

Reader Poses Questions Regarding Article's Methodology

I read "Validating the Clinical Research Nursing Domain of Practice" by Castro et al. (2011) with great attention. Oncology has long recognized clinical trials as an area of specialization for nursing (Hubbard & DeVita, 1976). What began as a role in administering investigational chemotherapy for U.S. nurses has evolved into an internationally recognized specialty practice for nursing across all therapeutic areas (Spilsbury et al., 2008). I'm pleased that the Oncology Nursing Society continues to champion clinical trial nursing.

To fully understand the methodology behind this survey, it would be helpful to have additional details on how the sample of 30 "expert" U.S. nurses was identified and selected.

Also, the proposed taxonomy and domain of clinical research nursing only considers RNs who practice at a clinical research site where trials are conducted with participants. It is unclear if or how this would apply to RNs who contribute to clinical trials in other practice settings (e.g., sponsors, contract research organizations, institutional review boards, regulatory agencies). Rather than limiting the domain of clinical research nursing to those who care for research participants or manage the protocol at the site, I hope this area of specialization will examine other roles for RNs in the clinical research process.

I welcome your response.

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References

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Authors' Response

The questions posed by Ms. Zimmerman are just the kind of thoughtful response we were hoping for to extend and refine the development of concepts related to the clinical and leadership roles of nurses in the field of clinical research.

The sample of experts in clinical research practice was developed using two primary contact sources. The first involved accessing a national "Clinical Research Think Tank" composed of nurse managers from the National Institutes of Health (NIH) Clinical Center, General Clinical Research Centers, and Clinical and Translational Science Award sites across the country. These nurses met in New York, NY, at Rockefeller University in 2006 and 2007 to discuss and characterize the specialty practice of clinical research. The second strategy involved a selection by the study group members of colleagues in the intramural program at the NIH Bethesda Campus, who provided, coordinated, or managed nursing care and study coordination at the NIH Clinical Center. In addition, a few nurses were referred by panel members before the start of the study and were invited and included if they met the overall criteria for expertise and experience. Because the intent of the study

was to achieve consensus and validate or revise a conceptual document, there was not an attempt to obtain a sample that was representative of all nurses involved in research. Our plan has been to use successive steps of conceptual development, consensus validation, and role delineation to create a valid and reliable tool to measure role activities and role focus across settings where clinical research nurses are in practice.

We intentionally limited the definition of clinical research nursing to the specialty clinical practice of nurses working in research, including research-related activities undertaken on the immediate behalf of a patient participant or to implement a study in the clinical setting. We have had several conversations with advanced practice nurses about where leadership and management fit in to the practice domain and how the concept of a specialized clinical practice relates to the scope of possible advancement for nurses in clinical research. We have also had to consider in detail the point at which a nurse interested in clinical science transitions into a focus on the investigator role or a focus on managing the clinical research enterprise itself. These questions were beyond the scope of the original Delphi project, but they pose exciting opportunities for future exploration and study.

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Correction

In the May 2011 article, "Lack of Communication and Control: Experiences of Distance Caregivers of Parents With Advanced Cancer" by Polly Mazanec, PhD, ACNP, AOCN®, Barbara J. Daly, PhD, RN, FAAN, Betty Rolling Ferrell, RN, PhD, MA, FAAN, and Maryjo Price-Paul, PhD, ACHPN, FPCN (Vol. 38, No. 3, pp. 307-313), the following funding should have been

disclosed: Mazanec received funding from the National Institute of Nursing Research (F31 NR010315-02) during her doctoral study in the Frances Payne Bolton School of Nursing at Case Western Reserve University in Cleveland, OH. The corrected version of the article can be accessed online at <http://ons.metapress.com/content/m2k25x74x764/?v=editorial>.