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Development and Preliminary Evaluation of a Training Workshop for the Collection of Patient-Reported Outcome (PRO) Interview Data by Research Support Staff

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Abstract

This paper describes the development and initial evaluation of a didactic curriculum to prepare research support staff with the core knowledge and skills required to collect patient-reported outcomes (PROs) via interviews. Research support staff members ($N = 77$) were recruited for eight separate workshops, each consisting of a didactic presentation followed by role-play scenarios with trained actors depicting common scenarios they may encounter as part of patient interaction. Trainees were observed and received feedback on their performance from trained facilitators and peers. In comparison to their pre-training assessment, trainees showed significant improvement in their confidence to conduct a research interview, handle a distressed participant, manage a wandering interview, ask participants sensitive questions, and handle irritated patients. Training research support staff in the effective collection of PROs via patient interviews can improve the confidence of these individuals in interacting with patients, which can ultimately lead to increased accuracy of data collection.

Keywords

Outcome Assessment (Health Care); Training; Data Collection; Hospital Medical Staff

Introduction

Accurate collection and documentation of adverse symptom events is essential to help investigators monitor interventions, adjust treatment, and ensure patient safety in clinical trials [1–4]. As compared to clinician assessments, patient self-reports have been shown to be more sensitive to underlying changes in functional status and have a tendency to identify symptoms earlier during a course of treatment. As such, use of patient-reported outcomes (PROs), defined as a measurement of any element of a given patient's health status that is derived directly from the patient in the absence of interpretation of the response by a physician or any other individual, has become the “gold standard” for the capture of patient

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Conflict of Interest

There are no financial relationships associated with these results that may reflect a conflict of interest or be perceived to reflect a conflict of interest.

adverse symptom information that cannot be objectively measured through lab tests [5,6]. As the use of PRO measures becomes commonplace in cancer and other clinical trials [7], it is especially important that the information obtained through the use of these instruments is collected accurately and efficiently.

Standardized, psychometrically sound measures offer the best means of collecting reliable, valid data for analysis; however, behaviors on the part of research staff and participants can introduce unintentional measurement error. Research support staff may vary in their ability approach and build rapport with patients. Variations in rapport can skew data by leading participants to over- or under-report symptoms [8]. Patient emotional states and behaviors such as distress, irritation, or wandering off-topic can lead to inconsistent answers or missing data.

Additionally, a large number of PROs rely at least in part upon structured or semi-structured direct patient interviews. When clinical trials depend on interview techniques for the collection of PRO information as the primary outcome assessment, the viability of the trial becomes heavily dependent on the interviewer's skills [9]. It is therefore critically important for research support staff approaching and interacting with these patients to be prepared to handle common PRO data collection situations in order to elicit the most complete and accurate information from patients, and avoid instances of selection bias [8] while simultaneously improving study compliance [10].

Research support staff interview training has been shown to increase patient response rates for both in-person and telephone administered interviews, thereby assisting the investigator in obtaining a sufficient sample size to achieve generalizable and meaningful results [11]. Proper interview training is also associated with participant retention, quality control, collection of unbiased data, and treatment fidelity [12]. It has also been suggested that well-trained interviewers are more adept at maintaining interaction, and are therefore more successful in obtaining cooperation from respondents [13]. Well-trained research support staff are also more likely to adhere to the data collection protocol and reduce the minimal psychosocial risks (e.g., research-induced distress) associated with PRO data collection from vulnerable clinical research participants [14].

Despite the need for effective training for research support staff who are collecting PRO interview data, such standardized training is not commonplace at research institutions. This paper describes the initial development and preliminary evaluation of a workshop for training research support staff techniques associated with well-executed, accurate and robust collection of PRO interview data at a tertiary cancer center. The overall educational objective was to develop a didactic curriculum to prepare research support staff with the core knowledge, skills and competencies needed to address challenges faced, with curriculum development guided by a participatory research method that draws upon the expertise of senior research staff, social and behavioral scientists, and clinical research professionals. We hypothesized that research support staff would demonstrate improvement in their skills and confidence related to the collection of PRO interview data as a result of this training.

Methods

Participants

Seventy-seven research support staff members (trainees) were recruited for eight separate training workshops titled, "Techniques for the Effective Collection of Patient-Reported Outcomes (TECPRO)." Trainee characteristics are summarized in Table 1. The voluntary TECPRO training was advertised institution-wide approximately 6–8 weeks prior to the

workshop. Additionally, trainee referrals were accepted from Principal Investigators and clinical research professional staff. All individuals whose primary job responsibility involves collection of PRO data at the institution who had yet to complete the training were eligible to participate in a TECPRO training workshop.

Materials

In order to evaluate this training workshop, we distributed a brief pre-training evaluation survey focusing on participants' self-appraisal of their confidence in handling a number of challenging situations often encountered in the collection of PRO (i.e., handling distressed patients, managing a wandering interview, asking sensitive questions, and handling irritated patientsⁱ). These items were rated on 5-point Likert-type scales ranging from 1 (not at all confident) to 5 (extremely confident). At the conclusion of the training workshop, trainees completed the confidence self-appraisal form as well as a course evaluation form, where they could rate how helpful they found the training to be, whether they felt more confident about interviewing now that they had completed this training, and whether they would recommend this training to their research staff peers. Additionally, trainees were given the opportunity to provide general feedback and suggestions for what should be included in future training workshops.

Patient Scenarios

Challenging PRO data collection scenarios were written by experienced research psychologists with input provided by research support staff. Compensated actors trained in educational role play took part in role-play sessions with the trainees in order to simulate common interview scenarios. Actors prepared for the simulations of these scenarios by studying descriptions of the potential situations encountered between research support staff and research participants (i.e., basic, irritated, distressed, and wandering interviews). Trainees were given a brief description of their simulated interview situation along with a set of sample questions that they would be asking the patient (actor). Table 2 summarizes the scenarios that were distributed to the actors and trainees.

Study Design

Upon enrollment in the workshop, trainees were sent a pre-test evaluation form via email and were then asked to complete and return it within one week of receipt. At the beginning of the training workshop, trainees took part in an hour-long didactic presentationⁱⁱ that summarized the emerging importance of capturing PROs using interviews, as well as an overview of situations they may encounter as part of data collection. Included was a discussion of the key methods of establishing and maintaining rapport [15], the importance of standardization in interview administration, ethical conduct considerations to protect patient's rights, as well as tips in communicating to patients that they are participating in a meaningful activity. Additionally, brief 2–3 minute trigger video demonstrations were shown throughout the didactic presentation to communicate proper and improper techniques for interviewing irritated, distressed, and wandering patients.

After the didactic presentation was completed, groups of 2–3 trainees were paired with a facilitator and actor. Facilitators were either doctoral level behavioral scientists or senior research staff, all of whom had extensive expertise in patient interviewing. Trainees then practiced interviewing skills using the role-play scenarios of different types of interview situations that included a wide spectrum of emotional states and behavioral responses

ⁱThe irritated patient scenario was not included in the first two training sessions.

ⁱⁱThe didactic presentation is available for use by request from the authors

including distress, irritation, or wandering. The role-play scenarios were videotaped. The facilitator's role was to observe the trainees as they completed their role-play sessions, review the videotapes to critique each trainee, invite for further feedback from observing peers, and provide trainees with suggestions for improvement. Facilitators were also available for questions from their assigned participants regarding any aspects of the role-play scenarios. Prior to conclusion of the workshop, course evaluation forms were distributed to and completed by each participant. This educational procedure was modeled after established principles of communication training [16].

Statistical Analysis

Differences between pre- and post-training test results were explored using dependent *t*-tests. Course evaluation results are presented descriptively.

Results

As shown in Table 1, participating trainees ($N = 77$) were college and/or graduate school-educated, primarily female research staff (78%) with varied levels of prior research experience. In exploring differences between pre- and post-training self-assessments (Table 3), dependent *t*-test results indicated that research support staff showed significant improvement in their confidence in conducting research interviews ($t(76) = 6.20, p < .01$), handling of distressed patients ($t(76) = 8.27, p < .01$), managing of a wandering interview ($t(76) = 5.49, p < .01$), ask research participants sensitive questions ($t(76) = 4.69, p < .01$), and handle irritated research participants ($t(56) = 6.12, p < .01$).

The training was well-received by participants, with 88% of participants rating the session workshop as being very helpful or extremely helpful on a 5-point Likert scale that ranged from "Not at all helpful" to "Extremely helpful." The majority of participants reported that they felt at least moderately more confident about interviewing as a result of having completed this workshop (84%) and nearly all participants (96%) indicated that they would recommend this training to their clinical research staff peers (Table 4).

Discussion

The collection of patient-reported outcomes via interviewing is steadily becoming more prevalent in research/clinical trial design [7]; however, there are currently no published standards for adequately preparing research support staff to capture this important information. The present study describes and evaluates a training workshop aimed at educating research support staff (most with less than two years research participant interview experience) at a tertiary cancer center in the best practices for successfully obtaining PROs from patients via one-on-one interaction. In comparison to their pre-training self-assessment scores, trainees were significantly more confident in their abilities to complete research interviews, ask sensitive questions, and handle irritated, distressed, or wandering patients after the conclusion of the training workshop. Participants also indicated that they were satisfied with the training and would recommend it to their peers. These results provide evidence that this didactic curriculum assists research support staff in conducting more thorough, accurate, and unbiased interviews with patients in the future, resulting in improved study accrual and retention, as well as an improvement in data quality and reliability.

In addition to improvements in patient recruitment and data acquisition, there are staff-relations benefits to this workshop. Training techniques for the effective collection of research participant interview data gives research support staff a concrete skill which can be applied across settings, thereby demonstrating a dedication to professional development that

may increase staff morale and retention [17]. As research support staff positions do tend to have higher rate of turnover, investing in staff development and education can improve retention by increasing job satisfaction and sense of workplace as an environment in which they can develop job skills and further their development as research professionals.

There are a number of limitations to this training workshop. Presently neither follow-up interviews, nor actual performance observations are conducted with workshop participants. This information would be meaningful to more fully assess the usefulness of this training and is planned as part of future iterations of the workshop.

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Table 1

Trainee Characteristics

Characteristic	No. of Participants (N = 77)	%
Age		
Mean, years	25.51	
Sex		
Male	17	22
Female	60	78
Education		
Some College	2	3
College Degree	41	53
Some Graduate School	14	18
Graduate Degree	20	26
Research Experience		
None	2	3
< 1 years	15	19
1–2 years	40	52
2 or more years	20	26

Table 2

Summary of Role-Play Scenarios for Trainees and Actors

Scenario	Summary
Basic - Trainee	You are a research study assistant conducting a study on quality of life with lymphoma patients while they are waiting for appointments in the oncology clinic. You have consented a patient and are halfway through the interview. You are about to ask the patient some questions about his/her health and ability to carry out various activities.
Basic – Actor	You were successfully treated for lymphoma several years ago and are in the waiting for a check-up with your oncologist. You are approached by a research study assistant who wants to ask you some questions about quality of life. You agree to the interview find it interesting to be part of a research study, making it easy to cooperate with the research study assistant's questions. You answer each question as instructed, truthfully, but without over-thinking.
Irritated – Trainee	You are a research study assistant conducting a study on quality of life with thyroid cancer patients while they are waiting for appointments. You consented a patient, and are mostly finished with the interview. You are about to ask the patient the final set of questions, which are about demographics. You are aware that the patient has another appointment at the main hospital in one hour, and that it takes about 30 minutes to get there.
Irritated – Actor	You are a patient who was diagnosed two weeks ago with thyroid cancer. You have two different appointments today, one where you are now, and one at the main hospital. Your next appointment is in about 90 minutes. While you are sitting there, a research study assistant approaches you and asks if you will answer some questions for a research study. You agree on the condition that the interview will be relatively brief. As the interview progresses, you find the questionnaire is becoming more personal. The research study assistant is showing no signs that the interview is about to be over, and you start to worry about making your next appointment. As a result, you find yourself becoming irritated at the research study assistant, as suggested through body language, sighs, and interrupting questions. The research study assistant intervenes with empathy and restructuring statements that you eventually find reassuring, and you are able to calm down and complete the study in a timely fashion.
Distressed – Trainee	You are a research study assistant conducting a study on quality of life with colon cancer patients while they are waiting for appointments in the colorectal surgery clinic. You have consented a patient, and during the interview, you are about to ask the patient some questions about how s/he has been feeling in the last four weeks.
Distressed – Actor	Three months ago, you went to the doctor because you noticed blood in your stool, and you were diagnosed with colon cancer. You had surgery six weeks ago to remove one third of your large intestine, and now you have returned to the colorectal surgery clinic for a follow-up visit. Even though you are feeling better physically, you have been feeling depressed, not sleeping or eating well, and have low self-esteem because you've had a couple episodes of not making it to the bathroom in time. You're worried how this will affect you socially. You are approached by a research study assistant who wants to ask you about your quality of life and you agree to answer questions. As you respond to questions about symptoms of depression, you start to become tearful.
Wandering – Trainee	You are a research study assistant conducting a study on inherited risk for hematologic (blood-related) cancers such as leukemias and lymphomas. You are approaching patients in the waiting room and asking them about their family history of cancer to see if they qualify for the study. The main information you need to determine eligibility is whether the patient has had a hematologic cancer (plus age at first diagnosis) and whether any of the patient's first degree relatives (parent, sibling or child) have had a hematologic cancer (plus age at first diagnosis). Patients qualify if at least two people in the family have had a hematologic cancer (either the patient + one relative, or two relatives). Other details about the patient's personal and family history of cancer (e.g., treatment history, recurrences) will be addressed during the study interview over at Clinical Genetics. You have just approached a patient, and are going to ask him/her the eligibility questions.
Wandering - Actor	You finished chemotherapy for non-Hodgkin's lymphoma three months ago, have been quite tired due to the treatments, and have not been going out much. You live alone, and you have been feeling a little stir-crazy because you haven't had much social contact. You are in the waiting room for an appointment with your oncologist, and you are approached by a research study assistant who wants to ask some questions and see if you qualify for a genetics study. Your father had the same disease you did when he was 68, with a recurrence at 73, and you are worried that you are going to have a recurrence as well. Your sister also had leukemia at the age of 50. The research study assistant asks you some questions about your family history of cancer, and you find yourself telling the research study assistant all about how your parent had a recurrence and why you think you might have the same outcome, going into more detail than the question calls for. The research study assistant intervenes with some empathic and structuring statements, and you allow yourself to be steered back onto the topic to finish the interview.

Table 3

Means (Standard Errors) and t-Statistics for Pre- and Posttest Comparisons by Question

Question	Pretest	Posttest	t-statistic
Conducting research interviews in general (n = 77)	3.35 (0.08)	3.88 (0.07)	6.20 *
Handling a distressed research participant (n = 77)	2.79 (0.09)	3.48 (0.07)	8.27 *
Managing a wandering research participant (n = 77)	3.13 (0.08)	3.62 (0.08)	5.49 *
Asking research participant sensitive questions (n = 77)	3.27 (0.09)	3.73 (0.08)	4.69 *
Handling an irritated research participant (n = 57) ^a	2.98 (0.10)	3.68 (0.09)	6.12 *

*
 $p < .01$

^a scenario was not included in the first two training workshops.

Table 4

Participant Responses to Post-Training Evaluation (*N* = 77)

How helpful did you find this training program to be?	Not at all helpful	Somewhat helpful	Moderately helpful	Very helpful	Extremely helpful
	0%	3%	9%	45%	43%
Having completed this training program, do you feel more confident about interviewing?	No more confident than before 5%	A little bit more confident 1%	Somewhat more confident 9%	Moderately more confident 45%	Much more confident 39%
Would you recommend that your peers (other RSAs) take this training program?	No 0%	Not sure 4%			Yes 96%