

THE RESEARCH PROGRAM COORDINATOR: AN EXAMPLE OF EFFECTIVE MANAGEMENT

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Careers in clinical research management are increasingly common. Despite nurses' important role in clinical research, their status as research professionals is underrecognized. In this article, we describe the role of a "program coordinator" (PC) in the context of a complex research program on migration and reproductive health. The PC role expands beyond the usual role of a research coordinator because he or she is involved in all aspects of the program of research and his or her responsibilities include research, education, clinical, and administration components. He or she ensures optimal organization and continuity across several studies and ensures ethical and scientific standards are applied for each individual study. His or her clinical knowledge assures data are accurate and subjects are safe. In addition, he or she assists with applying for funding, the maintenance of research partnerships, and dissemination of research findings; he or she supports students' learning and completes all regulatory aspects related to the program of research. Key to the PC role is relationship building and the application of Good Clinical Practice principles. The advanced role of a PC also warrants opportunities for professional development and a competitive salary. A PC is an effective approach for research management and a natural role for professional nurse. (Index words: Research coordinator; Professional nursing; Research program; Migration and reproductive health research) J Prof Nurs 26:223–231, 2010. © 2010 Elsevier Inc. All rights reserved.

THE ROLE OF nurses as coordinators of randomized controlled trials (RCTs) has been specifically described in the literature (Anonymous, 2003; Brown & Fishbaugh, 1995; Cooper & Lomax, 1989; Davis, Hull, Grady, Wilfond, & Henderson, 2002; Ecklund, 1999; Isaacman & Reynolds, 1996; Loh, Butow, Brown, & Boyle, 2002; McKinney & Vermeulen, 2000; Mueller, 2001; Ocker & Plank, 2000; Pelke, 1996; Pelke & Easa, 1997; Rico-Villademoros et al., 2004; Trilla, 1995;

Trocky, 2001; Waller, 2003). Focus has mainly been on the management of RCTs testing various pharmaceutical treatments, in particular those in the area of oncology. Responsibilities, as well as titles, have been wide in scope, ranging from direct recruitment and obtaining consent to protocol implementation, to overall data management, to more "study managerial" tasks such as overseeing protocol submissions to research ethics boards (REBs) and ensuring sponsor/funding agency requirements are met (e.g., report updates). Certain titles more clearly illustrate the function of the coordinator (e.g., data manager, clinical trials coordinator), while others used have been more general (e.g., research nurse, research manager, research coordinator, clinical research coordinator). Overall, the scope of the clinical research nurse's role is considered to have been poorly defined.

Increasingly, there is a move to formalize the research coordinator role and to establish an internationally recognized body of "research professionals/associates" for human subjects research (European Forum for Good

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Clinical Practice, 2005; The Association of Clinical Research Professionals, 2005; The Society of Clinical Research Associates, 2005). At the same time, research teams are more and more interdisciplinary, conducting national and international studies that involve community groups and that use a number of different approaches to collect data, which are biological and psychosocial in nature. Studies take place outside of clinical contexts (i.e., hospitals), include diverse populations, and not only are testing medical interventions (i.e., pharmaceutical and/or surgical treatments) but also are aiming to inform various types of clinical practice and policy and to provide direction for future research. The role of the coordinator can take many forms, and further discussion with greater detail provided on the types of coordinator roles, and the commonalities across these, is warranted. Many responsibilities of a coordinator have been specified; however, many responsibilities a coordinator may take on have yet to be highlighted.

There are many advantages to having more explicit descriptions of the various coordinator roles and responsibilities, including providing researchers more insight into the qualifications a prospective candidate should have for a given position and consequently determining the salary the candidate should receive; clarifying job expectations for the coordinator hired; and further creating a basis for formalization of this role (i.e., standards for education and licensing). These issues are particularly important for nursing, in that nurses often find themselves in positions of being “jacks of all trades,” with a lack of delineation of where their job begins or ends and taking on duties that are not officially recognized. In this respect, their professional status is minimized and the importance of their role in research not recognized. Learning “on the job” and feeling “professionally isolated” have also been particular issues raised by nurses in the research coordinator role (Ecklund, 1999; Rico-Villademoros et al., 2004), further supporting the need for advanced education in this domain. A consequential benefit of formalizing the coordinator role would be the generation of a “coordinator network,” thus providing a forum for the exchange of ideas and learning (Ecklund, 1999). Ultimately, professional research coordinators lead to quality research and more efficient research management.

The purpose of this article is to illustrate the effectiveness of the role of a “program coordinator” (PC), a research management position where a nurse is responsible for overseeing a range of activities related to maintaining a complex program of research. Responsibilities of a PC expand beyond those of the coordinator roles previously described in the literature and include research, clinical, education, and administration components. In each function, the PC interacts with a number of individuals, and thus, key to this role is an expertise in interpersonal relationships. The PC is a professional and offers organization and continuity across several studies, maintains high ethical and scientific standards in the conducting of each study, and ensures all aspects of the

program of research comply with university, hospital, and funding agency regulations. The PC is a skilled leader and support agent.

Program of Research

In Montreal, Canada, a research program (i.e., multiple studies on a similar theme), Migration and Reproductive Health Research (MiRHR), was developed to determine whether specific groups of migrants differ in their experiences of reproductive health events, outcomes, and related service use. Studies are generally multicentered and use survey, interview, and direct physical assessment as data collection techniques. The number of research activities, partners involved, and the geographical span of the collaborations and study sites are large, with more than 20 student projects and researcher-led studies at the local, national, and international level conducted within the last few years. Some of these were feasibility studies, others were specific to developing research collaborations, and others were to collect data or work with existing datasets and/or literature databases to answer research questions. Each project links to one or more of the other projects, and all involved an interdisciplinary research team and support from the clinical, nongovernmental, and governmental sectors (organized into advisory committees) to ensure relevancy and appropriate research methodologies. Identifying key research variables and culturally appropriate questionnaires to address the various research questions was an extensive task (Gagnon, Merry, & Robinson, 2002; Gagnon, Tuck, & Barkun, 2004). Sixteen questionnaires were translated into 12 languages and validated through several steps including working with migrant community members to ensure questionnaires and data collection protocols were community-responsive (Ruppenthal, Tuck, & Gagnon, 2005).

The population of interest in MiRHR is composed of multiple ethnic-linguistic groups with varying migration experiences and health and social needs. Particular attention is therefore required in developing and implementing recruitment and data collection protocols. Ensuring the staff has appropriate language and interpersonal skills is important to ensure informed consent is obtained and that data collection is valid. Sensitivity and understanding of participants' experiences and training staff to be responsive to these are also necessities. Migrant childbearing women, especially the most vulnerable (i.e., lacking language skills, history of abuse/torture, and no family/friends) may be isolated and difficult to access for participation in research. Women with no health insurance are especially likely to leave the hospital quickly and may be underrecruited. Frequent and regular contact with hospital sites is therefore needed to maximize participation rates. When recruitment from the broader community is required, access to potential participants is gained via community organizations, also requiring frequent contact.

To maintain the functioning of MiRHR, an intricate network of people is involved in a variety of ways (see

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