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Research nurse manager perceptions about research activities performed by non-nurse clinical research coordinators

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ABSTRACT

Objectives: There has been limited research to document differences in roles between nurses and non-nurses who assume clinical research coordination and management roles. Several authors have suggested that there is no acknowledged guidance for the licensure requirements for research study coordinators and that some non-nurse research coordinators may be assuming roles that are outside of their legal scopes of practice. There is a need for further research on issues related to the delegation of clinical research activities to non-nurses.
Methods: This study used nominal group process focus groups to identify perceptions of experienced research nurse managers at an academic health science center in the Southern United States about the clinical research activities that are being performed by non-nurse clinical research coordinators without supervision that they believed should only be performed by a nurse or under the supervision of a nurse.
Results: A total of 13 research nurse managers volunteered to be contacted about the study. Of those, 8 participated in two separate nominal group process focus group sessions. The group members initially identified 22 activities that they felt should only be performed by a nurse or under the direct supervision of a nurse.
Conclusions: After discussion and clarification of results, activities were combined into 12 categories of clinical research activities that participants believed should only be performed by a nurse or under the direct supervision of a nurse.

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Introduction

Clinical research coordination is a professional role for nurses who manage and implement clinical research protocols and provide care for pediatric or adult patients who are enrolled in clinical trials. There is no standardization of job titles for individuals working in clinical research positions. Nurses working in this role have a variety of job opportunities and job titles ranging from study nurse, clinical research nurse, clinical research coordinator, and research nurse

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manager, with titles varying based on the employer institution. Some nurses work in designated clinical research hospital or clinic units where study patients receive care related to their clinical research participation. Other nurses are employed by investigators or clinical research companies and are charged with coordinating single or multiple clinical research protocols. Castro et al. (2011) defined clinical research nursing practice as having "a focus on the care of clinical research participants and management of a clinical research protocol" (p. 8). Research nurse coordinators manage the operation of an average of six protocols and the care of 80 or more study patients annually (Getz, 2013; Getz, 2009). Mueller (2001) noted that the roles of nurses working in clinical research have evolved into independent roles following decades of task delegation by physician investigators (PIs) and that those independent roles constitute a unique specialization in nursing. Hastings, Fisher, and McCabe (2012) observed that nurses working in clinical research have made contributions to the research findings that support evidence-based practice through the key roles they perform in coordinating and managing research involving human subjects.

Nurses at the National Institutes of Health Clinical Center represent the largest critical mass of nurses engaged in research support and coordination in the country. In 2007, nurses at the Clinical Center embarked on a project to systematically document and describe the roles of nurses in clinical research. An expert committee of clinical research nurses identified and validated five dimensions that constitute the domain of clinical research nursing practice: (a) clinical practice, (b) care coordination and continuity, (c) study management, (d) human subject protection, and (e) contributing to the science (CRN2010 Clinical Research Nurse Domain of Practice Committee, 2009). Castro et al. (2011) conducted a study to describe the specific role activities performed in each of these five domains. Bevans et al. (2011) further differentiated the role activities of nurses working as clinical research nurses, clinical research coordinators (CRCs), and nurse practitioners in clinical research settings.

Nurses attending a national conference of clinical research nurses were surveyed to explore clinical research nurse perceptions about the activities of nurse clinical research coordinators (NCRCs) and non-nurse clinical research coordinators (NNCRCs), validated the nursing role delineation work of Bevans et al. (2011), and also raised concerns about the delegation of clinical activities typically requiring nursing licensure to unsupervised non-nurses (Jones & Wilson, 2014). Findings from this survey additionally suggested role conflict among the NCRC respondents and the need for further research on the delegation of clinical research activities to non-nurse research personnel (Jones & Wilson, 2013).

PIs in clinical research sites, including academic medical centers, hire both NCRCs and NNCRCs. These individuals may or may not be academically educated in clinical research and may or may not hold certification in clinical research. There are two widely recognized mechanisms for clinical research professionals to obtain "certification" in clinical research coordination. The Association of Clinical Research Professionals (ACRP) offers certification of clinical research coordinators who have experience in conducting "essential duties" as a clinical research coordinator. Those duties are defined by ACRP as "documenting adverse events; prepare or review documents submitted to the IRB; protocol review or study procedures planning; participate in conducting subject visits; maintaining source document; prepare for and participate in study visits with monitor, sponsor, auditors, etc.; and participate in consent process." Individuals graduating from an academic program may be eligible to take the certification examination with documentation of 1,500 hours of CRC experience. Those with an associate's degree or bachelor's degree or those who are registered nurses (RNs) can take the examination with documentation of 3,000 hours of CRC experience, and those with a high school diploma or registered as a licensed practical nurse or lab technician are eligible to take the examination with documentation of 4,500 hours of CRC experience (ACRP, 2014). The Society of Clinical Research Professionals (SoCRA) also has a certification examination for clinical research professionals. Eligibility for the certified clinical research professional examination requires 2 years of full-time experience as a clinical research professional or a 12-hour academic baccalaureate or graduate certificate or degree in clinical research with 1 year of full-time experience (SoCRA, 2014). Existing clinical research certifications offered exclusively for nurses working in this area of practice are lacking.

There has been limited research related to delegation of clinical research activities, and many researchers who have studied the roles and experiences of clinical research coordinators have not differentiated the roles of nurses and non-nurses working in clinical research in their studies (Duane, Granda, Munz, & Cannon, 2007; Getz, 2012; Granda, Duane, Munz, & Cannon, 2009; Gwede, Johnson, Roberts, & Cantor, 2005; Kellen et al., 1994). The Department of Veteran Affairs (VA) Office of Inspector General (2007) released a report raising concerns about "unlicensed research assistants practicing medicine" in a South Texas Veterans Heath Care System in San Antonio. This led to a call for additional policies about the delegation of clinical research activities, documentation of delegation of tasks for clinical trial protocols, and scopes of practice. Multiple VA research institutions have published their policies for delegation of research activities on websites. For example, policies of the Institutional Review Boards (IRBs) of the San Francisco VA hospital elucidate the research activities that may be delegated by investigators to nurses and non-nurses (San Francisco VA Medical Center, n.d.). Similar policies from the VA Medical Center affiliated with the University of Texas Health Sciences Center at