Who Participates in Research on Adherence to Treatment in Insulin-Dependent Diabetes Mellitus? Implications and Recommendations for Research

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Objective: Examine the implications of nonparticipation in studies of treatment adherence among adolescents with chronic health conditions.

Methods: Empirical data from an adherence study with adolescents with diabetes were used to demonstrate the influence of family participation on demographic and health outcome variables. Ninety-four families were categorized into one of three groups: (1) families that declined to participate in the study at recruitment (nonconsenters), (2) families that agreed to participate, but failed to return the study questionnaires (nonreturners), and (3) families that had at least one family member return the questionnaires (participants).

Results: Despite being similar demographically, nonreturners had significantly lower treatment adherence scores and the adolescents tested their blood sugar less frequently than participants. Participants and nonconsenters did not differ on any available data.

Conclusions: We discuss the implications of these group differences on the generalizability of research findings, offer suggestions about how to maximize and maintain participation in research studies, and suggest directions for future research.

Key words: adherence; chronic illness; diabetes; participation rate.
school-based and examined healthy children. Little attention has been devoted to assessing the impact of consent in other populations of children, especially hospital-based studies of children with chronic illnesses. Betan et al. (1995) found that participation rates were higher among studies of children with medical conditions (72.6%) than among studies of general/schoolchildren (50.8%). Such data are particularly important to gather with chronic illness populations because most of these studies are conducted with small convenience samples not likely to represent the population (Betan et al., 1995; Drotar, 1994).

To our knowledge, only one study has examined the impact of sample participation on adolescents with a chronic health condition. Roberts and Wurtele (1980) found that 82% of adolescents with diabetes who were targeted for recruitment because they demonstrated extreme noncompliance with their medical treatment refused to consent to participate in a study of medical noncompliance. The authors hypothesized that adolescents’ medical noncompliance and refusal to participate in their study may indicate a general pattern of noncompliance, but they did not test the hypothesis empirically.

The data here were obtained in the context of a project concerning the relationship between parent-adolescent conflict and treatment adherence among adolescents with diabetes (Riekert, 1997). In contrast to Roberts and Wurtele’s (1980) study, this study included a more general population of adolescents with diabetes and assessed the relationship of characteristics, including adherence, to their participation. Adolescents at the clinic were approached for participation regardless of their physician’s perception of their adherence level or their level of metabolic control. Subjects could exclude themselves from the study in two ways: (1) by refusing to participate at the first contact, where consent was obtained, a 10–15-minute adherence interview was conducted, and the demographic sheet was completed (nonconsenters) or (2) by failing to return questionnaires they were given to complete at home and mail back (nonreturners). Because examining the influence of participation rates on outcome variables was not the main focus of the original study, detailed a priori hypotheses were not made. Based on the prior research on the effects of nonconsent discussed above, we expected that the nonconsenter and nonreturner groups would include adolescents who had lower adherence scores, tested their blood sugar less frequently, and would be in poorer metabolic control than those adolescents whose families returned their questionnaires.

Research Design and Methods

Recruitment Procedure

To be eligible for participation in the study, the adolescent had to be between the ages of 11 and 18 and live with at least one parent. Adolescents were excluded from the study if they (1) had been diagnosed with insulin-dependent diabetes mellitus (IDDM) for less than one year, (2) had an additional chronic illness, or (3) evidenced developmental delay (i.e., had Down Syndrome). Over a 7-month period, 94 families met these criteria and were asked to participate in the study. This represented 55% of all adolescents ages 11–18 who were scheduled for appointments at the clinic during that time frame. All eligible adolescents were not recruited because of examiner time constraints and missed doctor’s appointments. Eighty families consented to participate in the study, participated in the adherence interview, and completed the demographic questionnaire (85% initial consent rate). Fifty-two of these families had at least one family member mail back his or her questionnaires for an overall participation rate of 55%. The current study consisted of 94 families who were categorized into one of three groups: participants ($n = 52$), nonreturners ($n = 28$), and nonconsenters ($n = 14$).

At the clinic the examiner obtained the parent’s and adolescent’s informed consent. The adolescent participated in the treatment adherence interview while the parent completed the demographic questionnaire. The remaining questionnaires were given to the family in a self-addressed return envelope with sufficient postage affixed. We estimated that it would take the parents approximately 30 minutes each to complete their packet of questionnaires regarding their relationship with the adolescent and the adolescent approximately 1 hour to complete his or her questionnaires concerning his or her relationship with the parent(s). If the questionnaires were not returned within 10 days of the interview, the family was called once to remind them to return the packet.

A medical chart review was conducted for all 94 adolescents. Information concerning their number of blood sugar tests per day and most recent level of metabolic control was obtained. For the families
who refused to participate, demographic information (i.e., child age, gender, ethnicity, and disease duration) was obtained from the chart.

**Measures**

*Adherence and IDDM Questionnaire-R (Hanson, DeGuire, Schinkel, Kolterman, 1995).* This semi-structured interview assessed the adolescent’s adherence to treatment and covers Dietary Behaviors, Insulin Adjustment, Glucose Testing, and Hypoglycemia Preparedness. Composite scores range from 0–41 with higher scores reflecting better adherence. Adequate reliability and validity of the measure has been demonstrated (Hanson et al., 1995).

*Number of Blood Sugar Tests.* Each adolescent in the study already had a reflectance meter with memory used to monitor blood sugar levels. These data served as an objective measure of the adolescent’s adherence to blood glucose monitoring. The meter records the number of tests done by date and time. In this clinic, physicians generally recommend that adolescents test their blood sugars three times a day.

*Metabolic Control.* The adolescents’ levels of metabolic control were evaluated using glycohemoglobin (GHb), which is routinely performed at the time of the clinic visit. The GHb provides an index of average blood glucose levels over the past 2 to 3 months (Sperling, 1983; Ziel, & Davidson, 1987). Normal GHb values for this clinic range from 4.0 to 8.0. Higher values indicate poorer metabolic control.

*Demographics Questionnaire.* The demographic questionnaire included questions such as the adolescent’s age, gender, ethnicity, disease duration, and number of hospitalizations. Parents were asked their marital status, number of children in the household, and highest level of schooling completed by both the mother and father.

**Results**

To assess the representativeness of the sample, the demographic and health status differences between participants, nonconsenters, and nonreturners were examined. Chi-square analyses were used with categorical data, t tests were used when comparing data from two groups, and ANOVAs were used when comparing data from all three groups. Demographic variables examined were the child’s age, gender, and ethnicity; the number of children in the family; the parents’ marital status; and the mother’s and father’s education level. The demographic characteristics were similar between the groups; the only demographic variable for which the groups differed was father’s education level. Fathers in the nonreturner groups were less educated than fathers in the participants group (13.93 years versus 15.35 years, \( t = -2.15, p < .05 \)). These data were unavailable for the nonconsenter group.

The groups did, however, differ on two of the five health-related variables. There was a significant main effect for group when examining the average number of blood sugar tests the adolescents completed per day (\( F = 7.87, p < .001 \)). Post hoc analyses indicate that when families failed to return their questionnaires, the adolescents tested their blood sugar significantly less frequently (1.56 tests per day) than adolescents from families who returned their questionnaires or did not consent to participate in the study (2.51 and 2.49 test per day, respectively). There were no group differences between adolescents in the participant and nonconsenter groups. Adolescents from families who did not return their questionnaires also had adherence scores that were significantly lower than families who returned their questionnaires (\( M = 20.29 \) versus \( M = 23.62, t = -2.80, p < .01 \)). Again, these data were not available for the nonconsenter group.

Because the adherence questionnaire includes questions pertaining to blood sugar testing, we examined the possibility that differences on the adherence questionnaire were due solely to differences in blood sugar testing. When blood sugar testing items were removed, there continued to be group differences between adolescents in the participant and nonconsenter groups. Adolescents from families who did not return their questionnaires had adherence scores (minus blood sugar items) that were significantly lower than families who returned their questionnaires (\( M = 15.7 \) versus \( M = 18.2, t = -2.30, p < .05 \)).

**Discussion**

We found significant group differences in adherence levels between study participants and nonreturners in a study assessing parent-adolescent
conflict and treatment adherence in adolescents with diabetes. The families that returned their questionnaires had adolescents who had higher adherence interview scores and tested their blood sugar more frequently than adolescents in families who did not return their questionnaires. While the current study sample was for the most part demographically representative of the clinic population from which it was drawn, the sample likely overrepresented adolescents and families who were more effective in managing their diabetes, as assessed by adherence levels. One important implication of our findings is that data gathered in studies of adherence may not generalize to adolescents and families who are the most nonadherent.

There are no clinical cutoffs on the Adherence and IDDM Questionnaire-R (Hanson et al., 1995). The small mean difference on adherence scores between the participants ($M = 23.63$) and nonreturners ($M = 20.29$) does not appear clinically significant. On the other hand, the difference in blood glucose monitoring is likely to be clinically, as well as statistically, significant, in that it might very well affect the quality of diabetes management. We discussed the group differences (1.56 versus 2.51) with the clinic's diabetes nurse, and he stated that a difference of this magnitude would affect his clinical decision making because he would not be comfortable recommending insulin adjustments based on an average of 1.5 blood sugar tests per day (Paul McGuigan, personal communication, March 18, 1998).

One possible explanation for the group differences between the participants and the nonreturners is that the doctors made different recommendations to families about how often to test blood sugar levels. As part of the adherence interview, families were asked how often the doctor had told them to test the child's blood sugar. Ninety-one percent of the participants and 83% of the nonreturners reported that their doctor had recommended that the adolescent test his or her blood sugar at least three times per day. On average, both groups fell below this recommended number of blood sugar tests, and differences in the recommended number of blood sugar tests is unlikely to explain the group differences.

A plausible explanation for the group differences between the participants and the nonreturners is that both adherence and successful participation in the study require organizational and planning abilities. For example, the second phase of the study required families to complete questionnaires at home and mail them back. Families who did not return the questionnaires may have misplaced them or failed to set aside time to complete them. Similarly, adherence requires organizational skills, such as remembering to test blood sugar levels, ensuring that appropriate foods are in the home, and that the timing of meals and injections are correct. An alternative explanation for why families did not return the questionnaires may be that the families lacked incentive to complete the questionnaires or did not want to confront questions about diabetes-related issues or parent-adolescent conflict.

An interesting finding was that nonconsenters did not differ from participants on either demographic or health status variables. Weinberger et al. (1990) found that differences on outcome measures between participants and nonparticipants increased as the experimental tasks became increasingly demanding of subjects’ time and effort. Eight-five percent of the families participated in the first phase of the research study while only 55% participated in the second phase. This finding is consistent with Weinberger et al.’s (1990) results that families were more willing to participate when the experimental demand was low (i.e., a short interview while waiting for their doctor) than when the demand on the family became higher (i.e., spending 0.5–1.0 hours completing written questionnaires). Thus, it could be hypothesized that the nonconsenters did not differ from the participants because the time demand was low and their decision not to participate may be more random rather than a systematic pattern. As the time demands of studies increase, other factors, such as organizational skills as discussed above, may become more influential. Consequently, under conditions of high demand, subjects systematically excluded themselves from the final analysis of the data.

**Implications for Future Research**

To evaluate sample representativeness, other adherence studies (e.g., Kovacs et al., 1992; Wysocki, 1993) have typically compared demographic variables of participants to nonparticipants. Our data indicated that despite being similar demographically, nonreturners differed on several adherence variables of interest. Consequently, investigators should consider that their study results may not generalize to subsets of their clinic populations.

Research is needed to examine variables that af-
fect participation rates and sample attrition and the influence on specific outcomes. Nonparticipation and attrition may have greater effects on some variables more than others. For example, Boyle, Offord, Racine, and Catlin (1991) found that while sample attrition did not affect the assessment of the prevalence of psychiatric disorders or the evaluation of the risk of developing a disorder, it did affect the identification of variables that predict the prognosis of the disorder over time. The greatest attrition was found among children with psychiatric disorders living in adverse family circumstances. Moreover, research is needed to identify potential variables that mediate or moderate the relationship between participation status and data concerning health outcomes. Janus and Goldberg (1997) found that lower maternal age at the birth of the child, lower paternal education, and greater disorganization of mother-infant attachment were all related to greater sample attrition for samples including children with cystic fibrosis and coronary heart disease. These studies, along with our results, emphasize the need for researchers to address the influence that participation and attrition rates may have on the results and conclusions of their research.

These findings underscore recommendations that journals should consistently require researchers, at a minimum, to describe consent rates of recruitment procedures and the time commitment required for participation in the interest of understanding the effects of attrition on sample representativeness and the validity and generalizability of results. (Betan et al., 1995). Furthermore, such data would permit better assessment of the types of recruitment procedures and study demands that maximize participation of adolescents and families in research studies.

Beyond journal requirements, individual researchers should address the impact of participation and attrition biases at each phase of their research, from study design and implementation to drawing conclusions from the data. When designing and implementing a new study, researchers should take steps to enhance family participation by making participation convenient for families and minimizing the experimental demand placed upon them. This may include the research staff making home visits or scheduling laboratory visits on the days of planned medical appointments to minimize the travel requirements for the families. Offering incentives, such as monetary reimbursement for the family’s time or small gifts for the children, may enhance participation rates and minimize attrition. Finally, the researcher may have to spend increasingly more time with each family to provide encouragement and support for study participation as the time demand and burden of the study increases or becomes more complex.

Even in the most carefully designed study, families may decline to participate or fail to complete the entire study. An important area of future research would be to assess where the breakdown in research participation occurs by asking families the reasons why the research requirements were not fulfilled. In such instances, the impact of nonparticipation on the data should be examined. To achieve this, as much data will be needed on nonparticipants as is ethically and practically possible to obtain. Investigators have several options for gathering this data. This data may be obtained from extensive reviews of medical or school files or from the families themselves. When patients refuse to participate in a study, they should be asked to provide demographic information themselves or give explicit consent for access to their (or their child’s) medical records.

It should be noted that, in some settings, it is regarded as ethically acceptable to access medical records without consent of the patient, or the patient’s legal guardian in the case of a minor, provided that (1) the patient’s medical doctor provides explicit consent, (2) confidentiality and anonymity are preserved, and (3) the person reviewing the chart can be disciplined for any breach of confidentiality (Report of a Working Group to the Royal College of Physicians Committee on Ethical Issues in Medicine, 1994). Our institution’s Institutional Review Board (IRB) approved our using medical records without obtaining explicit consent from the adolescents’ legal guardians. Researchers at other institutions should consult with their own IRBs about the state’s and institution’s requirements for accessing medical records. Some states have passed legislation that restricts access to medical records for research purposes (see Melton, 1997) and some institutions may have their own restrictions.

Once the researcher has examined the data to see if the study sample is representative of the population in terms of demographic and outcome measures, it would also be useful to ascertain whether the range of scores is restricted on some or all measures and to consider whether this restricted range may have an impact on the generalizability of the results. For example, in the current study, adolescents with low adherence scores were not well represented in the final sample. Thus, when discussing
the results of the study (Riekert, 1997), we had to qualify our conclusions by stating that it was unclear whether these patterns of relationships held true for adolescents with poorer adherence levels. Researchers may also want to implement statistical means to evaluate and control for sample attrition (e.g., Boyle et al., 1991; Flick, 1988).

Several unanswered questions remain concerning how a nonrepresentative sample affects the generalizability of results: does it affect only the magnitude of the effect or the direction also? Are some outcome variables more sensitive to a nonrepresentative sample than others? The development of research to address these questions would help researchers design more effective studies and assist them in drawing conclusions from their results.

References


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