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The role of clinical trial nurses: An Australian perspective

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Summary Over the past two decades, the number of clinical trials conducted globally has increased thereby increasing demand for nurses working as Clinical Trial Nurses (CTNs), sometimes known as Clinical Research Nurses. The role and professional issues for these nurses in Australia has not been empirically formulated. Sixty-seven clinical trial nurses were surveyed nationally using a modified version of the Clinical Trials Nursing Questionnaire (CTNQ). Findings revealed the complex CTN role can include the coordination of the trials on one or more sites. This involves all domains listed in the questionnaire from protocol development, ethics approval applications, recruitment and consenting of participants in trials, to administering or assisting with treatments within the bounds of their practice code and the evaluation of protocols. Professional issues documented were: being undervalued in the nursing workforce, having no formal educational preparation for the role and minimal recognition in publications emanating from research in which they were involved. These nurses bring their practice knowledge to benefit research outcomes that may contribute to improving patient/client care.

Introduction

Clinical trials have become the hallmark of evidence in creating the knowledge base for a broad spectrum of illnesses and appropriate treatments (Di Giulio et al., 1996). Over the past two decades, the number of clinical trials conducted globally has increased thereby increasing demand for nurses working as Clinical Trial Nurses (CTNs)—also known by various other titles including Clinical Research Nurses and Research Co-ordinators. CTNs can, potentially, influence the quality of clinical trials but little is written about the scope and contribution of their role in clinical trials in Australia. Prior to the study reported here, one study on the work satisfaction and professional issues of research co-ordinators in intensive care units in Australia was conducted by Rickard, Roberts, Foote, and McGrail (2007). Furthermore, in Australia, there is no industrial classification for these nurses, contributing further to their invisibility in the nursing workforce. This paper reports the results of a

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descriptive cross-sectional survey in Australia on the CTN role and associated professional issues.

Background

There are several studies in countries in the Northern Hemisphere which have focused on the role of the research nurse within specialities (e.g., Catania, Poire, Dozin, Bernardi, & Boni, 2008; Davis, Hull, Grady, Wilfond, & Henderson, 2002; Ehrenberger and Lillington, 2004; Kenkre & Chatfield, 2004; Nagel, Gender, & Bonner, 2010; Ocker and Plank, 2000; Spilsbury et al., 2008). To date, there is no clear picture of the qualifications required to be employed as a CTN (Ehrenberger and Lillington, 2004). Findings by Ehrenberger and Lillington (2004) indicate that there are varying pay rates for CTNs and a lack of consistency in the way they are employed. That is, some are employed according to nurses pay scales, and others are employed through the academic sector as administrative or research officers. This is confirmed in other studies in the UK (e.g., McCormack, 2004). The Royal College of Nursing (RCN) in the UK has suggested appropriate clinical grades and salaries for these nurses as part of a competency framework which has been developed for Clinical Research Nurses (RCN Competencies Working Group, 2008). Competencies include:

1. to demonstrate knowledge and understanding of the evolution of clinical research,
2. to apply knowledge and skills in the clinical research environment,
3. to work within and adhere to the requirements of research ethics, research governance and legislation,
4. to understand the principles and practice of obtaining valid informed consent.

However, these RCN standards were based on expert advice rather than empirical research.

Further, the knowledge, skills and duties required by CTNs varies and can include: information technology skills; project management; protocol management; ability to develop; assess and direct research processes; clinical assessment of subjects; patient advocacy; education of patient and family about clinical research procedures and drug administration (Di Giulio et al., 1996; Raja-Jones, 2002). According to Hill and MacArthur (2006), the position of the CTN is very complex due to a combination of contractual and accountability arrangements. This position can be intensified by feelings of isolation, a lack of professional recognition and support and limited specific educational opportunities (Hill & MacArthur, 2006).

Experienced CTNs are often highly skilled in terms of their specialist clinical knowledge, and have a comprehensive understanding of all aspects of the research process, including methodological, ethical and practical issues (Hill & MacArthur, 2006). Due to this increasing complexity of the role of the clinical research nurse (Bird & Krishbaum, 2005; Hill & MacArthur, 2006), tertiary education programs for these nurses around the USA, UK, Canada and Europe are being conducted. A new Clinical Trials Research course was developed in Australia in 2011 in response to the need for formal clinical research qualifications and is offered at the postgraduate level (Master of Clinical Trials Practice, Sydney Nursing School) at the University of Sydney. (http://sydney.edu.au/nursing/course_information/specialty_courses/clinical_trials/clinical_trials_m.shtml, retrieved 16 December 2011). Short courses are also available. The NSW Institute of Clinical Trials Network conducts programs and workshops for nurses working in clinical trials in cancer care (http://www.cancerinstitute.org.au/research-grants-and-funding/clinical-trials/nsw-clinical-trials-network, retrieved 30 November 2010) and some pharmaceutical companies and universities provide informal professional development on-the-job style education for these nurses. The aim of the present study is to delineate the role, and professional and demographic characteristics of CTNs in Australia.

Method

Research design, population and sampling

A quantitative descriptive survey design was used in this cross-sectional study. Participation was voluntary and self determined by CTNs attached to research projects from Universities and Medical Schools in Australia. This population can be considered hard to reach as there is no national register of CTNs in Australia and no single professional body or forum representing their interests. Therefore, the study population had to be sampled by approaching medical staff in universities who might employ CTNs, and the investigators depended on them to distribute the information about the questionnaires for this study. For this reason, it was impossible to accurately estimate the population and, therefore, to know the precise sample size of CTNs who received the information. Details of the distribution strategy are described below and the issue of response rate will be considered later in this paper.

Survey instrument

The Research and Clinical Trial Nurses Questionnaire (RCTNQ) was adapted, with permission, from the Clinical Trials Nursing Questionnaire (CTNQ) for oncology clinical trial nurses (Ehrenberger & Lillington, 2004) of the Oncology Nursing Society in the USA. A modified version of the CTNQ has been validated in Italy with 30 CTNs (Catania et al., 2008). The CTNQ was developed to identify significant aspects of the role of CTNs including the frequency and importance of clinical trial nursing activities. Ehrenberger and Lillington (2004) used the Nursing Role Effectiveness Model (p. 65) as a guide to determine variables and item generation relevant to the CTN role. The validity and reliability of the CTNQ was examined using a literature review, evaluated by an expert panel of judges, focus groups and pilot tests. The instrument has a Cronbach's alpha coefficient of 0.92 for frequency and 0.95 for the importance scales (Ehrenberger & Lillington, 2004). Test–retest reliability was conducted 2 weeks later after initial data collection with 40 participants and Cronbach's alpha was 0.88 for the frequency scale and 0.92 for the importance scale.

Some words and phrases of the RCTNQ were changed or deleted to adapt to the Australian context. For