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Evolution of the study coordinator role: the 28-year experience in Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and complications (DCCT/EDIC)

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Abstract

Background—The role of the study coordinator (SC) in multi-center studies of long duration has received limited attention.

Purpose—To describe the evolution of the SC's role during the 28-year Diabetes Control and Complications Trial (DCCT) and its follow-up study, the Epidemiology of Diabetes Interventions and Complications (EDIC) study.

Methods—The evolution in the SC position from the traditional role of protocol implementation to that of research collaborator and co-investigator, based on personal experience and observation, is described in detail. Findings from a survey regarding professional demographics and job satisfaction, completed by all 28 SC's in 2010, provided additional information. We used dimensions of the SC role specific to DCCT/EDIC to construct a classification schema of functions and responsibilities that describe the SC role.

Results—Among the 28 SCs, 24 were nurses, 12 held bachelor's degrees, 11 had a master's degree, 19 were Certified Diabetes Educators (CDEs), 12 had worked with DCCT/EDIC for more than 20 years and 5 had been with the study since its inception (> 26 years). Responses confirmed a high degree of functional consistency across sites with data acquisition, performing study procedures, recruitment and consent for additional ancillary studies, regulatory management, scheduling, clinical consultation and ongoing contact with study participants frequently reported. Study-wide leadership activities, a category not generally included in the usual SC role, were reported by approximately 30% of SCs. The level of professional satisfaction was high with two thirds being very satisfied, one third moderately to quite satisfied, and none dissatisfied.

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Limitations—The limitations include a relatively small sample size, self-reported data, and a single long-term multicenter trial and observational follow up study on which we based our findings and conclusions.

Conclusions—By optimizing their organizational and scientific contributions to the overall research endeavor, SCs in DCCT/EDIC have made major contributions to the unprecedented success of the study and report high job satisfaction. The efforts of the SCs have been integral to the remarkably high participant retention and data completion rates. The DCCT/EDIC experience may serve as a model for the role of the SC in future diabetes and other multi-center clinical trials.

Keywords

Clinical Trial; Study Coordinator; Research Nurse; DCCT/EDIC

Introduction

The role of the Study Coordinator (SC) varies widely across clinical research settings, and to date has received limited attention in the literature. Historically, the field of research nursing and/or study coordination has lacked clear and consistent definition, standardization and an established professional development trajectory[1, 2]. Reports describing the SC role in the 1980's emphasized the importance of selecting candidates with the appropriate skills and experience necessary to successfully implement clinical trials[3, 4]. Roles for nurses in cancer clinical trials became common and resulted in an attempt to standardize a job description by the Oncology Nursing Society[5, 6]. As the number of randomized clinical trials grew in both number and complexity, the opportunities for nurses to become involved in research grew as did the responsibilities and demands of the role[7, 8, 9].

Progress in delineating the role of the SC and defining its scope and standards of practice has continued over the last decade[10, 11, 12]. A questionnaire designed to assess the clinical trials nursing role specific to cancer research was developed by Ehrenberger and colleagues and shown to be a valid and reliable instrument within the oncology setting[13]. Castro and colleagues articulated the domains and dimensions of practice for two roles: clinical research nurse and research nurse coordinator. In addition, the first professional association for research nurses, the International Association of Clinical Research Nurses (IACRN) was founded in 2009, and clinical research certification programs are now offered by many academic institutions and commercial organizations[1, 14].

These developments have contributed to efforts to define the role, standardize practice and promote a professional identity for SCs. Nonetheless, there has been limited information focusing specifically on the role of the SC within multi-center studies of long duration[3, 4, 7]. The Diabetes Control and Complications Trial (DCCT) and the longitudinal, observational follow-up study of the same cohort, the Epidemiology of Diabetes Interventions and Complications (EDIC) study, together represent the longest duration study of individuals with type 1 diabetes. Sponsored by the National Institutes of Diabetes, Digestive and Kidney Disease (NIDDK) and now at year 28, the DCCT/EDIC study is one of the longest running clinical research studies of any sort to date. The DCCT/EDIC study provides a unique opportunity to analyze the evolution of the SC role and provides a model for other research groups as they consider staffing structures and ways to maximize SC contribution to the overall research endeavor.

In this paper we describe the 1) professional demographics of DCCT/EDIC SCs; 2) evolution of their role over time; 3) impact of the SC role on study participant retention and data quality and completion; and 4) professional development, leadership and career advancement opportunities for SC's made possible within this long-term multi-center study.

Background

The Diabetes Control and Complications Trial (DCCT: 1983-1993) was a multicenter controlled clinical trial that demonstrated the beneficial effects of intensive diabetes management on the development and progression of microvascular and neuropathic complications compared with conventional treatment in type 1 diabetes (n=1,441). Ninety-nine percent of the study participants completed the study and more than 95% of all examinations were completed[15]. At the end of the DCCT, all study participants were encouraged to implement or continue intensive therapy and were invited to participate in the follow-up study. Ninety-five percent of the surviving DCCT study participants (n=1375) enrolled in the Epidemiology of Diabetes Interventions and Complications Study (EDIC: 1994 – present). EDIC was designed to assess the impact of DCCT treatment group assignment on the progression of cardiovascular and microvascular diabetes-related complications over time[16].

To date, over 90% of the surviving DCCT cohort continue to participate actively in EDIC and 85-90% of outcome data has been collected. These achievements reflect to a large extent the efforts of the SC's. During the DCCT, the SC role consisted of practical implementation of the research protocol[34]. Over time, the SCs have assumed leadership and decision-making responsibilities previously confined to physician investigators. The SC role has evolved from coordinator to expert diabetes clinician and, ultimately, to research investigator.

Role of the Study Coordinator in DCCT (1983-1993)

The medical model of the 1980's dictated early organization of the DCCT clinical sites with physicians largely responsible for protocol design, study administration and clinical management decisions. Implementation of the complex DCCT protocol required a full time SC at each clinic to work with additional staff such as research nurses, dieticians, psychologists and administrative personnel. A model for interdisciplinary diabetes care provided within a clinical trial thus was established. Responsibilities of the SC included recruitment, screening and coordinating protocol-mandated testing and interventions for the study participants following randomization to their treatment assignment.

SCs planned and conducted monthly study visits for the intensive treatment group participants and quarterly and annual day-long visits for participants in both groups. The SCs were actively involved in initiating intensive therapy and providing ongoing treatment management aimed at achieving near normoglycemia. Weekly telephone calls were made to the intensive treatment group participants to review blood glucose monitoring results and convey protocol-driven insulin adjustments. The SCs (93% nurses) developed expertise in intensive insulin therapy and assumed responsibility for ongoing diabetes management and for patient/family education and support[3].

In 1984, an all-inclusive SC Group was created to provide a forum for discussing practical implementation of the core protocol and ancillary studies. This forum was a progressive concept within multi-center trials at the time and has since been replicated in other long term clinical trials[17]. The group was led by a SC who had been appointed by the Executive Committee, met quarterly throughout the DCCT, and provided a collective voice for the SCs in study-wide matters, with specific attention to participant adherence and data completeness and quality. This group provided guidance and recommendations to the entire research group based on an intimate working knowledge of the protocol and familiarity with the individual DCCT study participants.

Throughout the DCCT, the role of the SC evolved as members became more active in decision-making both locally and study-wide, monitoring data quality and completion and representing the study group at professional presentations[3, 4]. Several SCs participated in site visits to other clinics to offer expertise or hosted new SCs at their own clinics to teach them the specifics of the SC role. Many SCs were instrumental in the translation of the DCCT findings into clinical practice at their institutions after study close-out and became resources for innovative intensive diabetes treatments found to be beneficial in lowering glycemia and decreasing complications in type 1 diabetes. Several of the SCs were among the first to earn the Certified Diabetes Educator (CDE) credential (1986) and many assumed active roles in professional organizations on both a local and national level. Two papers were authored by SCs regarding their role and work within the DCCT[3, 4], and SCs were listed along with PIs as contributing authors of the primary outcome publication[15]. As the DCCT ended, its SCs were well positioned to assume additional responsibilities within the EDIC study.

Role of the Study Coordinator during EDIC (1993-present)

The EDIC study was initiated in 1993. SCs were named as co-investigators within the organizational structure of the EDIC research group and participated in study design with voting rights equal to Principal Investigators for all major study group decisions. The role of the SC had changed from clinic staff who implemented a research protocol on a local level at the start of DCCT, to co-investigators in a nation-wide longitudinal follow-up study. SCs were largely responsible for transitioning the original conventional treatment group participants to intensive insulin therapy. As the focus of the study had changed, the clinical sites no longer would provide diabetes treatment directly under the EDIC protocol. This change in the protocol necessitated a significant change in the participant-diabetes caregiver relationship from one of frequent contact to a yearly examination. The responsibility for sustaining this relationship required sensitivity to each study participant's situation and preferences, and was largely directed by the SC at each of the clinical sites.

The core EDIC protocol mandates annual 4-6 hour visits that include diabetes history and assessments of cardiovascular health, renal function, neurology, ophthalmology status, and quality of life[16]. Subsequent complex ancillary studies have been added, each posing new challenges in recruitment, implementation and study logistics. The SCs have a pivotal role in ensuring participant retention while monitoring study burden and the potential impact of adding new procedures to the core protocol.

Flexible scheduling, facilitating and arranging travel and overnight stays for out of town study participants, telephone and/or home visits, transfers between EDIC sites in the case of participant relocation, and consulting on diabetes management or EDIC test results are all part of the responsibilities of the SC. In addition, SCs advocate for study participants in situations such as navigation of health care systems or assistance with appointment scheduling and/or referrals. Educational resources pertinent to the EDIC protocol and testing being performed, and a semi-annual newsletter that provides study participants with updates on study results, diabetes advances and useful information about living with type 1 diabetes are developed by the SCs.

SCs also perform an essential role in overall data management and quality assurance. Responsibilities include accurate and timely data submissions and medical event verification, and training and certification of EDIC staff at their sites. Many SCs have assumed administrative responsibilities, including submissions and related correspondence to institutional review boards, logistical coordination with various clinical departments and research laboratories, and budgetary management. A committee of SCs facilitates donations of diabetes supplies to the EDIC participants across all 28 sites, including two Canadian

sites. This committee assists the study leadership with the management of contracts with industry suppliers. The suppliers have no role in the conduct of the study, but provide a limited amount of diabetes supplies as a token of appreciation to study participants.

Progressively throughout DCCT/EDIC, the Data Coordinating Center (DCC) and study leadership have supported the professional growth of the SC group. The close collaboration between the SCs and the DCC in the development of standard processes and procedures ensures data integrity while considering the potential impact on participant retention. To date, retention rates remain extraordinarily high. After a mean follow-up of ~23 years, 1351 (94%) of the original DCCT cohort are being followed, 90 (6%) study participants have died and 308 (21%) study participants have transferred between clinics.

The SC Group meetings are held three times annually. Attendees include all SCs, members of the Executive Committee, DCC, clinical laboratories, reading centers and ancillary study collaborators. These meetings promote cohesion among the group and provide a venue to discuss issues that have the potential to affect retention, adherence, and data collection. The agenda is developed in partnership with the DCC and is devoted to study operations, implementation and training for new protocols, and educational needs identified by the SCs.

Two SC co-chairs, appointed by the Executive Committee, lead the meeting and work extensively with the DCC to arrange speakers and develop presentations. The role of the chairpersons requires leadership skills, an in-depth knowledge of all aspects of the protocol and expertise in research methods. The chairpersons facilitate discussion during the meetings, formulate plans to translate new decisions into standard clinical site operations and follow-up with the local sites between meetings. The chairpersons represent the SC Group on the EDIC Executive Committee where they communicate SC concerns and participate in important policy decisions. Each co-chair has equivalent leadership responsibilities and voting privileges.

The SC Group meetings, supported by the DCC, have been instrumental in advancing the SC role by facilitating mentorship of new coordinators, fostering development of clinical expertise in diabetes treatment, developing new research initiatives, promoting engagement of all SCs in working groups or committees, and playing a major role in the initiation and refinement of ancillary study procedures. Educational sessions, often led by one or more SCs, were added to the SC meetings to advance clinical and professional development and examine issues that have direct applicability to the SC role in EDIC.

Role of the Study Coordinator in EDIC Ancillary Studies

Numerous ancillary studies, which augment the core protocol to provide further insights into the complications of type 1 diabetes, have been conducted successfully in the DCCT and EDIC (Table 1). The responsibility for implementing these often complex protocols resides primarily with the SC and may include submitting regulatory and human studies applications, arranging for test procedures to be performed by various departments or facilities, managing budgetary and personnel issues, learning to perform new procedures, and ensuring successful training and standardization across all sites.

SCs also participate in the decision to initiate ancillary studies, and in some cases, have taken a leading role in planning and implementing them. For example, a SC prepared the proposal to study cheiroarthropathy, remains responsible for leading the initiative during the data collection period and for preparing results for publication. The ongoing support of the DCC and a small working group made up of other investigators provides input and assistance throughout the process.

Obtaining consent from study participants for the additional testing required by ancillary studies without adversely affecting overall EDIC participation is a necessary interpersonal skill of the SC. Each ancillary study presents unique issues (e.g. safety, confidentiality) that must be addressed during the informed consent process. Therefore, the SC must possess an in-depth knowledge of the overall scientific goals of EDIC in order to balance scientific priorities against participant burden and satisfaction. While study participants can decline any test without jeopardizing their participation in EDIC, the completion rate for all ancillary studies has been ≥ 80%. In a retention survey administered to study participants in 2010, the performance of "cutting edge" tests, diabetes care, and the bond with EDIC staff were ranked highly as reasons to continue participation[18].

Methods

To describe more fully the current role of the EDIC SC, a survey was developed by the authors in 2010. Questions pertained to professional demographics, such as clinical practice and research experience, education/licensure/certification status, job titles, institutional departmental affiliation, length of time in DCCT/EDIC and reasons for the initial interest in the job in DCCT/EDIC. Professional satisfaction with the SC role was also assessed. Based on expert consensus and a review of the literature[11, 12, 14, 17] dimensions of the SC role specific to DCCT/EDIC were utilized to construct classifications of "functions and/or responsibilities that best describe your current EDIC role". Survey responses were tallied in Excel and frequencies are reported.

Survey results

All SCs (n=28) completed the survey. Approximately 43% (n=12) of SCs held a bachelor's degree, and 39% (n=11) had a master's level education. The majority (86%) came from a nursing background (n=24). Two thirds were Certified Diabetes Educators (CDEs) and all described their current role with EDIC as a coordinator, but additionally saw themselves as educators (71%), researchers (57%) and clinicians (39%). Before working in the DCCT/EDIC study, 40% had been in their current profession (nurse, nurse practitioner, dietician or physician's assistant) for 11-20 years with most having 5 or fewer years of diabetes related and research related experience. Half of the SCs had taken on the SC role during the DCCT and had worked with DCCT/EDIC for more than 20 years; 18% (n=5) had been with the study since the inception of the DCCT.

Employment titles for the EDIC SC varied across the academic institutions with 4 as administrator/managers, 10 as coordinators, 6 as research nurses and 8 other (nursing professional, advanced clinician, nurse practitioner, clinical research specialist, research clinician, faculty associate, physician's assistant). However, the majority (79%; n=22) used coordinator as their operational title within their EDIC site. Departmental affiliations included medicine 64%, pediatrics 18%, clinical research 10% and nursing 4%.

Survey data confirmed a high degree of consistency across sites in the self-described functions and responsibilities (Table 2). Over ninety percent indicated that the following activities were part of their current usual responsibilities: 1) data acquisition and management including performing tests and procedures per protocol, data mailings, and obtaining medical records; 2) protocol implementation including recruitment and consent for ancillary studies; 3) regulatory management and IRB submissions; 4) scheduling participant visits and coordinating tests and procedures with other departments and/or facilities, and 5) clinical consultation and ongoing contact with study participants.

Of note, study-wide leadership activities, a category not generally included in the usual SC role description were reported by approximately 30%. These activities included manuscript

preparation and review, serving as a resource person for an ancillary study, leading working groups, and securing diabetes supplies nationally. More than two thirds participated as members of committees or working groups with some of them (n=5) acting as chairs of committees such as the study-wide Data Quality Assurance and the Adherence Monitoring Committees. The level of professional satisfaction was high. Approximately two thirds reported being very satisfied, one third moderately to quite satisfied, and none dissatisfied.

Discussion

Previous work by the National Institutes of Health Clinical Center has offered guidance regarding the role of the nurse in clinical research, both as clinical research nurses and research nurse coordinators[11, 12]. Despite the descriptions of the domains and dimensions of research nurse practice that are emerging in the literature, the actual SC role varies based on the specifics of the protocol, the practice setting and the population under study.

Longitudinal multi-center trials such as DCCT/EDIC, afford opportunities for SC professional development that may be unique to this setting. The long term participant-provider relationships that are possible in this setting and the potential for scientific camaraderie serve to strengthen partnerships with the study participants, research team and colleagues and may contribute to the high level of job satisfaction and low attrition compared to those reported by coordinators working in other settings[19, 20].

In the DCCT, SCs were selected at each of the clinical centers to work closely with a multidisciplinary team in the recruitment, education, clinical management and support of study participants, while meeting data quality and completion standards. The dynamic nature of the “job” and the potential for role expansion and professional development of the SC became evident. Initially responsible for daily operations, protocol-guided care and participant education, the DCCT/EDIC SC role eventually progressed to designation as diabetes research investigator within the EDIC study group.

The evolution of the DCCT/EDIC SC role into a diabetes research investigator can be viewed as having occurred in 3 phases. In phase 1, the focus was on successful recruitment and effective implementation of the protocol in the local clinic. Developing expertise in clinical research methodology as well as in intensive insulin therapy and parameters for dose adjustment (all of which were experimental at the time) was critical to the safe and effective conduct of the trial.

Phase 2 began with the creation of a SC working group that met independently of the PIs. Meetings of this group allowed the SCs to share experiences and to exchange problem-solving strategies while providing the structured peer support often lacking for those in research coordinator positions[8]. Through this process there emerged a core group of more senior and experienced coordinators with leadership and mentoring abilities. Representatives of the core laboratories and reading centers provided detailed scientific presentations to the SC group and addressed increasingly sophisticated questions to ensure coordinators had an adequate understanding of the science behind each procedure. This process broadened the research experience of the whole research group and expanded each SC's perspective beyond their individual clinic. The formation of this unified and highly collaborative SC working group added to the strength and resilience of the DCCT/EDIC study over time.

Phase 3 of the SC role transformation began during the latter part of the DCCT and the beginning of EDIC, as the study moved beyond the core protocol with the addition of numerous ancillary studies. An in-depth understanding of the science gave SCs the confidence and knowledge to explain the reasons for asking the study participants to take part in new and more invasive procedures. In EDIC, it became standard practice for

collaborators to present the details of new ancillary studies first to the SC group. This produced informed commitment by SCs to obtain the new data and enhanced their self-identification as investigators, as well as coordinators. Moreover, their feedback to collaborating scientists helped shape the final protocol to promote maximal participation, thereby increasing the potential for more complete, high quality research data. SCs now serve as liaisons to ancillary studies, initiate and lead new studies, present EDIC data at scientific meetings and author publications[16, 21, 22, 23].

What are SC qualifications and study conditions that support this type of transformation in the SC role? First, the SC must view herself/himself as part of a multicenter research effort that encompasses collaboration and implementation on a national level. Second, in an interventional trial, the SC must understand the rationale for and be committed to the null hypothesis and the need to manage each study participant's care as closely as possible according to the protocol for the assigned treatment. Third, the evolution of the SC from research staff to research partner must be encouraged and accepted by the PI, who must value the SC's practical experience with protocol implementation and important role in maintaining participant retention and adherence. Fourth, the SC must commit to understand the clinical science underlying the study and be interested in and motivated to pursue additional education whenever necessary. Fifth, the SC must see her/his role in the study as an opportunity for professional growth and career advancement rather than simply an employment opportunity.

Limitations

The limitations of our survey findings and observations include a relatively small sample size and self-reported data. In addition, the transition from an interventional trial to an extended observational study may limit the ability to generalize the DCCT/EDIC SC experience. Furthermore, the development and expansion of the SC role have been supported by the study sponsor and leadership; the collegial relationship that exists among SCs has fostered the ongoing professional development of individual SCs and the group as a whole. In addition, the extraordinary length of time that the research group has been together has fostered the development of confidence and trust between the SCs and the PIs, study leadership, DCC and Central Reading Centers. In situations where the professional working environment is less supportive or in studies of shorter duration, applicability of these findings may be limited.

Conclusions

The DCCT/EDIC SCs have been empowered to assume professional responsibilities beyond the traditional SC role. Increased autonomy, accountability, responsibility and professional development have been supported by the NIDDK, the Data Coordinating Center and the Study Group. They have contributed critically to consistent data collection, and participant and coordinator retention (>90% and 50%, respectively), throughout the 28-year DCCT/EDIC experience.

The evolution from study coordinator to research investigator has benefited both the SCs as demonstrated by high levels of job satisfaction and professional accomplishments, and the landmark DCCT/EDIC study as demonstrated by extraordinarily high participant retention and data quality. The DCCT/EDIC study has offered professional development opportunities for SCs that optimize their scientific contribution to the overall research endeavor. A similar evolution can be anticipated in future diabetes and other multi-center clinical trials, though the pace and details of the process undoubtedly will depend on the nature and duration of the

trial. Nurses interested in advancing their expertise in clinical research may be encouraged by the DCCT/EDIC experience to consider the SC role as a career choice.

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Table 1

* Ancillary Studies Conducted in DCCT/EDIC

Ancillary Study	Data Collection Period
DCCT Family Study	1992
Lipoprotein Collections	1993-2006
Marker & Mechanisms of Vascular Disease in Diabetes	1993-2006
Carotid Ultrasounds	1993, 1996, 2005
Coronary Calcium Scans	2001
EDIC Genetic Family Study	2001-2004
Urological Complications I	2002-2003
Neurocognitive Study	2004-2006
Neurology (nerve conduction and autonomic nervous system testing)	2005-2007
Autonomic Nervous System 2(repeat component of neurology testing)	2009-2010
+**Cardiac MRI**	2007-2009
Comparison of Fundus Photograph Methods	2007-2009
Retention Survey	2008-2010
Epigenetics	2009-2010
Skin Fluorescence	2009-2010
@**Urological Complications 2**	2010-
@**Cheiroarthropathy (muscular limitations in upper extremities)**	2011-
@**C-Peptide**	2011-

*Consent rates ≥ to 80% of the expected cohort unless otherwise noted

+80% eligible; some excluded due to medical reasons

@Enrollment is ongoing and total enrollment not yet determined

Table 2
Functions and Responsibilities of the EDIC Study Coordinator (N=28)

Dimensions	N/%	
Diabetes Consultation		
Ongoing contact with participants	28	100
Diabetes management consultation	18	64
Diabetes education	24	86
Health related referrals	21	75
Educational mailings	25	89
Advocacy	20	71
Data Management		
Data collection	28	100
Data tracking	24	86
Data mailings	27	96
Verifying medical records	27	96
Participant/HCP feedbacks	23	82
Fiscal		
Budgeting/Invoicing	19	68
Laboratory		
Sample collection	22	79
Sample processing	22	79
Sample shipments	24	86
Protocol Implementation		
Recruitment (ancillary studies)	27	96
Participant consent	28	100
Regulatory		
IRB submissions/modifications	26	93
Point person for IRB communication	23	82
Scheduling/Travel		
Participant contact	26	93
Scheduling	26	92
Provide/arrange transportation	18	65
Study-wide Leadership Activities		
Abstract/manuscript preparation	9	32
Manuscript review	13	46
Ancillary protocol point person	8	29
Standing committee participation	17	61
Standing committee leadership	5	18

Dimensions	N/%	
Working group participation	18	64
Working group leadership	7	25
Securing diabetes supply donations	8	29
Creation of SC resources and tools	14	46