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Participant characteristics and study features associated with high retention rates in a longitudinal investigation of type 1 diabetes mellitus

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Abstract

Background—The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study has sustained an extraordinarily high level of participant involvement for over two decades.

Purpose—In order to identify specific characteristics of EDIC that contributed most strongly to retention, study-designed questionnaires were distributed to 1334 participants.

Methods—Confidential questionnaires were completed during EDIC Years 15–17. Participants were classified as Completely Adherent (completed all visits), Partly Adherent (missed >1 visit or major portion of a visit), or Inactive (did not participate for >5 years). Questionnaire items addressed specific aspects of clinic visits, evaluation procedures, staff–participant relationships, and medical/health-care support provided by EDIC.

Results—The most commonly cited reasons for continuing participation were Cutting Edge Tests to assess diabetes complications (79.3%), Annual Evaluations (67.7%), a desire to Help Others (65.2%), and Better Care for Diabetes (61.6%). Women chose Cutting Edge Tests as their first or second most important reason significantly more often than men, whereas men chose Better Care for Diabetes more frequently. Individuals with at least three diabetes-related complications were more likely than those with fewer complications to choose Annual Evaluations as their first or second reason for continued involvement.

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Limitations—The small proportion of individuals who discontinued participation restricted our ability to identify factors associated with suspended involvement. In addition, our analysis is limited to a cohort with type 1 diabetes followed in an observational study after an average participation time of 6.5 years in a randomized trial.

Conclusions—The primary reasons identified by respondents for their long-term commitment are consistent with shorter-term studies and underscore the importance of expert medical care, supportive staff–participant relationships, and involvement with clinically and scientifically meaningful research.

Introduction

The Epidemiology of Diabetes Interventions and Complications (EDIC) study is the observational follow-up investigation of the Diabetes Control and Complications Trial (DCCT) [1]. Completed in 1993, the DCCT established that intensive insulin treatment delays the onset and slows the progression of retinopathy, nephropathy, and neuropathy in type 1 diabetes [2]. At the end of the DCCT, 96% of the living participants consented to return annually to one of 28 DCCT/EDIC clinics for a standardized history, physical examination, and laboratory testing, which included assessments to determine glycemic, renal, retinal, neurologic, and cardiovascular status. Now in its 18th year of observational follow-up, EDIC continues to follow the DCCT/EDIC cohort in order to monitor the long-term effects of the DCCT treatment assignment on micro- and macrovascular outcomes and to describe the long-term course of type 1 diabetes.

Participant retention in DCCT/EDIC has been extraordinarily high, despite a broad time span and the transfer of over 300 individuals across clinics due to residential relocations. Between the onset of DCCT and the end of EDIC Year 15 (1983–2009), 74 deaths occurred among the 1441 DCCT participants. Of the surviving 1367 EDIC participants, 1296 (95%) continued their involvement in EDIC Year 15, 86% completed all scheduled examinations for that year and 73% had completed all 15 annual visits in EDIC.

Other longitudinal multicenter studies of diabetes, such as the Diabetes Prevention Program Outcome Study (DPP/DPPOS [3,4]) and Action to Control Cardiovascular Risk in Diabetes (ACCORD [5,6]), have also achieved high retention rates (81% and 98%, respectively), but their follow-up findings published to date have been based on considerably shorter time periods (9 years and 3.5 years, respectively [4,7]).

EDIC's high level of sustained retention may be attributable to a combination of factors, including the following: (1) comprehensive, multistage screening of applicants at the beginning of the DCCT; (2) aspects of the EDIC protocol that participants consider important (e.g., high-quality medical evaluations); (3) supportive long-term staff–participant relationships; and (4) ongoing oversight of retention by the EDIC Adherence Monitoring Committee [8]. While it is not possible to assess the impact of candidate screening or committee oversight on retention, questionnaires can illuminate participants' perspective on the influence of study protocol and staff. Several other clinical trials have employed this approach. In an investigation of 3-year participation in the Framingham Children's Study, families most commonly cited staff attitude, feedback to participants, assistance in coping with medical problems, and association with a scientifically valuable enterprise as positive influences on retention [9]. Dias *et al.* [10], using a modified version of the Framingham questionnaire for the Correction of Myopia Evaluation Trial (COMET), reported similar results. After a 3-year involvement in COMET, participating families most frequently attributed their study loyalty to staff support and responsiveness to questions, medical care and supplies, scheduling convenience and reminders, and commitment to the project.

In order to determine the extent to which these and other factors influenced 15- year retention in EDIC (21.5-years mean follow-up since the DCCT began), confidential questionnaires were designed, based on a similar instrument employed at the end of the DCCT. The questionnaires used in the current study addressed specific aspects of the EDIC clinic visits, evaluation procedures, staff–participant relationships, and medical/health-care support provided by the study.

Methods

DCCT/EDIC

Between 1983 and 1989, 1441 individuals with type 1 diabetes, 13–39 years of age, were enrolled in the DCCT. Approximately one-half of the sample ($N=711$) was randomly assigned to intensive therapy (three or more insulin injections daily or subcutaneous infusion with external pump and preprandial blood glucose level targets between 70 and 120 mg/dL). The remainder ($N=730$) was assigned to conventional therapy (one to two daily insulin injections and freedom from symptoms of hyperglycemia and frequent/severe hypoglycemia as therapeutic goals). The DCCT cohort was followed for a mean of 6.5 years (range = 3–9 years), and more than 95% of all scheduled examinations were completed. Further information about the DCCT protocol is published elsewhere [2].

At the end of the DCCT in 1993, intensive therapy was recommended for all participants because of its highly significant effect in reducing diabetic microvascular complications [2]. In 1994, 96.3% ($N=1375$) of the 1428 surviving members agreed to participate in EDIC for annual observational follow-up [1]. Strategies such as flexible appointment times and locations, travel assistance, and home visits have been used to promote maximal participation. In addition, individuals who have missed visits or been inactive have been contacted annually (to the extent allowable by institutional research review boards) to invite fuller participation.

The EDIC retention study

During EDIC Years 15–17, retention questionnaires were administered to participants, categorized into three groups on the basis of their participation over the previous 5 years. Active members were divided into the following categories: (1) *Completely Adherent* participants ($N=1225$), consisting of individuals who had returned annually to an EDIC clinic during this period for scheduled evaluations and (2) *Partly Adherent* participants ($N=71$), consisting of individuals who had missed at least one annual visit or a major portion of a visit during the previous 5 years (i.e., completed less than 80% of the scheduled evaluations). Finally, *Inactive* participants ($N=38$) consisted of individuals who had not participated in EDIC over the past 5 years but had not formally withdrawn consent (the remaining 33 inactive individuals who had withdrawn consent were not administered questionnaires).

A retention questionnaire was developed by EDIC staff for each of the three samples, with specific relevance to their level of EDIC adherence. The instruments were designed to be completed by the participant within approximately 15 min; completed questionnaires were mailed directly to the EDIC Data Coordinating Center without being reviewed by local EDIC staff to ensure confidentiality of responses.

Completely Adherent participants received a 43-item questionnaire, in which they were asked to indicate how much EDIC participation improved their scientific understanding and personal management of diabetes. The participants then ranked the top 5 factors (of the 12 listed) they believed had the strongest impact on their continuous participation. The participants also were asked to indicate the positive or negative impact of specific aspects of

the EDIC protocol on their overall willingness to participate, using a 5-point Likert scale (1 = bad effect, 3 = no effect, 5 = good effect). Six domains were addressed in detail: (1) Staff, (2) Clinic Visits, (3) Communication, (4) Exams and Evaluations, (5) Clinic Services, and (6) Interpersonal Support. Finally, participants were invited to provide free-text comments at the end of the questionnaire in order to raise other issues or to explain any of their previous answers in more detail.

Partly Adherent participants received a 44-item questionnaire. This instrument contained items identical to the questionnaire administered to the Completely Adherent participants, except that respondents were asked to rank the five most important reasons for their absence from, and return to (if applicable), full annual participation.

Inactive participants were mailed a brief two-item questionnaire to identify reasons for their suspended involvement with EDIC.

Statistical analysis

All analyses were performed using SAS version 9.1 [11]. Individuals who completed questionnaires and those who did not were compared using the Wilcoxon rank-sum test for ordinal and numeric variables. The contingency chi-square test was employed for categorical variables. Separate analysis of covariance (ANCOVA) models were used to assess the relationship between the top-ranked reasons for participation and various demographic and medical characteristics. Multivariate models were adjusted for concurrent age, gender, duration of diabetes, clinic, original DCCT treatment group, time-weighted DCCT/EDIC HbA_{1c}, and total number of complications. Effects nominally statistically significant at $p < 0.05$ are cited.

Results

Demographic background of Completely Adherent participants

Questionnaires were completed by 89.2% of the Completely Adherent individuals. Demographic characteristics of participants with no missing or incomplete responses on the questionnaire ($N = 1013$) are contained in Table 1. Briefly, 52.5% were men, 96.8% were Caucasian, mean age was 50.5 years, and 94.9% had health insurance at the time of this analysis.

The 1013 Completely Adherent participants (responders) were compared with 350 living individuals from all samples who did not return a questionnaire (nonresponders). A few modest albeit significant differences ($p < 0.05$) emerged: In comparison to nonresponders, responders were older at DCCT baseline (27.8 years vs. 26.4 years, respectively), fewer were assigned to intensive therapy (48.4% vs. 55.4%), and DCCT eligibility HbA_{1c} was lower (9.0 vs. 9.2). Responders and nonresponders did not differ with respect to race, gender, or duration of diabetes at DCCT enrollment.

Ranked reasons for sustaining participation among Completely Adherent participants

Table 2 displays the reasons for maintaining participation cited most frequently by Completely Adherent participants. More women than men included *Cutting Edge Tests* among their top two reasons for continued participation (53.9% vs. 44.2%; $p = 0.0021$). In contrast, more men than women endorsed *Better Care for Diabetes* as their first or second reason (35.7% vs. 25.4%; $p = 0.0004$). Finally, individuals with at least 3 diabetes-related complications more often than participants with fewer complications chose *Annual Evaluations* as their first or second reason for continued involvement with EDIC (40.5% vs. 30%; $p = 0.0476$; Table 3).

Multivariate regression models of the 4 most frequently ranked reasons by Completely Adherent participants for maintaining participation accounted for less than 2% of total variance in the mean rank of any reason ($R^2 = 0.005\text{--}0.019$). Gender emerged as a significant covariate of the mean rank of *Cutting Edge Tests* ($p = 0.0025$) and *Better Care* ($p = 0.0007$); in addition, weighted HbA1c was marginally related to the mean rank of *Help Others* ($p = 0.0371$). None of the other covariates (age, duration of diabetes, DCCT treatment group, number of complications, or clinic) was associated with the mean rank of any reason for long-term participation.

Ranked reasons for decreasing and resuming participation among Partly Adherent participants

Sixty-one of the 71 Partly Adherent individuals (85.9%) completed a retention questionnaire. Half the respondents ranked *Conflicting Responsibilities* among their five main reasons for *decreasing* participation; no other reason was endorsed by more than 18% of this group. No single cause was cited by the majority of Partly Adherent participants for *resuming* annual participation. The most frequently cited reasons for resumption – endorsed by 17%–19% of participants – were Helping Maintain Motivation to Take Care of Diabetes, Cutting Edge Tests, and *Emotional Bond with EDIC Staff*.

Responses from inactive participants

Only 5 of the 38 Inactive participants (13.2%) returned a questionnaire, precluding detailed analyses of their responses. Two of these individuals cited *Conflicting Responsibilities* as their primary reason for discontinuing participation, and one individual cited the *Number or Length of Study Questionnaires*; the remaining two participants' responses were either missing or mismarked.

Influence of specific EDIC protocol components on overall willingness to participate among Completely Adherent participants

Specific components of EDIC that positively or negatively affected overall willingness to participate were divided into six domains on the questionnaire: Staff, Clinic Visits, Communication, Exams/Evaluations, Clinic Services, and Interpersonal Support.

No item in any domain had a mean rating of less than 3 (1 = bad effect, 3 = no effect, 5 = good effect), indicating that no specific aspect of the study was perceived by the majority of the responders to exert a negative influence on willingness to participate. In contrast, at least one item in each domain had mean scale ratings at or above 4.0, indicating that a number of study features were viewed by the majority as positively influencing participation. These included, by domain: (1) Staff (overall influence of staff, provision of clinical services between annual EDIC visits), (2) Clinic Visits (flexibility of scheduling), (3) Communication (overall staff communication, staff's willingness to answer questions, and contacts between staff and participants' health-care providers), (4) Exams and Evaluations (overall number of tests each year, blood tests, history and physical exams, eye exams, neurological exams, and cardiac/carotid scans), (5) Clinic Services (medical supplies and cutting-edge tests), and (6) Interpersonal Support (support from spouse or significant other regarding study participation).

Free-text responses

In all, 416 Completely Adherent participants (41.1% of those submitting complete questionnaires) commented about their continued commitment to EDIC. Their remarks fell into five content areas. The most frequently mentioned was *Staff Characteristics* (43.2% of the respondents). Comments in this domain included descriptors such as compassionate,

encouraging, professional, and individually helpful to participants. The second most common domain, Perceived Impact of EDIC on Diabetes Knowledge and Health (27.2%), contained remarks expressing a sense of gratitude and pride in participation, as well as recognition of the study's beneficial effect on health. The third domain, *Study Components Viewed as Beneficial* (13.9%), included statements that emphasized the importance of testing, tracking health status over time, and access to expert care. The fourth content area, *Altruistic Reasons for Continued Participation* (9.1%), contained comments pointing out the personal significance of helping others with diabetes and improving diabetes research and clinical practice. In the last domain, *Perceived Impact of Study on Self-Care Practices* (6.5%), responders noted that EDIC challenged them to take better care of themselves, in general, and their diabetes, in particular.

Discussion

The validity of a clinical trial relies on the proportion of participants who remain in that study. The current research climate is characterized by reductions in funding and by doubts about the efficacy of the randomized clinical trials. In order to maintain adequate financial and scientific support, it is therefore essential that loss to follow-up in clinical trials be kept to a minimum.

The current study was designed to help explain why most participants maintained full participation over 15 years in EDIC. The Completely Adherent participants cited access to *Cutting Edge Tests* and *Better Care for Diabetes* as the two most important reasons for continued participation. One unexpected finding was that *Cutting Edge Tests* were more important to women and *Better Care for Diabetes* was more important to men. These gender differences run counter to expectations based on cultural stereotypes. Over time, the addition of complex assessments and cutting-edge tests to the core protocol has raised staff concerns about participant burden. A second unexpected finding was that participants' responses did not support this concern but suggested instead that they considered the benefits of increased monitoring to outweigh the inconvenience involved. More than 40% of the respondents who added comments indicated that staff characteristics and/or relationship with staff were important to their continued participation. Multiple regression analysis incorporating complication status, demographic predictors, and clinic location accounted for less than 1% of the variance in the rank of the most frequently cited reasons for full participation. These results suggest that the major influences on sustained participation were robust across a broad range of participant and site characteristics.

Investigations that employ participant questionnaires – such as the present one – differ from research that attempts to predict retention and dropout in clinical trials on the basis of participant characteristics (e.g., demography, psychological functioning, disease status [12–16]). The latter approach can be useful for studies with substantial attrition but has limited value when only a very small proportion of the cohort leaves the study.

DCCT/EDIC represents the largest and the most intensively studied cohort of individuals with type 1 diabetes. At DCCT study entry, enrollees consented to participate in an interventional trial; most have continued to participate in the ongoing DCCT/EDIC project (an average of 21.5 years at the time of analysis). Retention during the DCCT may have been bolstered by high-quality medical care; provision of medical supplies; altruism; and frequent, supportive communication between participants and staff. In EDIC, however, participants are assessed by EDIC personnel only annually; most receive diabetes treatment from local, non-EDIC health-care providers [1]. Despite the change in study structure from interventional to observational, the reduced frequency of contact, and limited provision of diabetes supplies, retention of the surviving cohort remains almost 95%. No multicenter

diabetes study has demonstrated retention rates over an extended time period comparable to DCCT/EDIC.

Over 50% of the Partly Adherent responders identified conflicting responsibilities as a major reason for their reduced level of participation. For those Partly Adherent individuals who resumed full participation, no single factor was identified by the majority to explain their resumption of annual study visits. In general, the reasons cited for resuming full participation were largely related to beneficial aspects of EDIC, whereas reasons cited for decreasing involvement primarily involved personal circumstances. The latter suggests that life events periodically may place limits on participation, regardless of how carefully a study is designed or conducted.

The high level of retention in EDIC limited our ability to identify participant and study characteristics that contribute to attrition. In addition, participants' perceptions of factors that most strongly influenced continued participation (e.g., the study's scientific importance and the quality of medical care provided) may have been shaped and reinforced by long-term exposure to EDIC staff and promotional material. A third drawback is that the questionnaire itself is not validated; we were unable to find a standardized instrument that addressed retention in the context of a diabetes study.

A fourth potential limitation of this analysis involves the DCCT/EDIC cohort's demographic characteristics. All participants have type 1 diabetes, most are Caucasian, over 60% are college educated, and almost 95% reported some health insurance coverage during the year the questionnaires were administered. These participant characteristics may limit generalization of results from the current investigation to long-term clinical studies with different clinical and demographic profiles. However, the key findings reported in the current analysis echo those found in investigations that employ other designs, disorders, and time frames [9,10]. All such studies underscore the importance of high-quality medical care, the positive impact of supportive and collaborative relationships between research staff and participants, and the motivational benefits of participating in personally and scientifically meaningful research.

The long-term clinical trials that are followed by an extended observational follow-up study, such as DCCT/EDIC, provide an opportunity to establish the safety and efficacy of new treatments and also test the degree to which outcomes are sustained over long periods of time. In such designs, it is likely that several factors in addition to those considered in the current article facilitate high retention rates: (1) comprehensive psychological and behavioral screening for clinical trial participation, (2) a target disease that is chronic and requires long-term surveillance to treat potentially serious complications, (3) a therapeutic strategy that is shown to be more effective than the standard of care, (4) adequate infrastructure and personnel to conduct an extended cohort study, and (5) continuous oversight by a committee appointed to monitor and maximize adherence. Investigations that address less-serious conditions or test treatments for which efficacy is not known for many years may be more challenged to maintain adherence. However, in such cases, attention to participant screening, a consistently high level of medical care, and collaborative staff-participant relationships may facilitate optimal levels of participant retention. These latter factors are important not only for research but they are fundamental to the conduct of all medicine. Indeed, DCCT/EDIC's success in minimizing attrition may be as attributable to such core factors as it is to the seriousness of type 1 diabetes and the demonstrated efficacy of tight control.

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Table 1

Completely adherent participants who completed retention questionnaires ($N = 1013$): Characteristics at EDIC Years 15–17

Characteristic	N (%) or $M \pm SD$
Age (years)	50.5 $\pm$ 6.7
Gender (% male)	532 (52.5)
Race (% White)	981 (96.8)
Insurance coverage	
Current health insurance coverage	961 (94.9)
Health insurance in the past 12 months	977 (96.5)
College graduate	643 (63.5)
Duration of diabetes (years)	28.6 $\pm$ 4.9
Treatment group (% intensive insulin therapy)	523 (51.6)
Weighted DCCT/EDIC HbA _{1c}	8.0 $\pm$ 1.0
Current marital status	
Married or remarried	741 (73.2)
Divorced	133 (13.1)
Never married	104 (10.3)
Separated	21 (2.1)
Widowed	14 (1.4)
Complications	
Scatter or focal laser treatment in either eye	195 (19.3)
AER $\geq$ 300 or end-stage renal disease	108 (10.7)
Cardiovascular event ^a	75 (7.4)

DCCT/EDIC: Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications; AER: albumin excretion rate; MI: myocardial infarction.

^aDefined as a nonfatal MI, stroke, silent MI, confirmed angina, or revascularization.

Table 2

Completely Adherent participants' top-ranked reasons for maintaining full participation

	% Who ranked (1–5)	% Who ranked as 1 or 2		
		Overall	Men (<i>N</i> = 532)	Women (<i>N</i> = 481)
Cutting Edge Tests	79.3	48.8	44.2	53.9 ^a
Annual Evaluations	67.7	26.2	28.4	23.7
Help Others	65.2	31.0	30.8	31.2
Better Care for Diabetes	61.6	30.8	35.7	25.4 ^b

^aDifference between males and females significant at $p < 0.01$.^bDifference between males and females significant at $p < 0.001$.

Table 3

Completely Adherent participants' reasons for maintaining full participation by number of complications

	% Who Ranked as 1 or 2			
	Zero (N = 532)	One (N = 337)	Two (N = 107)	Three or more (N = 37)
Cutting Edge Tests	50.0	47.5	43.9	56.8
Annual Evaluations	28.0	23.4	20.6	40.5 ^a
Help Others	29.5	33.8	33.6	18.9
Better Care for Diabetes	30.8	32.1	32.7	13.5

EDIC: Epidemiology of Diabetes Interventions and Complications; AER: albumin excretion rate; MI: myocardial infarction.

Complications are defined as any one of the following four at any point during EDIC: (1) scatter or focal treatment in either eye, (2) pain or numbness in hands or feet, (3) AER ≥ 300 mg/24 h or end-stage renal disease, and (4) cardiovascular event at any point in EDIC (nonfatal MI, stroke, silent MI, confirmed angina, or revascularization).

^aDifference between participants with 3+ complications and those with <3 complications significant at $p < 0.05$.