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The administration of patient-reported outcome questionnaires in cancer trials: Interviews with trial coordinators regarding their roles, experiences, challenges and training

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ABSTRACT

Aims: To explore cancer trial coordinators' roles and challenges in administering patient-reported outcome (PRO) questionnaires, and establish what PRO-specific training and guidance they received and needed.

Methods: Eligible cancer trial coordinators experienced with PRO assessment from approved Australian sites participated in an audio-recorded, semi-structured interview (transcribed verbatim). Recruitment continued until data saturation. Transcripts underwent content analysis.

Results: Twenty coordinators participated (professional training: nursing (n = 12), science/research (n = 4), both (n = 4)). PRO administration formed a minor component of most (85%) coordinators' roles. PRO administration challenges included managing 'English second language' participants, participants' companions who attempted to complete questionnaires, burdensome questionnaires, and balancing their duty of care against trial requirements. Coordinators reported inconsistencies in PRO administration, which appeared to arise as a result of confusion and inconsistent or contradictory PRO training. Inconsistencies concerned whether/when they explained the purpose of PRO assessment, which participants they approached to complete PROs, and whether they used PRO trial data to inform care.

Coordinators received PRO training from various sources; most commonly study-specific start-up meetings (45%) or from colleagues (30%). Two received no PRO-specific training. Despite the challenges reported, many (55%) felt they did not need further PRO training.

Conclusion: Trial coordinators receive inconsistent PRO-specific training and are often unclear how to prioritise different aspects of data quality when faced with everyday challenges, leading to inconsistent methods, missing data, poor quality data, and even bias. Agreement on how coordinators should prioritise the requirements of PRO studies is a necessary pre-requisite for the development of much-needed, consensus-based PRO administration guidelines.

1. Introduction

Patient-reported outcomes (PROs) provide information about the impact of disease and treatment on quality of life and symptoms from the patients' perspective [1]. Within a cancer clinical trial, PRO evidence may be interpreted in the context of survival and other outcome evidence to inform evaluations of comparative treatment effectiveness, which ultimately may inform shared-decision making and health policy [2].

In cancer clinical trials, PRO questionnaires are usually administered to the patient or trial participant (for the participant to self-complete) by a nurse or research team member known variously as a 'trial coordinator', 'clinical research coordinator', 'site coordinator', or 'research nurse' [3]. For the purpose of this paper, we refer to the role as 'trial coordinator'; reflecting the individual/s appointed at each trial recruiting centre, or 'site', who are responsible for 'PRO administration': preparing and providing instructions for participant self-completion of questionnaires, responding to participant queries, collecting completed

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questionnaires, and sometimes for entering questionnaire data; among other trial coordination and data collection duties.

Trial data collection methods related to physical examinations, imaging, laboratory tests, and PRO administration must be standardised to minimise the risk of bias resulting from inter-observer variability [4]. Standardisation of PRO administration methods is also an important strategy to minimise the risk of missing PRO data and subsequent generalisability issues [5]. Key aspects of PRO assessment may easily be standardised, for example, the choice of PRO questionnaire with which to compare treatment group outcomes, and the follow-up time points at which PRO questionnaires are administered. However the extent to which PRO administration procedures are standardised remains unclear. Reviews of PRO aspects of trial protocols suggest that although the basic aspects of PRO assessment are addressed frequently in trial protocols, guidance related to PRO administration procedures is often lacking [6,7]. It is possible that other forms of guidance, for example, standard operating procedures or staff training have been used to standardise PRO administration methods, however to our knowledge, no previous studies have explicitly examined this.

A recent UK study found trial staff working in various clinical trial populations were dissatisfied with the minimal PRO-specific training they had received, particularly with reference to handling concerning PRO responses or participants who become emotional when completing questionnaires. Only four of these participants worked in oncology, and the sample was heterogeneous in terms of specific trial-related duties [8]. Therefore the extent to which the issues reported in the UK study exist for cancer trial coordinators is unclear.

The aims of our study were to: understand the various roles of Australian cancer trial coordinators responsible for PRO assessment, determine their challenges regarding PRO administration, establish what training and guidance is typically offered to trial coordinators, and determine the self-perceived PRO-specific training needs of trial coordinators.

2. Methods

2.1. Ethics

Human Research Ethics Committee (HREC) approval was provided by The University of Sydney (2014/383), Royal Prince Alfred Hospital (X14-0282), and Royal Brisbane and Women's Hospital (HREC/15/QRBW/475).

2.2. Participants

Trial coordinators based at approved Australian sites who were responsible for administering PRO questionnaires in cancer trials and who had at least 6 months experience in the role were eligible to participate. In response to an email invitation sent to trial coordinators at each approved site, volunteers provided written informed consent and were contacted by phone to confirm eligibility and to schedule an interview. The email invitation clearly outlined the aims and goals of the research. None of the participants had previous or existing working relationships with the interviewer. Participants were aware that the study team was comprised of specialist PRO researchers, as the roles and position titles of investigators were described on study information materials. Recruitment of consecutive, interested trial coordinators continued until data saturation was achieved. Participants did not receive any incentives for participation.

2.3. Interview methods

Interviews were semi-structured, allowing key issues to be explored in further detail or for clarification [9]. A topic guide was prepared comprised of three sections: (1) trial coordinator roles and responsibilities, including time spent on PRO assessment and other non-PRO responsibilities; (2) general procedures for each key stage and aspect of PRO administration (e.g. consent, discussing PROs with trial participants, challenges with PRO assessment, and forwarding PRO data to the sponsor/central trial office); and (3) training, including what professional and PRO-specific training they had received, their perceived PRO-specific training needs, and preferred formats of guidance. The topic guide was discussed as a team regularly and allowed novel ideas raised in earlier interviews to be discussed in subsequent interviews. Interviews were conducted over the phone or face-to-face (if location was feasible), as per participant preference. Interviews were conducted one-on-one by a trained and experienced interviewer (RMB), as part of her doctoral research. All interviews were audio-recorded, de-identified and transcribed verbatim by an objective, external, professional agency – therefore we did not require participants to comment on interview transcripts. No repeat interviews were conducted.

2.4. Analysis

Interview transcripts underwent content analysis; a method enabling identification, organisation, and interpretation of patterns within the data [10,11]. Content analysis was appropriate for this study because we sought a content-sensitive method to synthesise the experiences, processes, challenges and needs of trial coordinator participants discussed during the interviews, and to quantify the findings when meaningful to do so [10]. We sought to present findings in a descriptive manner, to increase understanding of the trial coordinator role in the context of PRO data collection [10]. We acknowledge that the interview questions were formulated and the data interpreted through a 'PRO methodological researcher' lens, informed by our previous research findings, in order to highlight necessary future training topics, methodological and practical areas in need of improvement, and possible strategies to address these challenges. For transparency, we have presented quotes to support our interpretation. We have also highlighted where certain themes or practices were based on only a small number of interviews for transparency and discuss the broader role of trial coordinators for context.

A coding framework was developed based on an iterative process, using inductive (bottom-up or "data-driven") and theoretical (top-down or "theory-driven") methods [10–12], the latter based on past methodological work [5,8,13]. Coding was managed using Dedoose software [14]. RMB reviewed and coded all transcripts in depth and DK checked the coding framework and application of codes for 20% of the interviews. Based on team discussions, the codes were organised into categories for presentation. All authors agreed on the final code structure.

3. Results

3.1. Sample characteristics

Interviews were completed between July 2014 and April 2016. Twenty participants were interviewed from five Australian hospitals, two of which were private centres. The mean interview length was 47 min. Participant characteristics are presented in Table 1.

4. Findings

4.1. Roles and skills of trial coordinators

4.1.1. General roles

Coordinators described multiple responsibilities associated with trial coordination; commonly including: managing governance issues for multiple trials, consenting participants, reporting adverse events, completing case report forms, ensuring clinicians complete required paperwork correctly, reviewing prospective trial protocols, organising meetings with other trial coordinators, organising patient appointments for data collection (scans, blood tests), managing study budgets and