patients who were identified through MCO electronic claims files would receive a letter from the MCO about the study and would be asked to return a postcard if they did not wish to participate. Contact information for all identified members who did not return the postcard would be forwarded to the DCRI in order to administer the patient surveys. Upon re-review, the IRB determined that this passive consent mechanism would breach participant confidentiality because the DCRI would be given names and addresses of people with diagnosed heart disease without their active consent. To satisfy these IRB concerns, all recruitment responsibilities were transferred from the DCRI to the MCOs; patient information could not be shared with the DCRI unless the patient actually filled out the survey and returned it to the DCRI. This change in protocol forced one MCO to withdraw participation.

Sensitivities of the MCO are more acute when research requires contact with health plan members and, therefore, release of member information. In one instance, an MCO's legal department requested a language change to the Single Project Assurance, a standard federal document addressing human subjects protections that must be filed by all institutions participating in federally supported human subjects research. Subsequently, this legal department requested documentation of compliance with 45 CFR 46. Detailed discussions and exchange of documentation between the legal departments of the MCO and the ARO were required before project work could continue.

**Identifying Eligible Patients and Sharing Data**

Electronic claims files of the MCO were used by the CAD study to identify a sample of individuals who had recently been hospitalized for CAD, as defined by specific claims codes. To reliably capture care and health status in the transitional phase following a hospital admission, all eligible patients were required to have had a cardiac hospitalization within 3 to 6 months prior to study enrollment. This strategy was validated in a similar study of managed care patients by Kahn et al [6], who found that recall of events that occurred remotely in time is less reliable than that for recent events. Because the project did not have sufficient resources and the MCOs could not identify a sufficient number of eligible patients to sample only one time, a strategy of identifying patients on a quarterly basis over 6 consecutive calendar
quarters was implemented. Typically, a cohort of between 200 and 300 eligible participants was sampled each quarter.

With any retrospective study, there remains the possibility of identification errors. Unfortunately, in the CAD study, a few health plan members or their dependents were mistakenly included in the sample population and, therefore, approached for recruitment. These errors tended primarily to be data errors in the administrative claims database housed at the MCO and used for sampling. Although such occurrences are not unexpected during the course of any study, when the MCO is soliciting enrollment for research with an external collaborator, there is heightened sensitivity about member relations. From a public relations perspective, such inadvertent mistakes elicited questions from patients regarding their privacy and the accuracy of their data. Already the victims of negative publicity, MCOs have become less willing to endure such risks.

After eligible members were identified from the claims database, the MCO needed to assign a unique study identifier to each eligible participant prior to recruitment attempts. Because of the protocol change stemming from confidentiality concerns, this study number was the only identifying key available to the DCRI and it served as the universal identifier linking numerous data tables at both the DCRI (ie, survey data, which were mailed by the patient directly to the DCRI) and the MCO (eg, enrollment files, administrative claims data, pharmacy data). Once a study number was assigned, de-identified data could be transferred to the DCRI. The data management functions for this system involved a secure Microsoft Access database shared between the DCRI and each MCO. The development, distribution, maintenance, and support of this database required a notable amount of unanticipated resource use and lengthened the study duration. With the mounting enthusiasm for centralized/standardized databases for both inpatient and outpatient encounters, including patient registries, it is possible that simple identifying information can be shared between providers and MCOs. With these links established, the MCO would have access to current and reliable contact information. Additionally, the patient informed consent might allow for data to be forwarded directly to the research institution.

**Recruiting Patients Over Multiple Sampling Cohorts**

Each sampling cycle was to follow a standard sequential recruitment approach, similar to that of Kahn et al [6], with 2 surveys followed by attempted contact of nonresponders by telephone. The Table delineates the evolution of recruitment operations and the responsible parties for the CAD study, from the proposed protocol to that eventually approved by the Duke IRB to a pragmatic revision. Originally, an introductory letter explaining the purpose of the study was to be sent 2 weeks prior to mailing the survey. The response postcard was included with the introductory letter and again with all survey mailings. It offered eligible patients 3 options: refusing to participate in the study, thereby eliminating further contact attempts; requesting more information from DCRI about the study; or requesting a telephone administered survey with an interviewer at the DCRI. These options appeared with check boxes and were explained simply in one-line bullets.

The volume of serial mailings, responder tracking, and nonresponder telephone calls proved difficult for the MCOs, especially with the tight recruitment timeframe for each sampling cohort. Therefore, 10 months into enrollment, the introductory letter phase was combined with the first survey mailing in order to reduce this burden. Figures 1A and 1B display the configurations of response. Of 2032 patients who were sent introductory letters before the recruitment methodology was revised, 485 (24%) returned postcards and 131 of these eventually enrolled. In contrast, of 2571 surveys mailed after revising the methodology, only 96 postcards (4%) were returned and 46 patients eventually enrolled. Despite almost

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<th>Table. Data Collection Timelines</th>
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<tr>
<td>Task</td>
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<tr>
<td>Mailing of introductory letter and postcard</td>
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<tr>
<td>Electronically track returned postcards</td>
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<tr>
<td>Electronic transfer of &quot;passive&quot; consent sample, including names and contact information</td>
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<td>First survey mailing, 2 weeks after introductory letter and postcard</td>
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<td>Second survey mailing to nonresponders, 2 weeks after first survey mailing</td>
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<td>Telephone follow-up of nonresponders, 2 weeks after second survey mailing</td>
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<td>Telephone interview administration, if arranged during telephone follow-up</td>
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<td>Survey data entry</td>
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IRB = institutional review board.
equivalent rates of enrollment from the mailed surveys (592/2032 or 29% versus 759/2571 or 30%), the yield from the telephone follow-up dropped dramatically. The overall enrollment rate dropped from 40% to 32%. It appears that with the original recruitment methodology, response postcards were more likely to be returned, and patients who returned postcards were more likely to enroll. In addition, returned postcards translated to refusals being identified more quickly, reducing the number of patients left for telephone recruitment and increasing the efficiency of the overall process.

Patient recruitment was also hampered in the CAD study by member suspicions about the confidentiality of survey responses. MCO contact of members exclusively for research purposes was not consistent with the standard MCO business model of brokering health care, and many members did not expect and were wary of their health care plan conducting research. Despite the confidentiality and privacy assurances in the informed consent document, health plan members expressed concern to both MCO personnel and DCRI interviewers that their individual responses about their health, well-being, or opinions would be released without their knowledge to their employer or their health insurance company. In an attempt to alleviate these concerns, postage-paid preprinted envelopes were provided to participants so that they could mail completed surveys directly to the DCRI. Although impossible to quantify, privacy concerns likely had a negative impact on enrollment in the project.

Budget constraints prevented Duke from fully compensating the MCOs for assuming the recruitment effort. To compensate for the resource limitations at the MCO, the study investigators discussed contracting out trained DCRI data collectors to work at the MCO exclusively on this project. Besides the high costs incurred on a limited budget, this resourcing alternative was further complicated by concerns of both the MCO and the ARO regarding confidentiality and employee supervision. The logistical considerations relating to protecting and maintaining patient privacy eliminated the possibility of implementing this option.

For this particular project, the MCO setting thus resulted in poor response rates. Given the lack of compensation for tracking and surveying patients, the lack of an infrastructure to support such activities, and patient concerns about confidentiality, it is not surprising that the response rate failed to meet expectations. Response rates for mail-in surveys generally range from about 40% to 80% [7–9], and the response rate at our institution is customarily above 90%. There is a tendency for response rate to increase with repeated mailings and when an incentive is provided to the respondent. Resource constraints precluded implementing either of these options.

**Surveying Patients a Second Time in 12 Months**

MCOs typically update their electronic membership files using information provided by employers, acting as the intermediary, but this information is not always current. Confidentiality restrictions can also exist in a contract with a single employer, legally prohibiting the MCO from directly communicating with its employees. Obsolete contact information, restrictions on direct member contact, and inadequate compensation of the MCOs for the telephone recruitment activities were likely contributors to the poor yield from the telephone recruitment phase.

These factors also had a detrimental impact on the 1-year follow-up interview rates. For the CAD study, electronic membership files contained no telephone number for 31% of
the 1637 participants eligible for the 1-year interview. The CAD study deviated from the standard approach to longitudinal survey research by not collecting contact information at enrollment due to MCO concerns about member relations. Existing contact information could have been supplemented using secondary contacts and available internet search engines or by calling the primary care physician. However, with an interest in maintaining contractual relations, MCOs were reluctant to allow researchers to pursue these avenues.

**Discussion**

The CAD study is typical of the type of research that is crucial to understanding the health status of managed care patients. The study involves a collaborative initiative between an ARO and 3 MCOs to examine the impact of benefit features on quality of care for CAD patients. It incorporates a patient survey as well as reliance on MCO electronic files for patient identification and for resource utilization. Although more than 1600 patients have been successfully enrolled, the research has taken considerably longer than planned and has been complicated by the volatile MCO business environment, public relations fears, and especially patient confidentiality issues. As a result, a lower than originally planned response rate has been realized, and the study was unable to be completed within budget or within the projected timeframe.

Kahn et al [6] executed a similar study before HIPAA regulations came into effect, with a patient survey in 1996 and a longitudinal follow-up in 1998. The response rate to the 1996 survey was 49%, much higher than the 36% for the initial survey in the CAD study. Their recruitment procedure included a letter on the letterhead of the patient’s physician group along with an incentive to participate (the chance to receive $100), both of which may have contributed to the higher response rate. Although a similar incentive may have been possible in the CAD study, involvement of physician groups was proscribed by the MCOs, as indicated above. Sensitivity to HIPAA regulations could account for much of the difference between response rates.

Dudley et al [10] provide 6 guidelines for successful collaboration with MCOs: (1) support of senior leadership; (2) broad base of contacts within the MCO; (3) clearly defined roles; (4) mutual sensitivity to concerns such as negative publicity and need to publish results; (5) protection of client relations; and (6) targeting overlapping goals, such as data that serves both research and accreditation needs. In attempting to follow these recommendations, however, difficulties arise. For example, support of senior leadership is not stable; as indicated by Dudley et al [10], “Personnel turnover is common and institutional priorities change frequently.” In the CAD study, central offices of one MCO underwent extensive corporate restructuring and relocation soon after reaching agreement with the DCRI on the project protocol. After 2 years of discussions regarding legal, sampling, and operations issues, there was still no one formally designated at the MCO who could approve the study and the MCO withdrew. Given the uncertainties inherent in planning and conducting this kind of research, it would seem reasonable to allow a significant inflation factor to be included in the budget for MCO recruitment, with the understanding that unneeded funds would be returned. Perhaps offering financial incentives to MCOs that participate in research would facilitate recruitment. In fact, a financial arrangement between a funding agency and some MCOs whereby a designated person at each MCO would be available to help design and implement research could have allowed for a much smoother and efficient execution of the CAD study.
The use of MCO members as a research sample raises issues of patient confidentiality. To protect privacy regarding members’ disease status (ie, cardiovascular disease), patient recruitment for the CAD study was transferred from the DCRI to the MCOs. As a result, the work required of MCO collaborators increased in both quantity and complexity. Nonreimbursed recruitment activities were not well supported by the MCO organizational infrastructure. Eligible members were sometimes hesitant to participate in the study because of concerns that their responses would be shared with employers or the MCO. In addition, current contact information, which is critical for successful follow-up, was not collected by the DCRI because of MCO concerns regarding members’ perceptions of data privacy.

There is considerable public interest in the impact of health care financing and delivery on patient outcomes. However, the ability to successfully carry out studies that address these issues is being increasingly compromised by policies designed to protect patient confidentiality. The risk to patients from unintentional confidentiality breaches must be weighed against the costs of inhibiting research that may identify characteristics of health care delivery that are associated with better quality of care. Education by AROs of the general public regarding the purpose and potential societal benefits of independent research in this area, as well as the privacy safeguards provided by HIPAA, could increase participation rates by raising public confidence about this issue. In addition, reasonable interpretation by IRBs of HIPAA regulations as they relate to research will be necessary for this type of health services research to remain practically and economically feasible.

In retrospect, this study may have benefited from creative recruitment strategies while still remaining cognizant of patient privacy concerns. Although not previously conjectured, the introductory letter and postcard could have caught the interest of some patients and prevented them from discarding the survey without opening it. Possibly letters are more likely to be opened if they are not sent in large envelopes. Additionally, a disease management newsletter could have served as an additional recruitment tool, mimicking current strategies implemented by hospitals and even the National Institutes of Health. The letter, addressed to all covered individuals over a certain age, could focus on disease management in general but could include a brief description of the particular research project, the rationale behind the MCO’s support of such research, and a contact number for those people interested in participating to see if they are eligible.

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