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Motivations of Patients with Diabetes to Participate in Research

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Abstract

Background—Research on the motivations of research participants has focused primarily on vulnerable populations at risk of exploitation, and there is little research on the motivations and reasons of general medical patients participating in research. Given a significant increase in research studies recruiting participants with diabetes, we sought to better understand the motivations of patients with diabetes considering a general medical research protocol.

Methods—The analyses presented here compare the reasoning and willingness to participate in a hypothetical research study of medically ill subjects (patients with diabetes, n=51) with non-ill (n=57) subjects. Responses on the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) were correlated with demographic variables and scores on the Mini-Mental State Examination (MMSE) and Short-Form-36 (SF-36).

Results—Overall, 44% of the group with diabetes and 56% of the comparison group indicated a willingness to participate in the research study. The reasons diabetic and comparison groups offered for willingness or unwillingness to participate in research did not differ significantly. 75%

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mentioned reasons related to treatment, 63% altruism; none mentioned money. Of those patients with diabetes who would not participate in research, 94% cited risk, and 89% expressed an aversion to research.

Conclusions—The present study suggests that when research is not related to their diagnosis, persons with diabetes do not differ significantly from non-ill comparison subjects in their motivations to participate in research. Given the similarity of our subjects' motivations to those of other medically ill populations, it may be that investigators can now focus more closely on the decision-making characteristics of their patients involved in clinical research rather than their diagnoses.

Keywords

Research participation; Bioethics; Research subject motivations; Diabetes; General medical research; Empirical ethics

INTRODUCTION

Studies examining the motivations of research participants have understandably focused on vulnerable populations (Candilis et al. 2006; Kaminsky, Roberts, and Brody 2003; Roberts et al. 2002; Roberts et al. 2003). Empirical work with both medical and psychiatric patients has found a willingness to participate in research despite impairments in the ability to provide informed consent and significant risks to participants (Cassileth et al. 1991; Lidz et al. 1983; Mouton et al. 1997; Tomamichel et al. 1995). Yet little research has focused on the motives influencing research participation among general medical patients. Specific concerns with the reasons and capacities for entering research remain among the ethically and legally significant challenges facing medically ill research participants across all diagnoses.

To explore these influences on a rapidly expanding research population, we investigated the motivations of patients with diabetes to participate in medical research. This is a particularly salient population for study given the increasing prevalence and morbidity of diabetes in the United States and the extent of research being conducted on the disease worldwide. Data from 2011, the most recent available from the National Institute of Digestive and Kidney Diseases, estimates that 25.8 million people are currently living with diabetes in the US. Diabetes was the 7th leading cause of death in the U.S. with associated direct and indirect costs of $174 billion (National Diabetes Information Clearinghouse [NDIC] 2011).

A 2012 search of ClinicalTrials.gov, the National Institutes of Health (NIH) registry of federally and privately funded clinical trials conducted around the world, identified 8512 studies on diabetes either recently completed, recruiting, or active. The trend in diabetes research is toward increasing use of molecular biology and biotechnology techniques, such as genetic susceptibility testing (Bunnik, Schermer, and Janssens 2012), ethnic variability in genetic risk for disease (Winkelmann 2003), and stem cells for regenerative medicine (Wainwright et al. 2006). Although these molecular biology studies may represent less physical risk to subjects than lengthy and demanding trials such as the Diabetes Control and Complications Trial (1999), genetic research, especially predictive testing, may have a

greater potential for stigmatization, especially among minority populations which have a higher prevalence of diabetes (Haga 2009). These emergent challenges to the informed consent process warrant further study of the influences of disease-specific characteristics on the capacities and motivations of patients with diabetes to enter medical research.

Existing research on these issues among patients with diabetes is limited. Indeed, our study did not explore attitudes of patients with diabetes toward trials involving their own disease, but rather participation in a more general research trial. A 2003 report on patients enrolled in the United Kingdom Prospective Diabetes Study—a large ten-year clinical trial of Type II diabetes management and complications—is one of the only studies to explore the motivations for research participation of patients with diabetes (Lawton et al. 2003). Results indicated that patients joined the trial because they would receive the finest clinical care and hence reduce the threat of disease.

Palmer and colleagues (2005) undertook an examination of the capacity of patients with diabetes, schizophrenia, and Alzheimer's Disease to consent to research. Patients with diabetes performed better than the other two groups on two forms of decisional capacity assessment. However, there was considerable heterogeneity within the group of persons with diabetes, reinforcing the need for individualized assessments of capacity (Palmer et al. 2005).

There is further research among a subset of persons with diabetes or those at risk of diabetes that suggests a tendency toward incomplete, rapid research decision making. An interview study of 32 adolescents and their parents considering diabetes research suggested that risks were quickly assessed based on past experience with similar medical procedures. Investigators noted that the affective component of these memories was focused primarily on the magnitude, rather than the probability, of a bad outcome (Reynolds and Nelson 2007). Similar findings from another group indicated that even if participants knew the risks and the probability of the risks, patients with diabetes would not alter their decision making about research participation (Huber et al. 2001).

Several authors have comprehensively investigated factors motivating participation in clinical trials. Spilker and Cramer (1992) stressed the importance of understanding the general factors that influence research participation, including background, medical experiences, degree of disease severity, philosophical beliefs, economic status, and other characteristics, as well as characteristics of particular groups of patients such as those with diabetes. A 2009 study exploring motivations for refusal to participate in a diabetes clinical trial identified missing work, frequency and number of appointments, study length, access to study locations, and physical discomfort associated with procedures as major barriers to participation (Robiner et al. 2009).

Based on this prior work on factors influencing research participation, we hypothesized that the willingness of patients with diabetes to participate in general medical research would be associated with being more educated, having higher decision-making scores on the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum and Grisso 2001), and having higher scores on a cognitive capacity screen. We also

hypothesized that length of illness and view of prognosis would influence research participation.

METHODS

Subjects

The present analysis derives from a larger study examining the motivations of patients diagnosed with thought disorder, patients with diabetes, and patients with no illness regarding willingness and capacity to participate in research (Candilis et al. 2006; Candilis et al. 2008). The comparative data were previously published; this paper focuses in more detail on the motivations of patients with diabetes to participate in research.

Patients with Type I or Type II diabetes were recruited to serve as medically ill subjects for a comparison of research decision making with non-ill subjects. Research participants with diabetes were recruited from a single medical clinic where treating physicians had given permission for recruitment. Researchers only approached patients whose primary physicians had indicated were physically capable of completing a 45-minute interview. The primary physicians first discussed the research study with patients and clearly informed them that they could refuse participation without jeopardizing their medical care. Post-interview debriefing strongly suggests that subjects did not feel unduly influenced by the recruitment process.

Subjects without any acute or chronic mental or physical illnesses were recruited from the non-professional staff of the local state psychiatric hospital; This group was selected because of its likely demographic similarity to subjects with diabetes.

Researchers informed participants that they would hear a description of a hypothetical drug trial and then complete a number of questionnaires. They would be compensated ten dollars for their participation. All subjects provided written informed consent, and both the University of Massachusetts Medical School and Massachusetts Department of Mental Health Institutional Review Boards approved the study.

Measures

All subjects completed an interview with the MacCAT-CR, a well-validated and widely used instrument to assess decision-making capacity (Appelbaum and Grisso 2001). The MacCAT-CR can be adapted to provide information regarding specific research protocols and assess subjects' understanding, appreciation, reasoning, and choice. In our study, the instrument was used to assess the decision-making capacity of participants about a hypothetical antibiotic trial, an outpatient study of a new antibiotic for sore throat versus an established medication. Risks of the trial included blood draws and drug side-effects that were not life-threatening. Investigators explained that participants could not be guaranteed individual benefit. The design of the antibiotic trial followed the structure of established antibiotic research, and treatment assignment was random and blinded, involving possible exposure to a new compound.

The principal investigator (PC) conducted the majority of the assessments and trained the first author (CG) in administration of the instrument. After observing two interviews, the first author interviewed four subjects under the supervision of the principal investigator. Each scored the surveys independently and then discussed any differences. Interrater reliability was calculated from these four interviews and four audiotaped interviews by PC and CG. The two primary authors subsequently coded interviews independently, exchanged information, and resolved discrepancies through discussion (Candilis et al. 2008).

Participants in the study also completed the SF-36 (Short-Form 36) health-related quality of life questionnaire (Ware and Sherbourne 1992) and the Mini Mental State Examination (Folstein, Folstein, and McHugh 1975). Patients were asked about the length of their illness and their view of its prognosis as a proxy for assessing desperation for treatment. All instruments were administered in a single encounter, in the same order of administration, and by the same unblinded investigator.

The willingness of participants to enroll in the hypothetical drug trial was obtained from responses to the Communicating a Choice sub-section of the MacCAT-CR. This section reads, “Now that you have had time to think it over, I would like to ask you again whether you think you are more likely to say ‘yes’ or ‘no’ if you were asked to be in this study.” Answers to the questions in the Reasoning sub-section (“So you think you would chose to be/not to be in the study? What makes this the best choice for you?”) were coded for content. The analyses presented here compare the reasoning and willingness of medically ill subjects vs. non-ill subjects to participate in research.

Statistical Analysis

Between-group differences in proportions were evaluated using Fisher’s Exact test for 2 × 2 tables or the Fischer-Freeman-Halton (Freeman and Halton 1951) test for tables with larger dimensions. Differences between groups on ordinal measures were evaluated using the Mann-Whitney U-test. For continuous outcomes, the distributional characteristics of model residuals were evaluated using both the Kolmogorov-Smirnov Goodness of Fit Test for Normality (Siegel 1956) and by visual inspection of frequency histograms. When residuals did not deviate significantly from a normal distribution, differences were evaluated using either the Student’s or Welch-Aspin t-test depending on whether the variances were homogenous. If reasonable approximation to a normal distribution could not be achieved, differences were evaluated using the Mann-Whitney U-test as above. Analysis of variance for a factorial design was used to evaluate differences on continuous variables between groups controlling for a third variable.

Willingness to participate in research was modeled using logistic regression (Howser and Lemeshow 1989) with the group and variables found to be associated with willingness to participate included in models along with group x predictor interaction terms. Terms without significant contribution to the prediction of willingness to participate were removed by backward elimination, after controlling for the effects of other variables (Tarone 1985). Statistical analyses were performed using the statistical software package SPSS Version 15.0.

Qualitative Analyses

The two primary authors constituted the coding team, discussing potential response categories as surveys were completed. Familiarity with the entire group of surveys from the parent study allowed the development of preliminary codes that were used in the early stages. Regular discussion of independent coding led to resolution of disagreements and development of rules for consistent coding of responses.

RESULTS

Subject demographics

Demographic data for persons with diabetes and the comparison group are shown in Table 1. Fifty-one patients with Type I or Type II diabetes participated; length of time patients had been diagnosed with diabetes ranged from 0.1 to 47 years (mean= 17.0, SD=9.54, median = 16 years). Fifty-seven individuals without any acute or chronic mental or physical illnesses agreed to participate, serving as the comparison group; 7 potential comparison subjects (10.9%) declined.

As expected, there were no statistically significant differences between the two groups in gender, educational level, or ethnicity. However, statistically significant differences were found in age (subjects with diabetes were an average of 6 years older), education (subjects with diabetes had an average of one more year of education), and racial composition (the group with diabetes had a smaller percentage of black participants than the comparison group; 6% vs. 19%). These differences were not found to affect the variables of interest (capacity, willingness to participate).

Willingness to Participate in Research and Its Correlates

Overall, 44% of the group with diabetes (n=51) and 56% of the comparison group (n=57) indicated a willingness to participate in the research study. The willing subjects did not differ by sex from those unwilling, with 67% of men (61% for persons with diabetes and 73% for comparison subjects) and 74% of the women (72% for patients with diabetes and 75% for comparison subjects) agreeing to participate. Similarly, there were no statistically significant differences between groups in willingness to participate that depended on age or race. Demographics and MMSE scores of subjects by willingness to participate are summarized in Table 1.

Though the willing and unwilling groups differed on 12 SF-36 items, willingness to participate in research was not significantly associated with any SF-36 scales. Of the eight subscales of the SF-36, two were associated with willingness to participate: Physical Functioning and Role-Physical. The association varied by persons with diabetes vs. comparison group. In the comparison group, for each 1-point reduction on the Physical Functioning scale, there was a 1.06-fold increase in the likelihood that a subject would be willing to participate. There was no effect of Physical Functioning on willingness to participate for participants with diabetes. This difference between patients with diabetes and comparison groups was statistically significant (p=.032). On the Role-Physical subscale in the comparison group, for every 1-unit increase in the scale, there was a 1.03-fold increase

in willingness to participate, but again no effect in the group of persons with diabetes. This difference between patients with diabetes and the comparison group was also statistically significant (p=.013).

Among persons with diabetes, previous participation in research, the number of years that a subject had the disease, the perceived progression of the disease at the time, the time since diagnosis, and the anticipated prognosis within 6 months, 1 year, or 5 years were not associated with willingness to participate.

Motivations for Participation in Research

Responses to the Reasoning subscale of the MacCAT-CR, which asks subjects about the motivations for their decisions about participating in the research study, fell into six domains:

1. Money/desire for payment (MONEY)
2. General and specific risks associated with research (RISK)
3. Aversion to research and procedures (AVERSION)
4. Motives related to receiving treatment (including better treatment) (BETTER TREATMENT)
5. Altruism (ALTRUISM)
6. Other responses

In univariate analyses, money was not associated with decisions to participate in research; however, each of the 5 other main reasoning domains was associated with a subject's decision to participate in research. All were statistically significant except for risk (p=.88). However, membership in the study group itself was not associated with a subject's decision to participate or not participate in research. In multivariate analyses, aversion to research, altruism, and better treatment all contributed significantly to the decision.

Of the persons with diabetes who would not participate in research, 94% mentioned risk and an aversion to research. Of those who would participate, 75% mentioned better treatment and 63% altruism; none mentioned money.

Altruism and the belief that research is generally beneficial were the major motivations expressed by those willing to enter the study. Those participants with diabetes mentioning altruism were approximately 30 times as likely to express willingness to participate (p<.001); altruistic comparison subjects were 19 times more likely to express willingness to participate (p=.001); and those mentioning the potential for better treatment were more than 21 times as likely to express willingness to participate (p<.001). The results for willingness to participate for both patients with diabetes and comparison subjects are summarized in Tables 2 and 3. Table 2 shows comparisons between patients with diabetes and comparison subjects separately for the groups that were willing and unwilling to participate, while Table 3 compares the willing and unwilling separately for the two diagnostic groups for each motivation.

Conversely, a general aversion to research was significantly associated with refusal to participate, with those expressing a dislike for research much more likely to refuse to participate than those who did not (odds ratio 333, $p<.001$). Money did not have an impact; it was only mentioned by two subjects, both of whom indicated they would not participate. In the multivariate analysis shown in Table 4, altruism, better treatment, and aversion to research all remained significant predictors of willingness to participate in research even after controlling for other reasons.

Qualitative Responses

Most subjects with diabetes who were willing to participate and identified the potential for better treatment recognized that they would be "taking a chance," but that they might "improve medical care," help "medicine advance," or even help themselves "down the line." Others were interested in learning something from the research experience or being part of an interesting project. Those who expressed altruism thought their participation would "help mankind," "help out doctors and people in the future," "offer the possibility of improving medical care for the majority of people," and generally "do good for someone else."

Some of those *un*willing to participate expressed reluctance to be a "guinea pig," recognizing that the project would not be "benefiting me" or that they "would not want something unproven." Some respondents recognized there may be little or no information on how the experimental medication interacted with their diabetes, saying, "Maybe the medicine hasn't been tested with insulin, with diabetes," or "Being diabetic it [the experimental medicine] would affect more than my throat." Others said they would participate only if the research were relevant to their diabetes. Still others objected to the double-blind or random assignment procedures, saying they preferred to know what went into their bodies.

A small handful of responses demonstrated lack of understanding of research procedures or research priorities. These incorrectly noted that the study "would be changed" if there were a bad side-effect, that the project was, "very important for me to get well," or that "I will find out for myself if it's good for me." Overall, however, only 6 responses from 5 subjects (only one of whom had diabetes) could be characterized as demonstrating misconceptions of the purpose or conduct of the research project

In the reasons offered, persons with diabetes and comparison subjects did not differ significantly. Although the reasons above (altruism, better treatment, etc.) were associated with participation, they were not differentially associated by group. Education, demographics, and SF-36 items were not significantly associated with participation before or after controlling for these reasons.

DISCUSSION

The present study suggests that persons with diabetes and non-ill comparison subjects are equally willing to participate in general medical research and do not differ significantly in their motivations to participate. Because the study did not involve research into the patients' own illness, it may have the potential to help researchers better understand the attitudes of

medical patients toward general research, without the confounding influence of the patient's perception of the disease – a disease they may have suffered for many years. Indeed, Spilker and Cramer (1992) identified the general motives of altruism and wanting to help physicians with research among the most common reasons patients enroll in clinical trials. This held true for both groups in our analysis: the motives for participation in research such as the potential for better treatment, or motives for not participating such as aversion to research, were the same.

Contrary to the findings of other studies employing hypothetical scenarios—one using pharmacy students and another using patients with hypertension—we did not find payment to influence evaluation of risk or willingness to participate (Bentley and Thacker 2004).

The results of the current study offer reassurance to patients, investigators, and regulatory bodies concerning the motivations of patients with diabetes to participate in an expanding research enterprise. Subjects recognized the risk of their choices and endorsed recognizable motivations for participation.

Persons with diabetes in our study who were willing to participate expressed concerns about risk and aversion to research—'the guinea pig fear"—like those that parents of children with diabetes endorsed in a previous study (Buscariollo et al. 2012). Regarding positive reasons for enrolling in research, persons with diabetes in our study, like those of Roberts et al. (2006) with HIV and thought disorder, affirmed altruism and the growth of scientific knowledge as primary reasons to enter research. As with our participants, adolescents with diabetes and those at risk of developing the disease explained their research participation as conferring personal altruistic value even if it did not confer direct clinical benefit (Reynolds and Nelson 2007).

Most of those endorsing the potential for better treatment couched their responses in ways that took into account the nature and purpose of research. The chronic nature of diabetes, with its requirements for consistent education and continuous monitoring, may eliminate the negative influences of illness on decision making. A 2007 study by Hamann et al. of 1,393 patients with acute and chronic physical and mental disorders drawn from six clinical trials (i.e., schizophrenia, hypertension, depression, multiple sclerosis, breast cancer, and minor traumas) similarly found no clear differences across diagnoses except among those with multiple sclerosis. Younger age, higher education, and female sex were modestly but significantly associated with a greater desire to participate in research. However, these factors explained only 14% of variance in research participation, and there were no clear differences between acute and chronic conditions (Hamann et al. 2007).

In our data as well, there is little indication that severity of illness or poor physical function and quality of life make some chronically ill patients with diabetes more likely to enter research. It may be that subjects with diabetes are more careful about research participation because of their experience of illness over time.

Limitations

This study does not directly assess motivations or vulnerabilities of patients with diabetes to participate in *diabetes* trials. Rather the study investigates motives of patients with diabetes regarding participation in general medical research. It is possible that a medication trial specific to diabetes may have garnered greater support among diabetic participants than a more general antibiotic scenario. The design was intended to appeal to non-ill as well as medically ill participants.

Another limitation is that subjects were asked to consider a non-life-threatening hypothetical antibiotic protocol rather than a real clinical intervention. It will be important to replicate these findings with subjects facing the proximity and rigors of actual studies and among those considering protocols with different risk/benefit profiles. Finally, the hospital staff members who comprised our non-ill comparison group may be more positively oriented toward health care research than members of the general public.

Conducted with subjects considering a single protocol, this study does overcome limitations of earlier studies that used multiple protocols and multiple interviewers. Clinical assessments of capacity by blinded interviewers may also help to clarify the relevance of these group comparisons to the individual assessments of clinical researchers.

Given the similarity of our subjects' motivations to those of other medically and mentally ill populations, it may be that investigators may now focus more closely on the individual perceptions and values of their patients involved in clinical research rather than their diagnoses.

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Table 1

Demographics and MMSE by group

	Comparison Group n = 57	Diabetic n = 51	Test of Overall Difference	*p*
Age			t=2.052	**0.043**
Mean (SD)	41.04 (13.16)	47.00 (16.61)		
Median	41	48		
Ethnicity				
White	71.9% (41)	88.2% (45)	*Overall:* Fisher Freeman Halton Test	0.11
African American	19.3% (11)	5.9% (3)		
Hispanic	7.0% (4)	3.9% (2)	*White vs. Other:* Fisher exact test	**0.05**
Native American	1.8% (1)	2.0% (1)		
Gender				
Female	42.1% (24)	35.3% (18)	Fisher Exact Test	0.55
Male	57.9% (33)	64.7% (33)		
Education				
Less than College	86.0% (49)	70.6% (36)	Fisher Exact Test	0.10
Completed College	14.0% (8)	29.4% (15)		
MMSE				
Mean (SD)	28.56 (1.34)	28.41 (1.46)	t = 0.58	0.56
Median	29	29		

Table 2

Willingness to participate by group and reason*

Factors Affecting Motivation	Comparison Group	Participation Decision			
		Yes	*p*	No	*p*
Risk	**Diabetes**	84.4%	**0.046**	94.4%	**NS**
	Comparison	63.4%		78.6%	
Aversion	**Diabetes**	3.1%	**NS**	88.9%	**NS**
	Comparison	5.0%		100.0%	
Better Rx	**Diabetes**	75.0%	**NS**	11.1%	**NS**
	Comparison	75.6%		14.0%	
Altruism	**Diabetes**	62.5%	**NS**	0.0%	**NS**
	Comparison	60.0%		7.1%	

*% in group mentioning motivation.

Note. NS = Not statistically significant.

Table 3

Subjects willing and unwilling to participate in research by motivation for decision*

		Diabetics			Comparison		
Factor Affecting Motivation	**Participation Decision**	**%**	**OR**	**p**	**%**	**OR**	**p**
Risk	**Willing**	84.4%	*3.15* *	**NS**	63.4%	1.24#	**NS**
	Unwilling	94.4%			78.6%		
Aversion	**Willing**	3.1%	***248*** *	<.001	5.0%	***< 285*** *	<.001
	Unwilling	**88.9%**			**100%**		
Better Rx	**Willing**	**75.0%**	**24.0**	**<.001**	**75.6%**	**18.6**	**<.001**
	Unwilling	11.1%			14.3%		
Altruism	**Willing**	**62.5%**	**< 30.0**	**<.001**	**60.0%**	**19.5**	**<.001**
	Unwilling	0.0%			7.0%		

*% in group mentioning that motivating factor

#reciprocal of odds ratio is reported when OR<1.0

Note. OR = Odds Ratio,NS = Not statistically significant.

Table 4

Predictors of willingness to participate in research (multivariate results without regard to group)*

Reason	Significance	Odds Ratio	1/Odds ratio
Altruism	.02737	39.795	
Aversion	.00003	.003	334.3
Better Rx	.04076	14.614	

* Group membership is not predictive of participation in multivariate analysis