

This material is protected by U.S. copyright law. Unauthorized reproduction is prohibited.
To purchase reprints or request permission to reproduce, e-mail reprints@ons.org.

Development of a Measure to Delineate the Clinical Trials Nursing Role

Heidi E. Ehrenberger, PhD, RN, AOCN®, and Linda Lillington, DNSc, RN, CCRC

Purpose/Objectives: To identify the significant dimensions of the clinical trials nursing role and to construct a reliable and valid survey instrument to reflect these dimensions.

Design: Methodologic survey.

Setting/Sample: The judge panel consisted of six national nurse experts. The focus group sample was comprised of 24 clinical research nurses from the West, Northeast, and Great Lakes regions of the United States and five research nurses from Canada. The sample for instrument testing consisted of 40 oncology clinical research nurses from the Southeast.

Methods: Several strategies were used to develop the Clinical Trials Nursing Questionnaire® (CTNQ): literature review, conceptualization of the subscales, development of items for each subscale, development of the tool, expert judge panel evaluation, focus group testing, administration of the tool, and psychometric analysis of the results.

Main Research Variables: Frequency and importance of clinical trials nursing activities.

Findings: Content validity was established at 0.95. The alpha reliability coefficient was 0.92 for the frequency scale and 0.95 for the importance scale. A two-week test-retest reliability of 0.88 was obtained for the frequency scale and 0.92 for the importance scale. The final CTNQ contained 12 sections with 154 items.

Conclusions: The CTNQ has acceptable content validity, internal consistency, and stability reliability. This instrument is promising for the assessment of the research nurse role, and its use in further research is appropriate.

Implications for Nursing: A valid and reliable measure can be used to delineate the subspecialty of clinical trials nursing, thus providing a better understanding of how nursing professionals contribute to the cancer research enterprise.

The Oncology Nursing Society (ONS, 1998) position statement on cancer research and cancer clinical trials stated that “coordination of clinical trials (e.g., the coordination of clinical sites, development of standardized treatment orders, symptom management, patient education and advocacy, facilitation of informed consent, assistance with participant accrual and retention) is best accomplished by

Key Points . . .

- ▶ The current social organization of clinical research is undergoing a significant transformation, and a better understanding of the research nurse role is critical.
- ▶ Nurses are responsible for empirically demonstrating the skills and knowledge they bring to the clinical research enterprise.
- ▶ The systematic development and psychometric testing of a survey instrument are essential when planning to delineate the clinical trials nursing role.

registered nurses who have been educated and certified in oncology nursing” (p. 973). Little empirical data have been systematically collected and analyzed for the purpose of describing the role and responsibilities of the research nurse in cancer care. Mueller (2001) stated, “It will be up to nurses to empirically demonstrate that the skills and knowledge they bring to clinical research as nurses are qualitatively and quantitatively

Heidi E. Ehrenberger, PhD, RN, AOCN®, is a nurse consultant in Ann Arbor, MI, an adjunct assistant professor in the College of Nursing at the University of Tennessee in Knoxville, and a former visiting professor of nursing at Lincoln Memorial University in Harrogate, TN. Linda Lillington, DNSc, RN, CCRC, is a nurse manager in the General Clinical Research Center at the Harbor–University of California, Los Angeles, Research and Education Institute in Torrance, CA. Project support was provided, in part, by the Oncology Nursing Society Special Interest Groups project fund, an ONS Foundation/Oncology Nursing Certification Corporation Education Research Grant, and a General Clinical Research Center Grant M01-RR00425 from the National Center for Research Resources. (Submitted September 2003. Accepted for publication November 26, 2003.)

Digital Object Identifier: 10.1188/04.ONF.E64-E68

different, and therefore more beneficial, than those provided by other occupational groups” (p. 189). The current social organization of clinical trials research is undergoing a significant transformation, and a better understanding of the unique nursing role is critical. The number and complexity of clinical trials being conducted are increasing. Regulatory and economic pressures are mounting. Clinical trial processes need to be completed the right way (procedurally correct and as defined by the protocol), at the right time (protocol-specified time points), by the right specialist or specialty service (skill set or equipment) in a manner that is compliant with the Good Clinical Practice (GCP) guideline (International Conference on Harmonisation [ICH], 1996; Joshi & Ehrenberger, 2001). The purpose of this methodologic study was to develop a reliable and valid measure to delineate the subspecialty of clinical trials nursing.

Background

A work group of the ONS Clinical Trial Nurses (CTNs) Special Interest Group (SIG) membership was formed in October 2000 because an instrument to measure the domain of interest did not exist. Core members of the work group are listed in Figure 1. The intent of the group was to conduct an ONS SIG-sponsored survey. Gail Mallory, PhD, RN, CNAA, the current ONS director of research, and Judy DePalma, PhD, RN, who was the ONS senior research associate at the time that this study was conducted, were asked to initially serve on the work group in an advisory capacity. The work group set goals, developed action items, and collaborated in the development of the survey items (Ehrenberger et al., 2003). Each step of instrument development was approached to enhance the accuracy, precision, and sensitivity of the final measure (Mishel, 1998; Waltz, Strickland, & Lenz, 1991).

Conceptual Basis

The Nursing Role Effectiveness Model, based on the structure, process, and outcome model of quality care, was used to guide instrument development (Irvine, Sidani, & McGillis-Hall, 1998; Sidani & Irvine, 1999). This framework has been used to identify nurses' roles in health care and relate these roles to specific patient and system outcomes. It was adapted

-
- Monica Bacon, RN
Kingston, Canada
 - Kathy Burks, RN, MSN, OCN®
Baltimore, MD
 - Heidi Ehrenberger, PhD, RN, AOCN®
Knoxville, TN
 - Linda Lillington, DNSc, RN, CCRC
Torrance, CA
 - Kristi Ward, RN, BSN, OCN®
Indianapolis, IN
 - Janet Zimmerman, RN, MS
Princeton, NJ

Figure 1. Core Work Group Members of the Clinical Trial Nurses Special Interest Group

Note. Other individuals who provided assistance were Nancy Ellis, RN, BN, St. John's, Canada; Nancy LaSota, RN, MSN, AOCN®, Agoura Hills, CA; and Kathleen Shedlock, MS, MPA, ANP, CS, AOCN®, Manilus, NY.

for use in the present study to guide item generation and the selection of variables that are relevant to the CTN role and practice situation. Three components are included in the framework: (a) structure, which encompasses professional nursing and organizational structure variables; (b) process, which consists of the CTN role components (e.g., clinician, educator, administrator) and the ways that the role is enacted; and (c) outcomes, which include clinical guideline enactment. The structure component consists of variables that may influence the processes and outcomes of care. These variables include those related to role perception (e.g., role satisfaction), role characteristics (e.g., years of experience), organizational characteristics (e.g., primary work setting), and demographics (e.g., geographic location). The process component is composed of the CTN's role components in clinical research. These activities include those related to protocol assessment, protocol planning, subject recruitment, the informed consent process, investigational product, implementation and evaluation, data management, and performance of the professional nursing role. The outcome component is conceptualized as enactment of GCP standards.

Methods

Several strategies were used to examine the validity and reliability of the measure (i.e., literature review, expert judge panel evaluation, focus group testing, and pilot testing). Changes in the instrument, including item reduction and modification of the response format, were made through consensus of the work group members during the instrument testing and feasibility process. Before proceeding with the study, approval was obtained from the Lincoln Memorial University Institutional Review Board (IRB). The project presented subjects with no more than minimal risk as defined by applicable federal regulations, thus satisfying the criteria for exemption status through the IRB.

Item Generation

Sources used for the item generation included a comprehensive review of the published literature, the *Manual for Clinical Trials Nursing* (Klimaszewski et al., 2000), an analysis of 25 diverse CTN-related position descriptions, a review of the clinical research coordinator role and certification from the Association of Clinical Research Professionals (ACRP), the clinical research associate role and certification from ACRP, the clinical research professional role and certification from the Society of Clinical Research Associates, and the CTN experience of work group members.

Practice standards, including the *Standards of Oncology Nursing Practice* (Brant, 1996) and the *Statement on the Scope and Standards of Advanced Practice in Oncology Nursing* (ONS, 1997), also were examined. In addition, the ICH (1996) GCP guideline, an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials was reviewed closely. Numerous discussions occurred among work group members as preliminary decisions regarding item content, construction, format, and scaling were made. Guided by the conceptual framework, items were selected and assembled into a usable format using Dillman's techniques for questionnaire construction (Crosby, Ventura, & Feldman, 1989).

The initial version of the questionnaire contained 12 sections with a total of 170 items. Sections 1–8 contained a comprehensive list of the various and diverse clinical research nursing activities and responsibilities. The activities within these eight sections were to be scaled by the respondent for performance (i.e., frequency and importance). Section 9 included items regarding respondents' perceptions and experiences in their role as nurses involved in clinical research. Section 10 included items related to the professional characteristics of the nursing role (e.g., highest degree completed). Section 11 included items related to the employing organization (e.g., primary work setting, opportunity for advancement). Section 12 contained items to assess the demographic characteristics of the professional nurse.

Expert Judge Panel

Content validity was assessed using a six-member expert judge panel (see Figure 2). A structured procedure for the evaluation of the content validity was given to each expert (Lynn, 1986). Each expert independently rated the relevance of each item to an identified objective using a four-point rating scale: 1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, and 4 = very relevant. A content validity index was calculated for each item and section and for the measure overall (Lynn; Waltz et al., 1991). The overall content validity index for the instrument was 0.95, which is the proportion of items rated as content valid (a rating of 3 or 4) by the six experts. The judge panel also identified area(s) that could be omitted from the instrument and suggested areas of item improvement or modification.

Focus Group Testing

Focus groups were conducted to further validate the instrument in three different geographic regions of the United States: the West, Northeast, and Great Lakes. Several members of the work group were involved in facilitating or moderating these focus groups. Participants were recruited from the local ONS chapters within the geographic region and represented individuals who currently were engaged in the support of clinical research (N = 24). A script was used to guide the discussion of the focus groups. Participants were asked to review the survey questions for clarity, comprehensiveness, wording, and length. They also were asked to review the instructions for clarity. Each focus group lasted approximately 60 minutes. In addition, five Canadian research nurses examined the measure for language and acceptability. The proposed instrument then was revised for clarity based on the col-

-
- Jennifer Aikin, RN, MSN, AOCN®
Jeannette, PA
 - Deborah Berg, RN, BSN
Derry, NH
 - Donna Berry, RN, PhD
Seattle, WA
 - Marge Good, RN, BSN, MPH, OCN®
Wichita, KS
 - Angela Klimaszewski, RN, MSN
Canton, NY
 - Debbie Wujcik, RN, MSN, AOCN®
Nashville, TN
-

Figure 2. Members of the Expert Judge Panel

Table 1. Final Format of the Clinical Trials Nursing Questionnaire®

Section	Number of Items
1. Protocol assessment	16
2. Protocol planning	14
3. Subject recruitment	15
4. Informed consent process	14
5. Investigational product	10
6. Implementation and evaluation	23
7. Data management	18
8. Professional nursing role performance	10
9. Professional nursing role perception	10
10. Professional nursing role characteristics	11
11. Organizational characteristics	9
12. Demographic information	4

Note. Questions in Sections 1–8 contain a frequency and an importance scale.

lective results, reviewed by the work group, and finalized through consensus of the work group members.

Results

Reliability Estimation

Reliability of the present survey instrument was estimated using internal consistency (Cronbach's alpha) and test-retest methods. The test-retest method provides an estimate of stability over time. A sample of oncology clinical research nurses (N = 40) in the Southeast, representative of the relevant research population, completed the questionnaire on two occasions, two weeks apart. An acceptable test-retest reliability of 0.88 was obtained for the frequency scale and 0.92 for the importance scale. Reliability coefficients typically range from 0.00–1.00. The closer the correlation coefficient is to 1.00, the more reliable (stable) the measure is. Analysis of the instrument's internal consistency reliability revealed an alpha coefficient of 0.92 for the frequency scale and 0.95 for the importance scale. Each scale was internally consistent. An alpha coefficient of 0.70 is considered acceptable for a newly developed instrument (Burns & Grove, 1997).

Validity

Content validity of the Clinical Trials Nursing Questionnaire® (CTNQ) was assessed systematically and quantified through a two-stage process described by Lynn (1986). The developmental stage was accomplished through a thorough review of the literature, item generation, and instrument formation. The judgment-quantification stage was accomplished via the use of the expert judge panel. In addition, face validity was determined via focus groups in which participants were asked to review the questionnaire for acceptability of the format, clarity and understanding of each item, and ease and time of completion.

Final Questionnaire

The final survey questionnaire, a self-administered paper-and-pencil tool, consisted of 12 sections for a total of 154 items (see Table 1). The first eight sections of the questionnaire (120 items) assess the complex role components of the professional nurse who uses the nursing process in the support of clinical research. Examples of the items are given in Figure 3. Activities

1. Protocol assessment

- Assess a protocol for possible risks and inconveniences to the subject.
- Consider the ability to maintain the rights, safety, and well-being of the subject.

2. Protocol planning

- Participate in study initiation meetings.
- Identify clinical staff learning needs, including those based on specific protocols.

3. Subject recruitment

- Communicate general information about the nature and goals of clinical research to potential subjects.
- Apply culturally sensitive recruitment strategies to increase minority subject participation.

4. Informed consent process

- Explain the study to the potential subject using the basic elements of informed consent (e.g., purpose, benefits, risks).
- Assess the potential subject's understanding of the consent form information.

5. Investigational product

- Educate members of the research team about the use of the investigational product.
- Provide patient teaching about the investigational product (e.g., potential side effects).

6. Implementation and evaluation

- Perform psychosocial assessment of the subject and family.
- Assess and document identified toxicities and adverse events per protocol-specific criteria.

7. Data management

- Identify problems in data collection and management.
- Ensure subject records are protected in accordance with applicable regulatory requirement(s).

8. Professional nursing role performance

- Identify and support the discussion of ethical issues related to clinical trials.
 - Participate in the orientation or training of new research staff.
-

Figure 3. Examples of Items From Subscales 1–8

and responsibilities that nurses may assume in a variety of clinical research nursing roles are scaled by the respondent for frequency and importance.

The respondent indicates the frequency with which he or she has performed the activity during the prior year using a scale of 0 (never, not part of my role), 1 (once or twice), 2 (occasionally, as needed), 3 (repeatedly, at various times), and 4 (extremely frequently). The respondent indicates the importance of the activity to the safe and effective practice of clinical trials nursing using a scale of 0 (not important) to 4 (very important).

Section 9 (10 items) asks for the respondents' perceptions and experiences related to the role of a nurse involved in clinical research. Respondents answer using a five-point Likert-type scale from 1 (strongly agree) to 5 (strongly disagree). If

the item is not applicable to the current role, then "not applicable" is a possible response. Section 10 (11 items) contains questions about the professional characteristics of the nursing role (e.g., highest degree completed, years of experience, certification). Section 11 (9 items) consists of questions related to the employing organization (e.g., primary work setting, assigned position title, opportunity for advancement). Section 12, the final section of the survey (4 items), contains questions about the demographic characteristics of the professional nurse.

Discussion

The CTNQ was developed in an attempt to address frequent requests from the ONS membership regarding the role of the clinical research nurse. For a newly developed measure, the CTNQ has demonstrated acceptable initial validity and reliability. Additional testing is recommended in a larger, more varied population of nurses working in the research setting. An international survey of ONS members working in clinical research in various capacities has been completed recently using the CTNQ. This larger study will allow additional testing of the instrument to further establish the reliability and validity of the tool. Since its development, wide interest in using the tool has been expressed by other groups of nurses. The General Clinical Research Centers (GCRCs) Nurse Manager Group has requested permission to use the CTNQ to examine the role and responsibilities of the nurses working in GCRCs as a means of establishing general competencies required for basic and advanced levels of practice in these settings. Graduate nursing students in clinical research masters' programs and the Canadian Clinical Trials Research Nurses SIG also have expressed interest in using the tool, suggesting that the delineation of the unique contributions that nursing makes to the clinical research setting is needed desperately.

Conclusion

The CTNQ is considered a promising instrument for assessing the research nurse role, and its use in further research is appropriate, particularly among oncology clinical research nurses. Previous efforts by Bowen and Rice (1998) to answer the question, "Who is a clinical research nurse?" may now begin to be addressed systematically.

The authors gratefully acknowledge Angie Stengel, BA, ONS director of membership and leadership, for her assistance with this endeavor.

Author Contact: Requests for the Clinical Trials Nursing Questionnaire® and permission to use can be sent to Heidi E. Ehrenberger, PhD, RN, AOCN®, at ehrenber@umich.edu, with copy to editor at rose_mary@earthlink.net.

References

- Bowen, K., & Rice, L. (1998). Who is a clinical research nurse? Establishing guidelines and standards of practice for a growing profession. *Research Nurse, 4*(4), 1–4.
- Brant, J.M. (1996). *Standards of oncology nursing practice*. Pittsburgh, PA: Oncology Nursing Society.
- Burns, N., & Grove, S.K. (1997). *The practice of nursing research: Conduct, critique, and utilization* (3rd ed.). Philadelphia: W.B. Saunders.
- Crosby, F., Ventura, M., & Feldman, J. (1989). Examination of a survey methodology: Dillman's total design method. *Nursing Research, 38*, 56–58.
- Ehrenberger, H.E., Lillington, L., Bacon, M., Burks, K., Ward, K., & Zimmerman, J. (2003). The development of a virtual work group of the Oncology Nursing Society Clinical Trials Nurses Special Interest Group: Keys to productivity [Abstract 237]. *Oncology Nursing Forum, 30*(2 Suppl.), 166.
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Guidance for in-

dustry: E6 good clinical practice: Consolidated guidance. Retrieved April 10, 2003, from <http://www.fda.gov/cder/guidance/index.htm>

Irvine, D., Sidani, S., & McGillis-Hall, L. (1998). Finding value in nursing care: A framework for quality improvement and clinical evaluation. *Nursing Economics, 16*, 110–116.

Joshi, T.G., & Ehrenberger, H.E. (2001). Cancer clinical trials in the new millennium: Novel challenges and opportunities for oncology nursing. *Clinical Journal of Oncology Nursing, 5*, 147–152.

Klimaszewski, A., Aikin, J., Bacon, M., Distasio, S., Ehrenberger, H., & Ford, B. (2000). *Manual for clinical trials nursing*. Pittsburgh, PA: Oncology Nursing Society.

Lynn, M.R. (1986). Determination and quantification of content validity. *Nursing Research, 35*, 382–385.

Mishel, M.H. (1998). Methodological studies: Instrument development. In P.J. Brink & M.J. Wood (Eds.), *Advanced design in nursing research* (pp. 235–286). Thousand Oaks, CA: Sage.

Mueller, M. (2001). From delegation to specialization: Nurses and clinical trial co-ordination. *Nursing Inquiry, 8*, 182–190.

Oncology Nursing Society. (1997). *Statement on the scope and standards of advanced practice in oncology nursing* (2nd ed.). Pittsburgh, PA: Author.

Oncology Nursing Society. (1998). Cancer research and cancer clinical trials [Position statement]. *Oncology Nursing Forum, 25*, 973–974.

Sidani, S., & Irvine, D. (1999). A conceptual framework for evaluating the nurse practitioner role in acute care settings. *Journal of Advanced Nursing, 30*, 58–66.

Waltz, C.F., Strickland, O.L., & Lenz, E.R. (1991). *Measurement in nursing research*. Philadelphia: F.A. Davis.

For more information . . .

- ▶ National Institute of Nursing Research
www.nih.gov/ninr
- ▶ Oncology Nursing Society Clinical Trial Nurses Special Interest Group
http://clinicaltrial.ons.wego.net/index.v3page?v2_group=0&p=6657

Links can be found at www.ons.org.
