BRIEF REPORT

Patient Participation in Research in the Managed Care Environment: Key Perceptions of Members in an HMO

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This study's objective was to elicit the views of research among enrollees in an HMO. A questionnaire was mailed to 207 adult enrollees, 55% had been exposed to research and 45% had not. Ninety-four percent of respondents supported research within the HMO, and 87% thought using information from medical records for research was acceptable. Sixty-three percent thought participation in research increased patient understanding of health care. Significantly more prior research participants thought that participation in research improves care. More patients would participate if written information were provided (67%), if feedback of results was provided (72%), and if their clinician invited them (67%). Only a modest percentage (20%) of patients would participate in a randomized trial.

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With few notable exceptions, HMOs and other managed care delivery systems have not participated in research activities.¹ The principal mission of these organizations is the delivery of health care, rather than the pursuit of academic activities such as research and teaching.² With the increasing penetration of managed care into urban medical marketplaces, many observers have expressed concern that managed care threatens the vitality of academic medical centers and, therefore, the future of medical research in the United States.^{3,4} A growing number of managed care organizations, however, are becoming involved in research.⁵ Research and teaching activities are part of the mission of these HMOs.^{6,7} It is criti-

cal to understand what enrollees would consider to be the advantages and disadvantages of participation in research, if this activity is to be encouraged and sustained within the managed care environment. The aim of this study was to elicit the views of enrollees about HMO-based research.

METHODS

Key informant interviews were held with researchers, clinicians, HMO managers, and research administration staff. Information from these interviews was used to produce discussion guides for two focus groups of HMO enrollees (one for participants in research at the HMO, another for those not "exposed" to research). Audiotapes of the focus group meetings were systematically reviewed to identify domains of interest for a subsequent survey of adult HMO enrollees.⁸ A questionnaire designed to elicit opinions in these content areas was formally pilot tested in a small, random sample of respondents, revised, and fielded late in calendar year 1996. The split-half consistency of the main scale items of the questionnaire was found to be satisfactory (Cronbach's $\alpha = .77$).⁹ The full survey instrument, data on instrument performance, and complete survey results are available upon request from the authors (TI).

The main content areas included questions about the advisability of the organization's participation in research, enrollee perceptions of the risks and benefits of personal participation in research, several scenarios designed to elicit member perceptions of willingness to participate in research of different types (surveys about the quality of care, clinical research that requires blood tests, and participation in a randomized trial of treatment for a chronic disease), respondents' experience with research, and a demographic profile.

The sample included 188 patients known to have participated in HMO-based research (research participants), and a sample of 188 from the general member population (general members) matched on age by decile, gender, health center, and by condition/disease (where appropriate). Research participants were randomly sam-

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pled from lists of patients taking part in research studies at the time of the survey.

The questionnaire was mailed to 376 adult members; 11 questionnaires were returned as undeliverable. After a further reminder, 207 responses were received, for overall response rate of 57%. One hundred fourteen (61%) research participants and 93 (49%) general members responded. A telephone interview version of the questionnaire was completed by a randomly selected sample of 10% of nonresponders.

The Harvard Pilgrim Health Care Human Studies Committee gave approval for the study.

The Statistical Analysis System (Version 6.12, Cary, NC) was used for all data analyses. Bivariate associations were assessed for statistical significance using Fisher's exact test with a significance threshold of $P < .05$.

RESULTS

The majority (51%) of respondents were age 40 to 64 years, followed by those under 40 (29%), and 65 and over (19%). There were 92 males and 102 females; 13 respondents did not give their gender. Fifty-four percent had at least a 4-year college degree. The majority (70%) of the 194 who indicated their racial group were white; 18% were African American.

A large majority of respondents (Table 1) felt that HMOs should participate in research (94%), that research should be more visible to members (80%), and that research should be done using patient records with appropriate safeguards for confidentiality (77%). Particular enthusiasm was expressed for research on alternative medicine therapies (86%). A majority (59%) thought that funding from outside the HMO itself should pay for research.

Sixty-four percent of respondents felt that participating in research would have a major impact on medical care (Table 2), 63% that it would increase patient understanding, 39% that it would facilitate care, 42% that it would improve their health, and 94% that it would be a good or neutral experience. Only 8% of patients felt that participation in research would increase their anxiety.

Previous research participants were more likely to think that research would facilitate care than the sample of general members (44% vs 33%, Fisher's exact test $P < .05$). There were no other significant differences between research participants and general members.

Approximately two thirds of patients were more likely to participate in a research if written information about the study were provided (67%), and a similar proportion would be more willing to participate if a clinician known to them invited them to take part (67%) (Table 3). Forty-one percent of patients were more likely to participate if there was a financial incentive, and 72% were more likely to participate if feedback of results was promised. Only 23% would be likely to take part if there was no direct benefit for their health and 20% if they could not determine which treatment they would receive (i.e., treatment was allocated on a random basis).

Telephone follow-up of 10% of the nonrespondents using an interview-based version of the questionnaire revealed similar rates of responses on all items to those obtained by mail.

DISCUSSION

HMO enrollees in this setting were strongly supportive of research and, in general, perceived the effects of research on care as positive. Previous work has suggested that Americans value medical research as a function of health care delivery systems, but the views of managed care enrollees in particular are unknown.¹⁰ Ironically, it is possible that patients in nonacademic settings may be more interested in taking part in research than those who attend academic health centers.^{11,12} Respondents in this study were also advocates for the use of medical record information for research, so long as safeguards are taken to preserve confidentiality. This finding is particularly interesting in view of the current debate about the confidentiality of medical record information.

The only significant difference between those who had taken part in research studies and the general member sample, was that research participants were more likely to think that participation in research would have a

Table 1. Enrollees' Views About the HMO's Involvement in Research

	Agree, %	Neither agree nor disagree, %	Disagree, %
HMO should actively participate in research, $n = 188$	94	4	2
Research should be paid for by HMO, $n = 193$	33	40	27
Research should be paid for by organizations other than HMO, $n = 193$	59	35	6
Research should be more visible to members, $n = 194$	80	19	1
Research should include studies of alternative medicine treatments, $n = 195$	86	12	2
Research should be carried out with information from member's medical records (with appropriate safeguards for confidentiality) $n = 195$	77	10	13

n indicates the number of respondents for each item.

Table 2. Impact of Research on Medical Care

	Agree, %	Neither agree nor disagree, %	Disagree, %
Has a major impact on medical care, <i>n</i> = 193	64	32	4
Increases understanding of health problems, <i>n</i> = 193	63	36	2
Facilitates usual health care routine, <i>n</i> = 191	39	55	5
Improves health, <i>n</i> = 193	42	48	10
Good experience, <i>n</i> = 193	44	50	6
Anxiety producing, <i>n</i> = 191	8	70	22

n indicates the number of respondents for each item.

positive effect on their health care. Previous experience of research in patients who have cancer has also been shown to be associated with more positive views about research.¹³

The value of a personal invitation from a known clinician and the provision of written information have been highlighted in other patient groups, including those with serious illness.^{14,15} These findings among this population of HMO enrollees are therefore not dissimilar from the findings of studies in other patients groups and healthy volunteers.¹⁶

The least affirming responses from enrollees were expressed in the scenario exploring their willingness to participate in a randomized trial, confirming recent findings that this design is difficult for potential participants to appreciate.^{17,18} In addition, only a minority would take part in clinical research if there was no direct benefit for their health. The latter finding is a challenging one for researchers, since from methodologic and medical perspectives we cannot promise direct benefit from any treatment in a research study. On the basis of data from the focus group discussions, however, we believe that many respondents thought that their *experience* of participating in research was a positive experience and 'benefit.' In many cases, this was because of the incidental effects of activities that constitute being part of a study, such as learning more about their health problem, having longer clinician contact time, or having their opinion valued in an interview. We suggest that these effects may represent an indirect benefit to patients, independent of any possi-

ble direct benefit in terms of improved outcome in a clinical trial. This observation clearly should not undermine the importance of managing the expectations of research participants and ensuring that they understand that they may not gain *medical* benefit from taking part in research studies.^{19,20}

The most important limitation of this study is the response rate of 57%. Attempts to optimize the response rate included personally addressed hand-signed letters, a reply-paid envelope, and sending a reminder letter with a second copy of the survey after 3 weeks. The limited response rate on the survey may exert a positive bias in favor of research, because it is possible that those who responded had more positive feelings about research. It is reassuring that the random sample of nonresponders produced responses that did not differ significantly from the mailed survey responses.

The respondents were a highly educated group, and the majority were white. Data on education and race are not routinely captured by the HMO for the membership at large; therefore, comparison of the study sample with the general HMO population is not possible. The racial composition of the study sample is nearly representative of the urban Boston metropolitan population (18% African American vs 22% in the 1990 U.S. census).

The findings of this study suggest that researchers within HMOs need to develop enhanced systems to inform enrollees about safeguards to assure the confidentiality of information used in research, provide summaries about the content and purposes of research, and alert patients

Table 3. Willingness to Participate in a Study that Involves Taking a Drug for High Blood Pressure

	More likely to participate, %	Neither likely nor unlikely to participate, %	Less likely to participate, %
Written information was provided, <i>n</i> = 191	66	27	7
Request came from clinician, <i>n</i> = 192	67	27	6
Financial incentives provided, <i>n</i> = 188	41	46	13
No direct benefit for health, <i>n</i> = 191	23	50	27
Cannot determine which treatment, <i>n</i> = 190	20	44	36
Feedback would be provided, <i>n</i> = 192	72	21	7

n indicates the number of respondents for each item.

and their physicians to their opportunities for participation in research. Researchers should also consider providing feedback of results to participants, and ensure greater patient understanding of the meaning, purpose, and design of research studies, and randomized trials in particular.

Although some authors have raised concerns that economic and demographic pressures created by the growth of managed care may decrease research in academic centers, new opportunities for specific types of research are emerging in managed care populations. Our results suggest that HMO members value research as a specific activity of the health plan. Our findings also suggest that patients perceive that they can gain indirect benefits from participating in research that are independent from any direct effect on health outcomes. This does not negate the importance of truly informed consent, confidentiality and respect for individual patient needs, but may inform the debate on the ethics of patient participation in research studies.

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