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The implementation of complex, multi-site clinical trials presents challenges that make recruitment efforts, participant follow-up, and organization of staff critical to the success of the overall outcome. This article describes a unique staffing model utilized by the TODAY (Treatment Options for type 2 Diabetes in Adolescents and Youth) study, an NIH (National Institutes of Health) sponsored trial designed to explore treatment options for type 2 diabetes in youth. At each study center, the program coordinator (PC) and diabetes educator (DE) work together to implement the study protocol. A staffing model that provides this type of mutual support for two key members of the study team may decrease the burden customarily encountered solely by the PC in complex trials, and furthermore allows for cross-coverage and flexibility. To determine the degree of overlap and task sharing between the PC and DE across study sites, a self-administered survey was distributed to all PCs and DEs. Survey results as well as specific examples demonstrating an effective collaborative approach by front-line study personnel in managing various challenges encountered in study implementation are included.

Background

The TODAY study, which randomized its first participant in 2004, aims to identify optimal treatment regimens for type 2 diabetes specifically for adolescents and youth, as incidence has dramatically increased.[1-4] The study follows an ethnically diverse group of 704 overweight youth (aged 10-17 at enrollment) with new onset type 2 diabetes (less than two years duration) for a minimum of two to six years at 15 clinical centers across the United States. The goal is to compare the efficacy of three treatment arms (two medication-only arms and one intensive lifestyle intervention combined with medication arm) on glycemic control.[3] Study participants have routine medical visits every two months for the first year and quarterly thereafter. Interim medical visits are scheduled as needed for management of comorbidities or reinvigoration of diabetes management.

The study participants are adolescents and their families who are coping with a new diagnosis of type 2 diabetes, and are also typically dealing with extreme socioeconomic challenges, psychiatric problems, and/or other chronic health concerns. Many of them have life circumstances that are inherently unstable; the recent diagnosis of a chronic illness creates additional disruptions in their lifestyles. It is not unusual for them to present a number of pressing issues at each study visit requiring extensive interaction with personnel with two distinct protocol-driven roles: PCs and DEs.

Unlike the typical staffing model in large clinical trials where the designated PC assumes most of the responsibility for the daily work of implementing the protocol,[5] in the TODAY study, the PC and DE at each study center work together to schedule and conduct visits, as well as collect outcome data. Although the study design and roles are protocol-driven, placing specific

expectations on the PC and DE, the reality of carrying out each visit requires flexibility and task-sharing; the demands often lead to overlap in these roles at each study site.

In order for this type of staffing model to be effectively implemented, teamwork and cross-training are essential and are supported by weekly conference calls and periodic study group meetings among all PCs, DEs, and staff of the Data Coordinating Center (DCC). The calls allow the opportunity to offer thoughts and perspectives on current study issues, as well as the opportunity to explore specific questions or challenges of protocol implementation. Both PCs and DEs attend study trainings that emphasize implementation of the trial and care of the enrolled population. This cross-training assures that the DE or PC can each help with the other's tasks where necessary, in order to facilitate timely completion of the study visits.

There are limited published reports regarding effective staffing models of large clinical trials, and although the typical tasks performed by a research nurse[6,7] and/or clinical research coordinator[8,9] have been described, the roles remain poorly defined. Little is known about workload distribution and job satisfaction, and many of the reports are anecdotal in nature.

In the Diabetes Control and Complication Trial (DCCT), the PC role was filled almost exclusively by nurses. During the planning phase of the DCCT, the anticipated scope of duties of the research trial coordinator was unclear. In 1984, the second year of the trial, 21 trial coordinators (19 nurses, one physician's assistant, one dietician) were surveyed about their job activities, and subsequently reported diverse duties, including spending almost 50 percent of their time in medical management and 30 percent in administrative activities.[10]

In the 1990s, there were few resources available for inexperienced PCs and the expectations of the role remained vague. It was not uncommon for studies to employ a model of hiring a PC with no clinical background, but who excelled in other skills such as problem solving, communication, and organization.[5] In some studies, dieticians were selected for the PC role due to the necessity of delivering nutrition education as part of the study protocol.[11]

In 2004, a survey of the standard tasks performed by 41 oncology clinical trial research coordinators showed that they all participated in activities such as recruitment, data collection, adverse event reporting, and audit preparation.[8] Those with a nursing background had significantly greater involvement than non-nurse coordinators in clinical care, such as assessment of response to therapy, adverse effects, and query resolution. In 2007, a report of survey results from 205 PCs (50 percent registered nurses) examined factors related to PC turnover. The findings revealed three major themes: the need for formal training, lack of promotion opportunities, and poor allocation of workload.[9]

In the TODAY study, a combination of clinical management and administrative tasks are required at each study visit. In general, the PC is primarily responsible for administrative aspects of study implementation, such as IRB correspondence, budget preparation, supply ordering, equipment maintenance, data entry, and shipping of lab specimens. The DE's central responsibilities focus on medication adherence and adjustment, patient and family education, and clinical management of diabetes and its comorbidities. However, scheduled participant visits do not necessarily fall into discrete components solely requiring the skills of one type of staff

member (clinical) or another (administrative). In addition, many study visit appointments occur during non-routine work hours in order to accommodate the participants' work and school schedules. It is neither practical nor feasible, within the constraints of staffing limitations, to always have both staff members available for each visit, especially when visits occur after hours and on weekends.

To determine if the degree of overlap between the roles of the PCs and DEs across all sites was consistent with our expectations, given the complexity of the study visits, a questionnaire was developed and administered to all eligible PCs and DEs.

Methods

Participants. The sample consisted of 31 TODAY staff members (n=15 PCs; n=16 DEs). The authors, who represent DEs and PCs, were not included in the sample to avoid bias of the results.

Measures. The authors developed a questionnaire designed to examine specific responsibilities related to conducting study visits and participant follow-up. It included a demographic section (i.e., role assignment as a PC or DE, years of experience working on the TODAY study, years of experience working in diabetes care/research prior to TODAY, education level, and employment status with the TODAY study—part-time or full-time), and an 18-item list of the tasks expected to be most frequently performed by PCs or DEs as described in the TODAY study manual of operations and through author consensus.

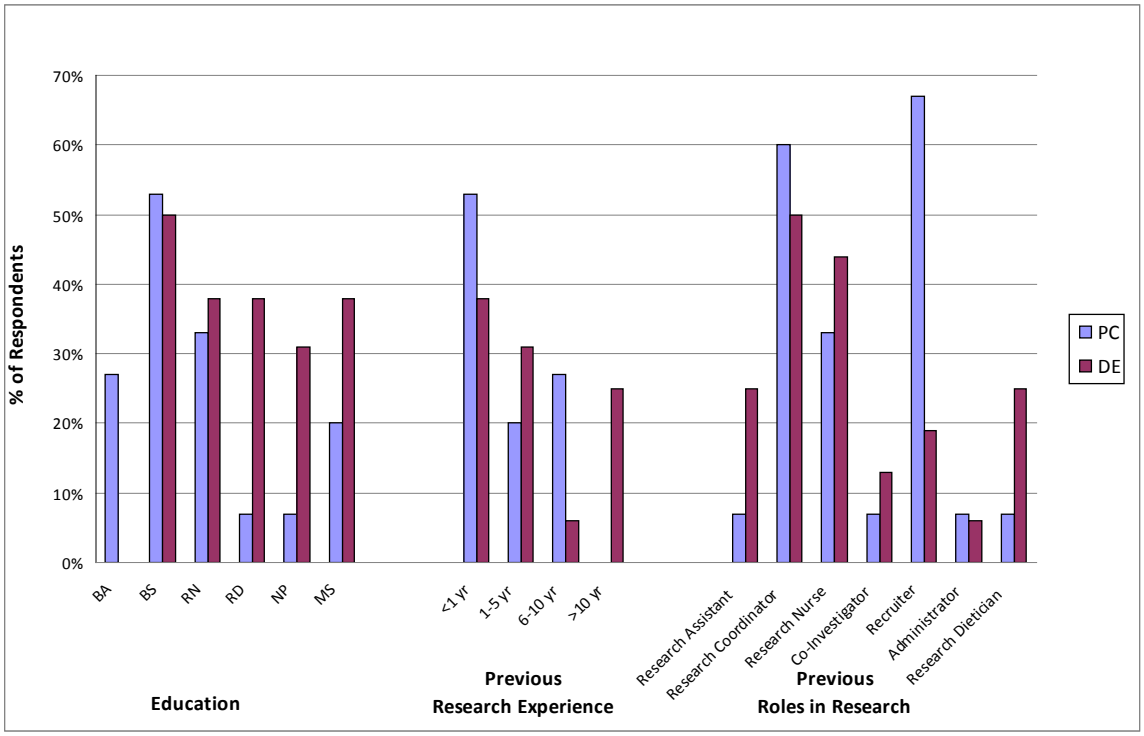
Procedures. The survey was administered during a national study group meeting in June 2008. To preserve anonymity of the respondents, the survey was distributed and collected by a DCC representative. To be sure that all PCs and DEs had the opportunity to participate, the DCC also distributed the survey via e-mail following the meeting. Responses to the electronic survey were sent directly to the DCC, where results for all of the surveys were tallied and categorized according to role group (PC/DE).

Results

Thirty-one responses were received out of a total possible sample of 43 representing a response rate of 72%. Demographic information regarding the sample is summarized in Figure 1.

Most respondents (65%) held a bachelor's degree, and close to one-third had a master's level education. Of the 31 respondents, the majority came from a nursing background (54%), while the remainder was evenly divided between dietetics (22%) and other disciplines (22%). Before working in the TODAY study, 45% had less than one year of research experience, while 13% had greater than 10 years. The most common previous research experiences included roles as a research coordinator (55%), recruiter (42%), and research nurse (39%). About 50% of those who responded were working part-time on the study, while 50% reported working full-time. Approximately half of the respondents had been with the study since its inception and half had started after the beginning of the trial. The majority (65%) had greater than five years of experience in diabetes-related patient care.

Figure 1 Background and professional affiliation of PCs and DEs in the TODAY Study

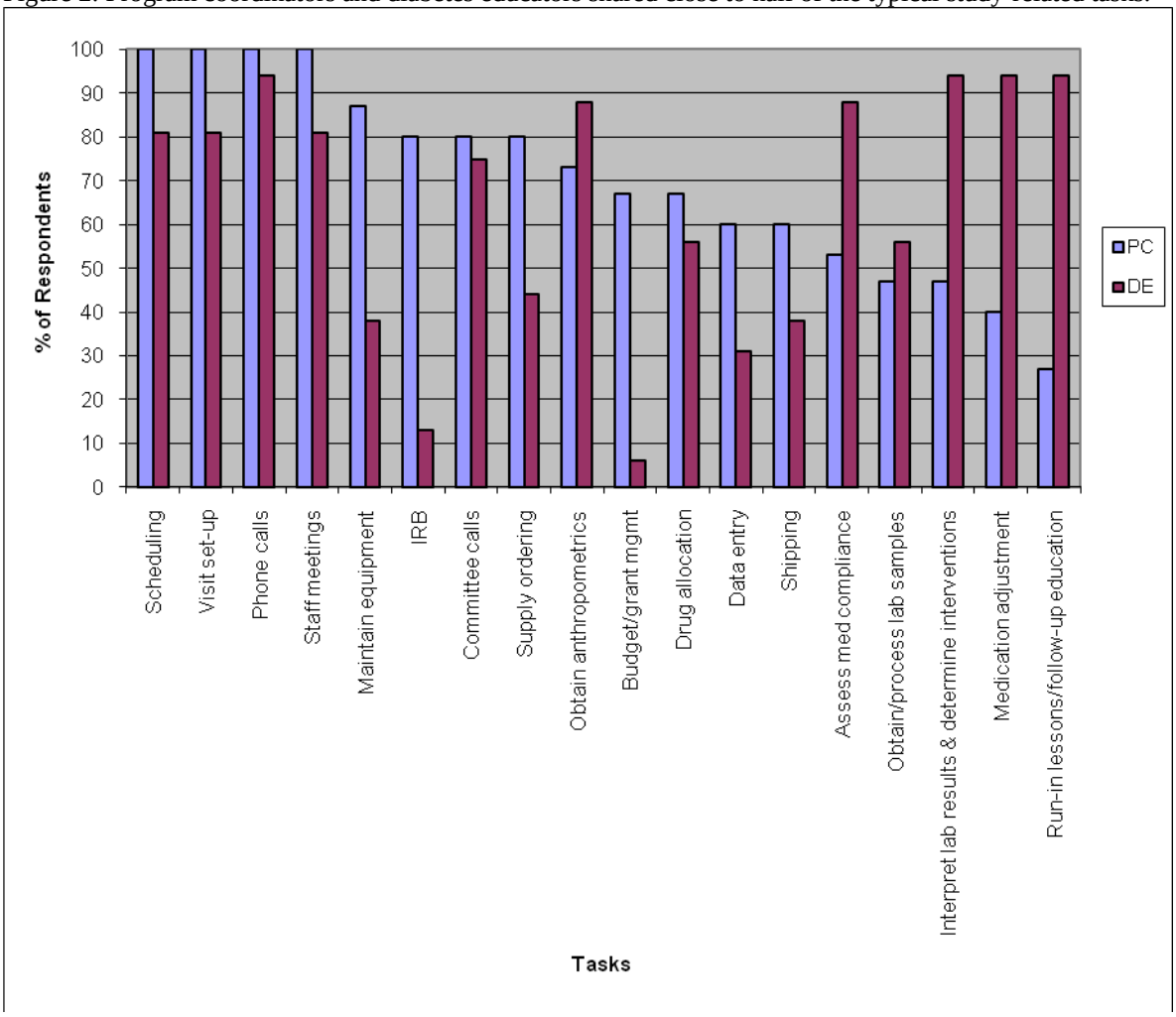


Consistent with our cross-training goals, a high degree of overlap is confirmed by the answers to the self-report survey. As shown in Figure 2, the respondents share (defined as over 50% of both PCs and DEs report performing on a regular basis) close to half (8 out of 18) of the typical study-related tasks, such as: scheduling visits, maintaining phone correspondence, attending meetings, setting up study visit charts, allocating medication from the central dispensing center, assessing medication compliance, and obtaining anthropometrics. In addition, DEs obtain lab samples slightly more often than PCs.

Discussion

Results from the current study are consistent with the hypothesis that coordination of the TODAY study involves cross-training and task-sharing between two roles, the PCs and DEs, across all sites. An example of the benefits of cross-training can be seen in scheduling appointments and maintaining communication with the participants. These are typically two of the most time-demanding tasks for the PCs, as participants frequently reschedule multiple times due to conflicting plans. In addition, because of the challenges that many study families face which include other health issues and socioeconomic and language barriers, contact information may change frequently, making it difficult to stay in contact. During some phases of the study, frequent contact by phone may be required between the DE and the family, for example, when it is necessary to adjust insulin doses and review blood sugar levels. Because of the frequency of phone contact utilized in this activity, the DE can also assume the administrative task of scheduling appointments, thus alleviating the burden on the PC.

Figure 2: Program coordinators and diabetes educators shared close to half of the typical study-related tasks.



Another benefit of having staff members from both groups (PC and DE) working closely with the participants is that different information may be reported to each individual. For example, the PC collects general information from the participant and/or the family during check-in. This information is often very important and related to diabetes self-management and may not always be shared with the DE. It is important for the DE and the PC to communicate throughout the visit to make sure that all relevant information gathered by the PC is provided to the DE for review and clinical interpretation. For instance, if the participant has exceeded a certain threshold of weight gain or an elevated blood pressure prior to the last visit, the results will be brought to the attention of the DE so that he/she can intervene by reinforcing education or evaluating whether a study MD should be consulted.

Study visits, which involve gathering anthropometric data, administering questionnaires, assessing medication compliance, downloading blood glucose meters, and providing medication and monitoring supplies, can range from 1-7 hours in length and are often complicated by unanticipated difficulties in schedule flow. Managing new comorbid conditions such as hypertension, hyperlipidemia, or poor glycemic control may necessitate unexpected time spent for teaching insulin injections, low-fat meal planning, or instructing the family in the use and

side effects of new medications. As a result, PCs may need to re-prioritize the goals of the visit, allowing more time with the DE than planned, without disrupting the schedule of data collection or jeopardizing adherence to the protocol.

Conclusions

The PCs and DEs in the TODAY study collaborate to facilitate study visits, track participant progress, and nurture relationships with participants and their families. As described previously, the PCs and DEs have a working knowledge of each others' roles, which fosters team cohesion, especially during subject appointments. Task-sharing provides opportunities for preemptive problem solving among the front-line study staff. Depending on staffing, each site may function slightly differently, but it is essential for the DE and the PC to work together as a team throughout the study visit to ensure complete data collection and efficient time management.

This staffing model provides mutual support for the PC and DE at each study center, decreases the challenges customarily encountered solely by the study coordinator in a complex trial, and allows for cross-coverage and flexibility. While the roles retain their specific responsibilities and specialties as dictated by the study protocol and design, there is significant overlap, redundancy, and cross-training between the two groups, allowing flexibility of participant scheduling and the ability to respond to unanticipated needs of participants as they may arise.

The limitations of this staffing model include the added resources which may be necessary to train and support both role groups as well as the need for continued communication between staff members in order to facilitate this level of collaboration.

This type of collaborative staffing model (where the specific job responsibilities and procedural protocol are clearly laid out while allowing for the burden to be shared for some of the most time-consuming and tedious elements of study coordination) could potentially increase job satisfaction and reduce staff turnover in long-term trials. For example, research conducted in community mental health settings suggests that the implementation of manualized protocols such as those utilized to guide the implementation of the TODAY study can enhance staff satisfaction and decrease staff turnover.[12] While this effect was not measured or reported in this article, future research may be aimed at describing the relationship between staffing models, staff attrition, and subject retention.

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