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Do Patient Consent Procedures Affect Participation Rates in Health Services Research?

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BACKGROUND. Few studies have examined the effects of Institutional Review Board (IRB) requirements to contact potential research participants.

OBJECTIVE. To examine the association between requirements to contact potential research subjects and participation rates in a multisite health services research study.

RESEARCH DESIGN, SUBJECTS. Prospective observational study of survey participation by 2673 individuals with diabetes and 1974 individuals with congestive heart failure treated at 15 clinical sites in the United States that had implemented a quality improvement intervention.

MAIN OUTCOME MEASURES. Telephone survey response rates.

RESULTS. Of 15 IRBs, seven required sites to obtain authorization from participants to release contact information to the study team. Five required oral and two required written advance permission. The response rate was 58% (913/1571) at sites where no advance permission was required, 39% (989/2530) from sites that required oral advance permission and 27% (145/546, $P < 0.001$) at sites requiring written advance permission. Although 85% of eligible participants contacted directly by the study team consented to complete the survey, only 43% of individuals at sites requiring written advance permission allowed the release of contact information to the study team.

CONCLUSIONS. Many potential participants did not grant advance permission to be contacted by the study team. Requiring advance permission reduced participation rates, especially at sites requiring written authorization.

Key words: Health services research; participation rates; response rates; subject recruitment. (Med Care 2002;40:283–288)

Although previous reports have documented inconsistencies and variation in the Institutional Review Board (IRB) process,[1–6] few studies have focused on the impact of requirements to contact potential research participants. Requiring written consent for medical record review or written permission before contacting potential research subjects has been associated with low response rates.[1,7] Higher response rates have been noted when patients were asked to give consent for the use of their medical records for research in an ambulatory care setting.[8]

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The Improving Chronic Illness Care Evaluation (ICICE) is a multisite study to assess the effectiveness of a Quality Improvement (QI) intervention. One important component of the evaluation is a telephone survey of individuals with diabetes or congestive heart failure who received care at intervention sites. Although regulated by the same federal guidelines, the Institutional Review Boards at the clinical sites varied in required procedures to contact potential participants. The purpose of this paper is to describe the association between site-specific contact procedures and participation rates. We present our data as a real world example of conducting survey research in the current regulatory climate.

Materials and Methods

The ICICE study was designed to evaluate the effectiveness of an intervention intended to improve care for individuals with chronic disease. Based on the Chronic Care Model,[9] the intervention was disseminated to teams from participating clinical sites through a Collaborative sponsored by the Institute for Health Improvement.[10] In three workshops, team members (typically a physician, a manager, and a care coordinator) were introduced to QI methods and clinical and health services delivery practices previously shown to improve targeted outcomes for specific long-term conditions. Between workshops, the teams implemented these practices locally and had ongoing contact with each other and expert consultants to enhance their efforts.

ICICE researchers at RAND and UC Berkeley conducted an independent evaluation of the effectiveness of this QI intervention.[11] Diabetes and congestive heart failure (CHF) were the focus of the first phase of the evaluation. Of 27 clinical sites eligible for the evaluation, 12 sites sought to improve care to persons with diabetes, and 15 targeted care for CHF. The clinical sites were located in 10 states across the United States.

One important component of the ICICE evaluation was a telephone survey of individuals who received care at intervention sites. The clinical sites used a standardized case-finding protocol to identify potential participants who were the target group for the QI intervention, and another set of patients who would not receive the intervention initially and could act as a control group for the evaluation. The patient survey asks questions regarding health-related quality of life, disease-specific quality of life, self-efficacy, knowledge and self-care behaviors related to their specific long-term condition, patient satisfaction and access, patient education and other demographic characteristics. The survey was administered by trained interviewers and took approximately 30 minutes to complete.

All the clinical sites and their IRBs reviewed an identical standardized study protocol provided by RAND that offered several options for enrolling subjects into the evaluation study. At some sites, potential participants had signed a release to allow the use of their records in QI projects and their contact information (name, phone number, and address) was released to the study team without additional authorization. At other sites, the local IRBs required advance permission from potential participants, either oral or written, before allowing contact information to be released to the study team. Advance permission is not consent to participate in the study, but authorizes the study team to contact an individual about enrollment in the study. All potential participants were sent an introductory letter either by the clinical site (in advance permission sites) or by the RAND study team describing the purpose of the study before the first telephone contact. The letter provided a toll-free telephone number and a contact number at the clinical site for questions or to opt out of the study. Informed consent was obtained from all participants by the study team at the start of the telephone survey. During the study, we systematically recorded IRB requirements for subject contact at each site in addition to collecting various measures of participation.

We used the American Association for Public Opinion Research (AAPOR) definitions for cooperation and response rates to measure study participation.[12] The cooperation rate is the percentage of those completing the survey among those who were contacted. The response rate is the percentage of those completing the survey among potential participants. Two estimates of response rate were calculated. First, the minimum response rate (AAPOR RR1) includes as potential participants those completing or partially completing the survey, eligibles who were not interviewed (because of refusals, death, language or other problems) and those of unknown eligibility who were not interviewed. A second response rate (AAPOR RR3) defines potential participants as those completing or partially completing the survey, eligibles

who were not interviewed and the estimated number of those with unknown eligibility who would have been eligible. We used the eligibility rate for sites with no advance consent requirement to estimate eligibility among those who were not contacted.

Results

Of 27 potential sites, 12 did not participate in the evaluation. Despite our offer to pay for the costs of IRB review and patient contact, four sites concluded that recruitment and consent procedures were too burdensome. Of the 15 remaining sites, 10 underwent full IRB review, one had an expedited IRB review, and four sites deferred to the IRB at RAND. Overall, eight sites required no advance permission to contact the potential participants for the telephone survey, five sites required oral and two sites required written advance permission.

Figure 1 outlines the steps that were required for successful completion of the telephone survey. At sites requiring advance permission, participants first had to be contacted by the site. If advance permission was given, contact information (name, address and telephone number) could be released to the study team. The study team then recontacted them, determined eligibility, described the study, obtained informed consent, and completed the telephone survey. Of the sites requiring written or oral advance permission, 79% and 71% (respectively) of potential participants were contacted by the clinical site. Of those recontacted by the study team, 88% and 92% were eligible to participate. At sites that did not require advance permission, the contact rate by the study team was higher (94%), but the percentage of those contacted who were eligible was lower (73%) (Fig. 1). Overall, the product of the contact rates and eligibility rates were similar across different sites (Table 1). The refusal rate was 3% (n = 160), including a small number of individuals who opted out of the study before being contacted by either the clinical site or the study team.

Of the sites without advance permission requirements, 85% of eligible participants agreed to complete the telephone survey (Fig. 1). The sites with advance permission requirements had lower cooperation rates. For these sites, the cooperation rate is the product of the rate of advance permission and the consent rate to complete the survey.

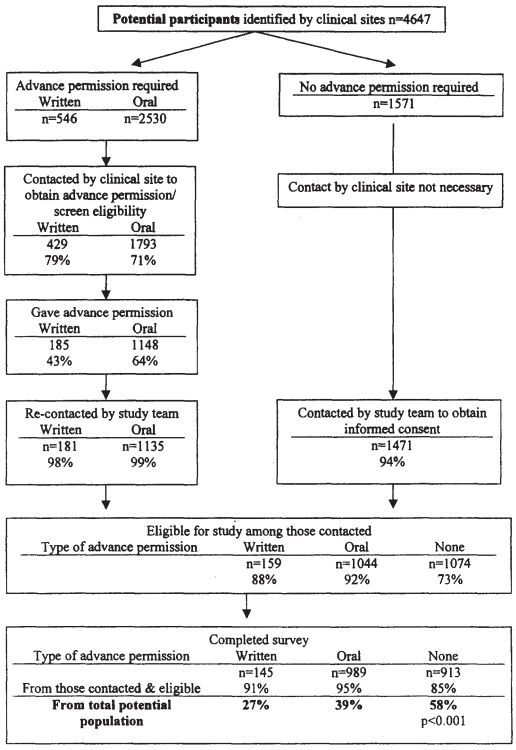

FIG. 1. Study Flow Chart.

The sites with written advance permission had the lowest overall cooperation rates at 39%, with only 43% of potential participants signing written authorization to allow for release of contact information to the study team.

Response rates varied by the type of recruitment procedure and were highest for sites that did not require advance permission (Table 1). Of the total population at these sites, 58% completed the telephone survey, compared with 39% from sites with oral advance permission and 27% from sites requiring written advance permission ($P < 0.001$). If we assume that all sites had an eligibility rate of 73% (the rate among sites with no advance permission), then the response rates based on those presumed eligible are 1/0.73, or 1.37 times larger, as shown in Table 1.

From the sites that required advance permission, we have no demographic information on individuals who did not authorize study team contact. At sites where no advance permission was required, participants who finished the study did not differ significantly from those the study team could not contact or who did not consent to the

TABLE 1. Contact, Eligibility, Cooperation, and Participation Rates by Type of Advance Permission Requirement

	Advance permission		
	None %	Oral %	Written %
Contacted and eligible*	68	64	68
Permission to contact		64	43
Consent to survey	85	95	91
Cooperation rate†	85	61‖	39‖
Response rate RR1‡	58	39‖	27‖
Response rate RR3§	80	54‖	39‖

Definitions from: American Association for Public Opinion Research. Calculating Outcome Rates from Final Disposition Distributions. Standard Definitions.

*for sites with oral and written advance permission, combined contact rate = (contact rate by site) × (re-contact rate by study team), then contacted and eligible = (combined contact rate) × (eligibility rate).

†cooperation rate = COOP3 = (permission to contact) × (consent to survey).

‡participation rate = RR1 = completed survey/potential participants = (contacted and eligible rate) × (cooperation rate).

§participation rate = RR3 = completed survey/(73% of potential participants presumed eligible).

‖*$P < 0.001$, χ^2 compared to sites with no advance permission.

survey (Table 2), although patients with CHF and those in the intervention group were slightly more likely to complete the survey than individuals with diabetes and those in the control group.

Discussion

We found a substantial variation in requirements to contact potential research participants in this multisite health services research study. When asked for advance permission, many individuals did not grant authorization to be contacted by the study team. Requiring advance permission, especially written authorization, significantly reduced the rate at which potential subjects participated in the study. In our study, busy clinic personnel requested advance permission. They may have had variable knowledge about the study and limited time to perform this additional task. Seeking advance permission provided an opportunity for individuals to refuse to participate, most likely before they were fully informed about the purpose of the study or the potential benefits and risks associated with participation, exercising what might be considered an "uninformed refusal."[13]

A strong association was shown between requirements for contacting potential research subjects and study participation as measured by response rates. To be conservative, we calculated response rates based on the total number of potential participants.[12] We have no reason to believe actual eligibility rates differed by site. Sites requiring advance permission had higher eligibility rates when contacted by the study team, most likely because these sites did some advance eligibility screening on their initial contact. The com-

TABLE 2. Characteristics of Eligible Participants at Sites With No Advance Permission Requirements

	Total	Refused/Not located	Completed survey
Age (mean)	65.9	66.0	65.8
Female (%)	50	51	50
CHF patient (%)	50	48	51
Intervention patient (%)	37	33	39
Number of participants	1174	261*	913

*Includes 100 not located, 161 refusers.

bined rate of contact and eligibility was similar among all sites, as expected because procedures for identifying potential participants were similar.

Our findings are limited by the inability to control for other site or patient characteristics that may have been important determinants of participation. We did not have enough sites to control for location, type of clinical site, or other site-specific characteristics. Several clinical sites did not participate in the evaluation study and it is possible that the samples of institutions from which our data are drawn are not representative of the larger group. Because we do not have information on nonresponders from sites that required advance permission, we are unable to account for patient factors that may determine study participation.

Our results are consistent with other studies that have documented low response rates when written consent was required for medical record review[7] or before contacting a patient for a health related survey.[1] When researchers were required to contact potential participants for written consent before medical record review, the contact rate was only 53% after multiple telephone and written contacts, with only 19% authorizing the use of their medical records.[7] In another study, the response rate was less than 30% for sites requiring a return post card before contact could be made, as compared with more than 90% in those where contact could be made directly after a patient was sent an introductory letter.[1]

Stringent policies about contacting potential participants raise the cost of research and threaten the validity of conclusions. Obtaining advance permission takes time and money, and together with multisite IRB procedures, greatly increases the duration and cost of research. Scientific validity can also be threatened, given differences in demographic and health characteristics between those who consent and those who did not consent to participate in health services research.[8,14] High participation rates are the best way to reduce biases caused by such selection.[15] For multisites trials such as ours, there is an additional threat to validity when local IRBs impose different requirements, resulting in large variation in response rates across sites.

The main risk in survey research is the potential to violate patient confidentiality. The potential harms to a participant from a confidential conversation are much smaller than from medical treatment. Despite increasing public concern about health care privacy,[16] our experience suggests that once individuals are given detailed information by trained survey staff (as at our sites with no advance permission requirements), the majority agree to participate. A reasonable strategy for contacting potential subjects in most populations could be written notification containing a description of the study and an option for the individual to decline participation. If the individual does not opt out of the study, they could then be contacted about study participation. Obtaining authorization to be contacted about studies involving medical record review at the time of routine ambulatory care has also yielded high response rates.[8]

Procedures for contacting potential research participants may impact the ability of researchers to conduct efficient and valid studies in many fields besides health services. New regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA)[17] are changing the regulatory environment for researchers by creating an enhanced set of standards for research review.[16,18] Under HIPAA, contact information from potential research participants could be released to researchers without individual consent, provided a waiver is obtained from an IRB or privacy board.[16] However, our data suggest that when choices are left to individual IRBs and privacy boards without a standardized review of research waivers, local decisions will exhibit considerable variation, with some sites imposing stringent contact procedures that affect participation rates, scientific integrity and costs of research.

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