Building Research Relationships With Managed Care Organizations: Issues and Strategies

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Managed care is now the dominant form of healthcare in the United States. The need for clinical research about the organization, delivery, and outcomes of primary care services in managed care models is high, yet access to managed care organizations as sites for clinical research may be problematic. The purpose of this article is to describe issues involved in obtaining access to managed care settings for clinical research and practical strategies for successful collaboration using literature review and case description. Three steps for developing collaborative relationships with managed care organizations (MCOs) are presented: 1) assessment of organizational structure, history, and culture; 2) finding common ground; and 3) project implementation. These steps are discussed within the context of MCO systems issues and a relationship-centered approach to communication between researchers and individuals from the MCO. Successful relationships with MCOs for clinical research are possible when careful attention is paid to inclusion of MCOs as collaborators in the development of the research questions and design, and as partners in the research implementation process.

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Rapid changes in the financing and delivery of primary healthcare services have fundamentally altered the clinical research environment. Over the past decade, there has been a dramatic shift from traditional indemnity insurance plans to health maintenance organizations and other types of network plans (Marquis & Long, 1999). Managed healthcare is the dominant form of healthcare in the United States, with more than 73% of employed Americans who receive health insurance from their employers now enrolled in managed care plans (Simpson & Fraser, 1999). More than six million Medicare beneficiaries and half of Medicaid recipients are enrolled in managed care plans (Fox,

2001). At the same time, clinical research in academic health centers, the traditional site for conducting randomized clinical trials (RCTs), has declined (Blumenthal & Thier, 1998). The need for research to inform the larger, systems-based issues of the organization and delivery of primary care services has never been greater (Dudley, Landon, Rubin, et al., 2000; Institute of Medicine, 1996; McNeese-Smith & Nyamathi, 1999). Yet, access to managed care organizations (MCOs), sometimes also called healthcare organizations, as sites for clinical investigations may be both challenging and problematic (Baum, Logemann, & Stemzel, 1999; Durham, 1998; Meyer, Genel, Altman, et al.,1998; Parkerton, 1999).

The issue of researcher access to MCOs was brought sharply into focus for us by a NIMH study section review we received for a RCT of a nurse practitioner intervention for somatizing patients within an MCO. Somatizing patients have a proclivity for unexplained physical symptoms and are often disproportionately high utilizers of outpatient visits, laboratory investigations, and costly surgical procedures (Smith, 1991). Patient satisfaction with care is low and provider frustration regarding interactions with somatizing clients is high (Barsky & Borus, 1995). Managed care organizations have both incentives and opportunities to improve care to somatizing patients, but research on effective interventions requires successful collaboration between clinical researchers and MCOs (Barsky & Borus, 1995). In our RCT, we proposed to examine the effectiveness of a nurse practitioner intervention with somatizing patients that is based on a relationship-centered approach to provider-patient interactions (Smith, 2001; Smith, Lein, Collins, et al., in press).

Although our grant application contained letters of support from MCO administrators, the NIMH study section expressed reservations about our access to potential subjects and the feasibility of conducting a randomized clinical trial within a private managed care organization. NIMH reviewers recommended a full-scale pilot of the randomized clinical trial prior to our next proposal submission.

The purpose of this article is to describe the multidimensional systems and relational issues (Doherty & Heinrich, 1996; Tresolini & the Pew-Fetzer Task Force, 1994; Weitekamp & Ziegenfuss, 1995) we encountered in negotiating research access in a managed care setting and the practical strategies we used for successful collaboration with the MCO for our pilot intervention. Specifically, we will describe how aspects of the relationship-centered approach (Tresolini & the Pew-Fetzer Task Force, 1994) that formed the cornerstone of our experimental intervention with patients also were used to facilitate a cooperative relationship with the managed care organization, and that we needed to go well beyond the dyadic provider-patient relationship (Doherty & Heinrich, 1996).

HEALTH SYSTEMS CHANGE AND CLINICAL RESEARCH

Clinical research has been influenced in at least two ways as managed care has grown to be the dominant form of healthcare delivery in the United States. Academic health centers (AHCs) have traditionally been the hub of basic and applied biomedical research. Research in academic medical centers has been funded in part by a process of cross-subsidization of research from patient care revenues. As a result of price competition from MCOs, academic medical centers have less revenue to support intramural research, particularly in the areas of pilot funds for new ideas, support of new investigators, and bridge funding for established investigators (Meyer et al., 1998). Increasingly, clinical researchers are expected to neutralize the cost of research by production of more clinical revenue (Meyer et al., 1998). The

result of changes in the research environment of academic medical centers has been demonstrated in investigations of the relationship between managed care penetration and research productivity. Since 1990, NIH research grant support has been growing less rapidly in AHCs in markets with high MCO enrollment than at institutions with low or moderate MCO penetration (Blumenthal & Thier, 1998). The amount of institutional support as a proportion of total funding is more than twice as high in less competitive markets compared with the most competitive markets (Weissman, Saglam, Campbell, et al., 1999). Further, clinical researchers located in AHCs in highly competitive managed care markets reported substantially lower publication rates than colleagues in less competitive areas (Campbell, Weissman, & Blumenthal, 1997).

An important issue that has received less attention in recent literature is access to research subjects within the changing clinical research environment; this includes the recent HIPAA (Health Insurance Portability and Accountability Act) regulations where stringent privacy rules add a new dimension to access. An Institute of Medicine report on the future of primary care in the United States presents a convincing argument that primary care research must be conducted in the same setting in which the results will be applied (Baum et al., 1999; Institute of Medicine, 1996; Peek, 2000). Only in this way can translation of research to practice occur. With an increasing proportion of primary care clients enrolled in managed care organizations, research on the process and outcomes of clinical interventions in these settings is critical (Baum et al., 1999; Starfield, 1996). Promising avenues for increasing research within managed care settings include the formation of primary care research collectives and development of collaborative relationships between medical academia, funding agencies, clinical investigators, and managed care organizations (Thompson & Moskowitz, 1997). However, access to managed care settings, particularly in instances of investigator initiated research, continues to be a substantial barrier to clinical research in primary care (Baum et al., 1999).

CLINICAL RESEARCH AND MCOS

Successful collaboration between clinical researchers and MCOs requires that the parties involved can reach mutually beneficial research agendas (Dudley et al., 2000; Parkerton, 1999). To initiate dialogue between these groups, the Agency for Healthcare Policy and Research (now AHRQ) and the American Association of Healthcare Plans convened a series of annual conferences for health services researchers and managed care organizations. In the introduction to the first conference in 1996, Bernstein and colleagues painted a less than optimistic picture of the potential for collaboration:

> HMOs are private organizations designed to provide services to individual members... they base their operating decisions on local, often specialized data. Academics and government researchers want to produce representative, meaningful statistics to further policy and legislative debates and to guide policy implementation to improve healthcare and to contain healthcare costs.... At the heart of the issue is the tension between two cultures, each with different motives, and incentives to conduct, disseminate and apply the results of health services research (Bernstein, Bernstein, & Shannon, 1996, pp. 45-46).

In subsequent conferences, a series of important issues were outlined regarding collaborations between MCOs and researchers. Both academic researchers and managed care plan administrators first may need to put aside pre-formed notions

about the absence of mutual goals in order for successful dialogue to begin (Baum et al., 1999). Rather than viewing MCOs as merely a source of research subjects, researchers must view MCOs as full partners who have early and continuing input into the research question and design (Meyer et al., 1998). Successful collaborations will be more likely if researchers focus at least a part of the study on pertinent issues in the healthcare marketplace such as cost effectiveness and clinical outcomes (Dudley et al., 2000; Mechanic & Dobson, 1996). Such close partnerships are the essence of health systems research where the various systems of care must be understood. Greater application of clinical trials methodology to answer questions of interest to both scientist and providers in the managed care environment is one way to bridge the gap between cost-sensitive approaches to managed healthcare and more traditional academic research (Baum et al., 1999). Both parties may need to confront loss of control in some areas as they attempt to gain a better understanding of differing approaches to the same problems (Donohue, Lewis, Ockene, & Saperia, 1999). Last, researchers will need to assure the staff of the MCO that the research design will not compromise clinical care or place undue burden on the administrative and support staff (Dudley et al., 2000; Meyer et al., 1998).

Organizational attitudes toward clinical research in managed care organizations appear to be gradually shifting and successful collaborations are reported more frequently in the research literature. By the time of the AHCPR/AHCP conference, "Building Bridges IV," dialogue between researchers and MCOs had grown substantially (Fraser, Wong, Arent, & Carmell, 1999). Development of better working relationships between MCOs and researchers, use of strategies to address communication issues in the research process, and formulation of joint research agendas continue to be areas that require further emphasis if successful collaborations are to be achieved (Fraser et al., 1999).

In the remainder of this article, we will describe the practical strategies we used to establish successful collaboration between our clinical research team and the administrative, clinical, and clerical personnel of a managed care organization.

Practical steps

Conceptual issues aside, clinical researchers wishing to engage in research in a managed care setting are confronted with the need to forge relationships with individuals within the organization (Dudley et al., 2000). Often, clinical researchers write a research proposal and begin to confront site and sample availability issues late (or too late) in the grant submission process. In our experience, time devoted to developing relationships with key individuals early in the formulation of a research proposal was time well spent. Two practical steps are critical prior to proposal submission. Initially, we assessed the organizational structure, history, and culture and then entered the process of negotiation to find a mutually acceptable common ground. These two steps in the early stages of our successful project implementation allowed us to fit into ongoing operations and to develop and maintain effective communication. In our experience, it is preferable to miss a submission deadline if there has not been sufficient time to engage in the steps necessary to develop relationships at multiple levels within the organization.

Assessment of organizational structure, history, and culture

Typically, researchers looking for a setting in which to conduct clinical research consider several possible organizations.

Some aspects of organization structure and history can be determined prior to initiating contact with the managed care organization, and this information can help the researcher narrow the number of organizations he/she will contact. Managed care organizations differ widely in purpose, organizational structure, and suitability for particular research designs. Wagner provides a comprehensive overview of many types of managed care organizations and includes detailed information on organizational structures and reimbursement systems (Wagner, 2001).

Informal contacts with colleagues who have been associated with the MCO for non-research activities (e.g., nurse practitioner education or provision of clinical services) can produce important information to help the researcher determine a potential match between the organizational structure of the MCO and the research design. Informal contacts may yield information on prior collaborations with academic researchers, ongoing research projects, and importantly, internal commotion within the organization (e.g., restructuring of clinical or information management services). Given the rate at which alliances between healthcare organizations are changing, informal contacts can also provide information about recent and anticipated changes at the corporate level. In our case, we determined that the organization we were interested in approaching for collaboration was a staff model HMO that had experienced a recent change in management staff.

Organizational culture refers to the basic assumptions, norms, and values shared by the members of an organization (Cummings & Worley, 1993). Although organizational culture is difficult to quantify, norms are reflected by such visible elements as dress codes, standards of formality/informality in the use of titles, and organizational communication mechanisms (Conrad & Poole, 1998). There may be significant differences between the academic organizational culture and the corporate culture. It behooves investigators who are approaching a corporate culture to be aware of these differences. For example, informal attire often acceptable in academic settings (worn sport coats and denim) may be frowned upon or even prohibited by the MCO employee dress code. Since we considered ourselves to be guests in the organization, we felt that it was important to respect these aspects of the organizational culture as we planned for our initial contacts with the organization.

Finding common ground

In early stages of the proposal development process, researchers must examine their own attitudes about collaboration with an MCO. We emphasize strongly the difference between a researcher's attitude that the MCO is the *source of subjects* and the attitude that the MCO is a *collaborator* in clinical research. The former perspective is reflected by a harried, hurried researcher rapidly approaching a grant submission deadline who arranges a meeting with the CEO of an organization to solicit a letter of institutional support (with the intention of working out details if the grant is funded). In contrast, a collaborative relationship approach involves beginning contact with the MCO early in the idea phase of the proposal with the goal of developing a proposal with joint benefit to the organization and the researcher. It reflects a two-way street where clinicians and researchers are in dialogue from the outset.

Who from the MCO should be included in the preliminary research meetings? A question that we have found helpful in our initial contacts with MCO administrators is, "Who else from your organization would need or want to be present for this meeting?" Our initial meetings included the CEO, Director of Quality Assurance, the Medical Director, and a representative from

nursing services. Subsequently, the meetings were expanded to include representatives from departments such as support services, medical records, and claims/billing. An added benefit to including representatives from multiple departments in early negotiations became apparent to us when we started to implement our pilot study. A new CEO who had not had prior contact with us was appointed in the MCO. The Director of Quality Assurance, who had attended all of our planning meetings, was a strong advocate for us with the new CEO and facilitated the beginning stages of our pilot study within the organization.

The cornerstone of our randomized clinical trial with somatizing patients was a five-step, relationship-centered approach to provider/patient interactions designed to build a strong relationship between the provider and patient (Smith, 2001). Without initially realizing it ourselves, we applied a similar approach when developing a collaborative relationship with the MCO, albeit on a much broader scale involving multiple relationships (Doherty & Heinrich, 1996; Tresolini & the Pew-Fetzer Task Force, 1994). It proved to be an effective tool to promote mutual understanding between the research team and the organization. The five steps of this approach include:

1. Setting the stage: Making sure that people are comfortable; introducing each person; getting acquainted; talking about non-business subjects, such as the baseball game or a movie.

2. Setting the agenda: Getting everyone's needs on the table and beginning the meetings with a specific focus.

3. Non-focused discussion: Listening to MCO members discuss general issues that may not be related directly to the research; learning about the major MCO issues of concern to them; asking questions and actively listening for topics with potential impact on research collaboration. Key information arose here that otherwise would have been unsuspected, and these data usually reflected underlying institutional concerns. In addition, this is a good time to learn in an open-ended manner about MCO clinicians' medical interests. In this way, their problems are acknowledged and the research team can sometimes facilitate identification of a relevant research question, further enhancing the collaboration. This helps to maximize the integration of research and practice.

4. Focused discussion: Developing depth to the discussion by focusing on the MCO's general concerns and developing further understanding of them. These typically involved emotions of fear of one or more of the following: financial jeopardy, being overrun by the research, and taking more time than expected to conduct the research. We not only clarified these issues, but we also addressed them empathically with understanding, assurance of our support, and by acknowledging their concerns. This process occurred over time and issues often were revisited with much give and take on both sides. In time, we identified common interests and goals and, more importantly, developed trust and respect.

5. Transition to discussing specifics: Addressing, at most sessions, specific details that the research team needed to know. These included volume of patient flow, contact person for medical records access, identifying MCO members who will have a role in the research project, setting up a meeting with MDs about identification of potential participants, and identifying specific activities for followup and the agenda for the next meeting.

The process of finding common ground between the research team and representatives from the managed care organization was the focus of several preliminary meetings. MCOs are unlikely to view the accumulation of knowledge and publication productivity as the primary

benefit of a research project for them. Perceived benefit to the organization is more likely to be in the realm of positive impact on the availability of cost-sensitive approaches to patient care, new information about cost and cost off-sets, and results that can be used as part of the institutional quality improvement program (Dudley et al., 2000; O'Kane, 2001). Meetings with MCO representatives early in the proposal formulation stage can help assure that the final research design will be compatible with the clinical and informational needs of the organization. These meetings also provide an excellent opportunity for the researcher to develop realistic cost estimates for study implementation and data collection. While the MCO information system may be an excellent source of cost data, the expenses for retrieval of information for research purposes may be significant (Slubowski, 2001). Similarly, subject selection from an enrollment database or clinical records may be labor intensive. Inclusion of these expenses in the grant budget prevents undue burden on the MCO.

The focus of our study (clinical intervention with somatizing patients) was of high interest to the MCO because of the service utilization rates of this group of patients (Dudley et al., 2000). The clinical staff was enthusiastic and perceived the intervention as helping them with challenging, frequently attending patients. However, the MCO was concerned that the project might disrupt the delivery of clinical services. Several meetings focused on strategies to minimize the disruption to the organization while maintaining the integrity of the randomized clinical trial. At the request of the MCO, the outcomes in our study were expanded to include a cost of care/cost-offset component and we expanded our research team to include a health economist. These preliminary meetings helped us develop a broad base of support for the project within the MCO that was invaluable to us as we began to implement the pilot study.

Project implementation

Organizations have an established pattern of operations that can be abruptly disrupted when researchers enter the arena (Dudley et al., 2000). The implementation stage of our study was preceded by another series of meetings with representatives from key departments in the MCO. At this stage, our goal was to be inclusive but unobtrusive in the clinical environment. Through these meetings, we hoped to cultivate a broad base of support at all levels of the organization and solicit advice on ways to avoid unnecessary burden in the project implementation phase.

Significant organizational and personnel changes had occurred in the time elapsed between our pre-proposal meetings and the initiation of the pilot study. Using the relationship-centered approach that was the basis of our research intervention, we worked actively to reestablish a sense of common purpose and to demonstrate our respect for the routines of the organization. Personnel at all levels, known on a first-name basis as a result of our pre-proposal meetings, were asked about the details of operations in their departments and how the tasks of the study could fit most smoothly within existing mechanisms. For example, medical records personnel were asked to describe day-to-day operations and to provide suggestions on how to streamline the chart review and sample selection process. In one instance, they provided a suggestion that we flag potential study patient charts at medical records to bring study eligible subjects to the attention of the primary care provider on subsequent primary care visits; this facilitated identification of subjects and recruitment for the research team. Primary care providers gave us useful suggestions on

TABLE 1

Summary of Practical Steps for Successful Collaboration

1. Evaluate available MCOs for best fit
2. Assess MCO structure, history, and culture
3. Engage the MCO early
4. Establish a relationship with key MCO personnel
5. Find a common ground:
    a. Identify and facilitate the MCO's interests
    b. View the MCO as a collaborator with unique needs
6. Meet with key personnel, ask who they are, be comprehensive
7. For meetings:
    a. Get to know the people personally – use first names when comfortable
    b. Have specific agendas and make needs explicit
    c. Hear MCO concerns/interests, especially about proposed research
    d. Express your own interests and needs
    e. Pin down details and plan for next meeting
8. Stay abreast of problems and maintain the relationship

guidelines for communication between the nurse practitioner implementing the study and the primary care provider. By maintaining a relationship-centered approach with key individuals, we were able to prevent some chaos and successfully resolve project issues that did arise. Importantly, we learned that research implementation faltered when we neglected systems issues and failed to ask at each juncture "Who else would want or need to be involved in this decision?"

As a result of the support of individuals at all levels of the MCO, we were able to complete a pilot clinical trial and incorporate our results in a federal grant application. With the awarding of NIMH funding for this project, we implemented a randomized clinical trial. During the year our proposal was in the scientific and funding review, significant organizational changes occurred in the HMO. Although we had developed a successful collaboration within the staff model HMO during the pilot phase, we faced new organizational issues as we implemented the project on a larger scale. The principles we have outlined in this paper applied in the conduct of the full study, now nearing a successful conclusion. We were thus able to sustain our collaborative relationship. Indeed, we have extended this to additional research projects. That is, we have begun to institutionalize a mutually beneficial relationship. Writ large, we all can aspire to much greater success stories with long histories of research collaboration, for example, Group Health Puget Sound and Kaiser of Northern California.

CONCLUSIONS

A changing healthcare environment has changed the research atmosphere for academic-based investigators in many ways. With the new focus on the MCO, there is an even greater need than before to incorporate systems and relational issues

when we conduct research in partnership with MCO colleagues. Table 1 summarizes the practical points that we have found useful in successful collaboration with an MCO.

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