Review Article

The Oncology Clinical Research Nurse Study Co-Ordinator: Past, Present, and Future

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ABSTRACT

Clinical research nursing is a specialty practice that has evolved over the past century. Clinical research nurses (CRNs) work directly (e.g., direct care provider and advance clinician) or indirectly (e.g., manager, educator, and study co-ordinator) to support clinic research. For more than 50 years, oncology nurses have contributed to the body of evidence describing and validating the responsibilities and importance of the nurse in clinical research, especially the study co-ordinator role. This article will focus on the CRN study co-ordinator role in oncology clinical trials highlighting the historical evolution of the role, the contributions of dedicated members of the Oncology Nursing Society, and the future landscape of clinical research nursing through the International Association of CRNs.

Key words: Clinical research nurse, Clinical Research Nurse Study Co-ordinator, clinical trials nurse, evolution

Introduction

Clinical research (i.e., research on human beings) provides nurses with many opportunities to expand their roles and responsibilities. These roles include, but are not limited to, direct care provider, advanced clinician, study co-ordinator, manager, educator, scientist, and regulatory specialist [Table 1].[1-6] Regardless of the role or employer job title, these nurses are part of the clinical research nursing specialty practice and collectively can be referred to as clinical research nurses (CRNs).[1] For example, a CRN in a study co-ordinator (CRNSC) role may have a variety of job titles: clinical trials nurse (CTN), research nurse, research nurse co-ordinator, clinical research nurse, study coordinator, or clinical research coordinator.[1]

CRNs work in a variety of settings ranging from a dedicated clinical research facility or unit to a physician office to a pharmaceutical company to a national office responsible for approving new health-care products.[1,3] Regardless of the role, the CRN skill set needs to include strong critical thinking skills and a broad understanding of the complex scientific, ethical, and regulatory aspects of

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clinical research.[1] This article will focus on the CRNSC role in oncology clinical trials highlighting the historical evolution of the role, the contributions of dedicated members of the Oncology Nursing Society (ONS), and the future landscape of clinical research nursing through the International Association of CRNs (IACRN).

Historical Overview

It is essential to acknowledge the initial identification and development of the CRN role. In 1910, Rockefeller Institute Hospital opened as the first center for clinical research in the United States (US).[6] The hospital's founders knew that well-educated nurses would be required for a successful research program. In 1909, Nancy P. Ellicott was hired as the superintendent of nursing. Nurse Ellicott understood that nurses could play an important role as a member of the research team and needed specialized training.[1,7] Over the past century, CRNs globally have more clearly defined the roles, described responsibilities, identified required specialized training, defined competencies, and documented the value of the CRN.[3,4,8-61]

The increase in cancer chemotherapy trials in the 1960s provided an opportunity for the oncology nurse to become a critical member of a clinical trial team in the role of the chemotherapy research nurse.[10,11] While the primary responsibilities of this nurse was administering the investigational chemotherapy drugs, other responsibilities included:

- Providing continuity of care ensuring research participant safety
- Keeping the research participant informed about the trial
- Collecting and organizing data for the publication.[10]

The oncology nursing literature between 1980 and 2000 continued to describe the responsibilities of the oncology CRNSC. Table 2 provides a sample of the literature highlighting the identified responsibilities.

Table 1: Nursing roles in clinical research

Role	Primary responsibility
Direct care provider	Provide direct care to research participants
Research coordinator	Coordinate day-to-day activities of one or more clinical research studies
Advanced clinician	Provide advance nursing care to research participants
Manager	Provide leadership for a clinical research unit/facility
Educator	Provide clinical research specific education and training
Scientist	Conduct research on various aspects of health, illness, and health care.
Monitor	Assess clinical research practices at the site for compliance with research regulations and the protocol
Regulatory specialist	Provide a wide variety of activities related to regulatory document preparation and communication with regulatory authorities
IRB/IEC administrator	Provide oversight, administration, implementation, and management of all IRB/IEC activities

IRB: Institutional Review Board, IEC: Institutional Ethics Committee

Table 2: Oncology clinical research nurse study coordinator responsibilities

Author (years)	Sample list of responsibilities
McEvoy *et al*. (1991)[19]	Co-ordinate care Provide direct care to the participant Provide participant and family education related to protocol, procedures, and associated toxicities Assist individual to define their own goals and purpose for participating, or not, in a clinical trial Collect data
Di Giulio *et al*. (1996)[23]	Provide participant and family education Participate in the informed consent process Provide care Provide protocol coordination Facilitate communication strategies Adhere to protocol procedures Provide nursing summaries to augment the protocol
Ocker *et al*. (2000)[24]	Assists to assess protocol feasibility Explain the research plan and evaluate participant's understanding Communicate financial concerns to appropriate individuals within the research site Secure informed consent Maintain protocol integrity Coordinate protocol activities Assess toxicities of protocol treatments Provide care including drug administration

Oncology Nursing Society

In 1989, the ONS arranged for nurses with subspecialties or interests to meet at the 1989 Congress (i.e., annual conference) in San Francisco. It was there that Janet Zimmerman, along with Mary Zimny, started the Clinical Trial Nurses (CTNs) Focus Group (FG) which at the time, was the first step in becoming a formal special interest group (SIG). More than 25 oncology nurses working as study co-ordinators attended the first meeting. With the guidance from ONS staff and the work of CTN FG volunteers, the CTN SIG was formerly recognized the following year. Note that ONS referred to the CRNSC as the CTN.

Over the years, networking and learning opportunities were offered to the CTN SIG members through the SIG newsletter, fall institute, and the annual ONS Congress where the SIG had a dedicated meeting. It was often during these meetings that projects or needed resources were identified. Three major initiatives developed by the SIG were a manual for CTNs, the CTN Questionnaire (CTNQ), and CTN competencies.

Manual for Clinical Trials Nurses

With limited "how to" resources available for the CTN, the SIG organized a work group to develop a manual that

would serve as a one-stop resource for oncology CTNs. The first edition of the Manual for Clinical Trials Nursing was published by ONS in 2000.[62] The manual served as a comprehensive handbook for CTNs outlining their role and providing oncology and clinical research regulatory guidance. Since the SIG had members from outside of the US, the manual included the following five international chapters: Canada, Britain, Europe, Scandinavia, and Brazil. A second edition of the manual was published in 2008 and in 2012, an editorial team was developed to revise the 2nd edition. The team substantially revised the content to remove the general oncology information since that was already available in other formats from ONS and to include other content that had not previously been in the manual (e.g., financial factors such as contracting and billing, ethics, and maintaining essential documents). The 3rd edition was published in 2016 and included 16 international chapters plus a chapter dedicated to the European Union directives.[63]

Clinical Trial Nurse Questionnaire

In 2000, a CTN SIG working group began to develop a survey to determine the various activities of the CTN within oncology. The outcome of this work was a valid and reliable tool that assessed the responsibilities of the CTN – the CTNQ.[26] The final questionnaire contained 12 sections (e.g., protocol assessment, participant recruitment, informed consent, data management, and professional performance) with 122 items used to assess the frequency and importance of CTN activities. Further studies have found the CTNQ to be a valid and reliable tool to assess the CTN role when translated into Italian, Korean, and Swedish.[27,52,60] The questionnaire has also been translated and validated in Chinese with slight modifications for both a nurse and nonnurse study coordinator role.[59] In addition, the CTNQ has also been used to describe the responsibilities of the CTN in the Children's Oncology Group as well as the CTN in Italy and Australia.[34,39,40]

Clinical Trials Nurse Competencies

The ONS embarked upon defining the core values, skills, knowledge, and expertise required to be an oncology CTN.[36,38] In 2007, a project team was established comprised of five CTN SIG members working in oncology clinical trials and an ONS staff member with prior experience as an oncology CTN. A three-step process was used to develop the competencies:

- Draft competencies after the literature review and solicitation from the experts for both role and competency development
- Field review by CTNs followed by revisions
- Expert review by experts in the field with final revisions.

Table 3: Oncology Nursing Society clinical trial nurses competency category comparison

2010 competency categories	2016 competency categories
Protocol compliance	Adherence to ethical standards
Clinical trials-related communication	Protocol compliance
Informed consent process	Informed consent
Management of clinical trials patients	Patient recruitment and retention
Documentation	Management of clinical trial patients
Patient recruitment	Documentation and document management
Ethical issues	Data management and information technology
Financial implications	Financial stewardship
Professional development	Leadership and professional development

The resulting competencies, available in 2010, were divided into nine categories [Table 3] and included 54 competency statements.[36] The competencies defined the CTN as a specialty role for nursing that required "a unique framework of knowledge for working with patients involved in clinical research trials."[36] The competencies were designed for novice CTNs (i.e., <2 years in the role). Although developed for the oncology CTN, these competencies are applicable to CRNSC in other disease specialties.

In 2014, a project team was established to review and revise the competencies. The team included four members from the original team plus two CTN experts, and the same three-step process was used. Since the initial competencies, there had been an emergence of other work defining other nurse competencies and competencies for clinical research professionals including CRNs that was considered when drafting the revised competencies.[4,5,33,37,47,64] This included developing one competency statement for each category with behavioral activities.

The 2016 competencies still contain nine categories, but the category of clinical trials-related communication was removed since it was already covered in the other categories and added Data Management and Information Technology [Table 3].[51] Each competency category includes

- One competency statement
- Level 1 behavioral activities for CTNs in the role <2 years
- Level 2 behavioral activities for CTN in the role >2 years
- Knowledge needed to meet the behavioral activities
- Resources for acquiring the knowledge.

The competencies have been used to write job descriptions for CTNs, guide orientation, evaluate CTN performance, identify CTN learning needs, and develop a CTN education curriculum.[2,51]

International Association of Clinical Research Nurses

In 1960, the National Institutes of Health (NIH) in the US began funding clinical research centers referred to as General Clinical Research Centers (GCRCs).[65] In 1989, the nurse managers of these centers began meeting to exchange knowledge and ideas, establish nursing standards in clinical research centers and set standards for CRN education, training and common research procedures. By 2000, the group expanded to include CRN nurse managers working in research centers outside of the NIH funded GCRCs, including nurses from the United Kingdom and Ireland.[1] The GCRC program was replaced in 2006, and as a result, the nurse manager group and nurse leaders from the NIH Clinical Center established the National Clinical Research Nursing Consortium to advance the specialty of clinical research nursing.[42] In 2009, seven forward thinking nurse mangers created the IACRN and the consortium merged with IACRN.[1]

IACRN is a professional nursing organization dedicated to defining, validating, and advancing the specialty practice of clinical research nursing focused on "maintaining the equilibrium between the care of the research participant and fidelity to the research protocol."[66] The association's first meeting/conference was held in Boston, Massachusetts, in 2009.

In 2016, the American Nurses Association recognized clinical research nursing as a specialty practice and approved the CRNs Scope and Standards of Practice.[1] The scope of practice defines who, what, when, where, why, and how of clinical research nursing and the standards of practice describe the art and science of clinical research nursing and details the associated competencies for each standard. There are 17 standards that divided into two sections: one for practice and the other for professional performance. Each standard has associated competencies.

Table 4: International Association of Clinical Research Nurses Committees and Chapters

Committees	Chapters
Chapter governance	Full chapters
Conference planning	Boston
Education	Japan
Membership, marketing, and communication	New York City
Research	Ohio Valley
	Rocky Mountain
	United Kingdom/Ireland
	Pilot chapters
	Africa
	China
	Houston
	Michigan
	Shanghai
	University of Florida

An annual conference has been held every year since 2009. Membership continues to grow, and many oncology CRNs have joined. As of March 2020, the association has five committees, six full chapters and six pilot chapters [Table 4].[67,68] The association is currently developing a core curriculum and CRN certification.[66]

Conclusion

Clinical Research Nursing has a rich history. Since the early 1900s, nurses have been involved with clinical research in a variety of roles and in a variety of settings. One key role is a study co-ordinator. In response to increasing cancer chemotherapy trials, the oncology CRNSC evolved as an integral member of the research team. Through efforts of the ONS, competencies for the oncology CRNSC were developed to support the knowledge, skills, and abilities that are needed to perform critical work functions. With the development and recognition of clinical research nursing as a specialty practice, IACRN is well poised to further promote the specialty while providing networking and professional development opportunities.

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Conflicts of interest

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References

1. American Nurses Association and International Association of Clinical Research Nurses. Clinical Research Nursing: Scope and Standards of Practice. Silver Spring, MD: American Nurses Association and International Association of Clinical Research Nurses; 2016.
2. Ness EA, Royce C. Clinical trials and the role of the oncology clinical trials nurse. Nurs Clin North Am 2017;52:133-48.
3. Ness E, Parreco LK, Galassi A, O'Mara A. Career sphere: Consider a career in clinical research. Am Nurse Today 2012;7:39-42.
4. Castro K, Bevans M, Miller-Davis C, Cusack G, Loscalzo F, Matlock AM, *et al*. Validating the clinical research nursing domain of practice. Oncol Nurs Forum 2011;38:E72-80.
5. Bevans M, Hastings C, Wehrlen L, Cusack G, Matlock AM, Miller-Davis C, *et al*. Defining clinical research nursing practice: Results of a role delineation study. Clin Transl Sci 2011;4:421-7.
6. Rockefeller University Mission and History. Available from: https://www.rucares.org/clinicalresearch/mission-history. [Last accessed on 2020 Mar 30].
7. Rockefeller University Hospital. Launching the Modern Field of Research Nursing. Available from: http://heilbrunnfamily.

rucares.org/History. [Last accessed on 2020 Mar 30].
8. Gray FI. The nurse participates in cardiac catheterization research. Am J Nurs 1950;50:771-2.
9. Vankinscott V. Metabolic research. Am J Nurs 1955;55:70-1.
10. Hubbard S, Devita V. Chemotherapy research nurse. Am J Nurs 1976;76:560-5.
11. Hubbard SM, Donehower MG. The nurse in a cancer research setting. Semin Oncol 1980;7:9-17.
12. Henke C. Emerging roles of the nurse in oncology. Semin Oncol 1980;7:4-8.
13. Hubbard SM. Cancer treatment research: The role of the nurse in clinical trials of cancer therapy. Nurs Clin North Am 1982;17:763-83.
14. Mullin SM, Warwick S, Akers M, Beecher P, Helminger K, Moses B, *et al*. An acute intervention trial: The research nurse coordinator's role. Control Clin Trials 1984;5:141-56.
15. Gross J. Clinical research in cancer chemotherapy. Oncol Nurs Forum 1986;13:59-65.
16. Ahern JA, Kruger DF, Gatcomb PM, Petit WA Jr., Tamborlane WV. The diabetes control and complications trial (DCCT): The trial coordinator perspective. Report by the DCCT Research Group. Diabetes Educ 1989;15:236-41.
17. Hazelton J. The role of the nurse in Phase I clinical trials. J Pediatr Oncol Nurs 1991;8:43-5.
18. Wheeler VS. Preparing nurses for clinical trials: The cancer center approach. Semin Oncol Nurs 1991;7:275-9.
19. McEvoy MD, Cannon L, MacDermott ML. The professional role for nurses in clinical trials. Semin Oncol Nurs 1991;7:268-74.
20. Cassidy J, Macfarlane DK. The role of the nurse in clinical cancer research. Cancer Nurs 1991;14:124-31.
21. Fay M. The role of nursing in clinical research trials. Gastroenterol Nurs 1992;14:195-7.
22. Arrigo C, Gall H, Delogne A, Molin C. The involvement of nurses in clinical trials. Results of the EORTC Oncology Nurses Study Group survey. Cancer Nurs 1994;17:429-33.
23. Di Giulio P, Arrigo C, Gall H, Molin C, Nieweg R, Strohbucker B. Expanding the role of the nurse in clinical trials: The nursing summaries. Cancer Nurs 1996;19:343-7.
24. Ocker B, Pawlik-Plank D. The research nurse role in a clinic-based oncology research center. Cancer Nurs 2000;23:286-92.
25. Mueller MR. From delegation to specialization: Nurses and clinical trial co-ordination. Nurs Inq 2001;8:182-90.
26. Ehrenberger H, Lillington L. Development of a measure to delineate the clinical trials nursing role. Onc Nurs Forum 2004;31:64-8.
27. Mori C, Mullen N, Hill E. Describing the role of the clinical research nurse. Res Pract 2007;8:220-8.
28. Catania G, Poirè I, Dozin B, Bernardi M, Boni L. Validating a measure to delineate the clinical trials nursing role in Italy. Cancer Nurs 2008;31:E11-5.
29. Offenhartz M, McClary K, Hastings C. Nursing and realities of clinical research. Nurs Manage 2008;39:34-9.
30. Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J, Mason S. The role and potential contribution of clinical research nurses to clinical trials. J Clin Nurs 2008;17:549-557.
31. Grady C, Edgerly M. Science, technology, and innovation: Nursing responsibilities in clinical research. Nurs Clin North Am 2009;44:471-81.
32. Bell J. Towards clarification of the role of research nurses in New Zealand: A literature review. Nurs Prax N Z 2009;25:4-16.
33. National Institutes of Health Clinical Center, Nursing and Patient Care Services. CRN 2010 Domain of Practice Committee 2009. Building the Foundation for Clinical Research Nursing: Domain of Practice for the Specialty of Clinical Research Nursing; 2009. Available from: https://www.cc.nih.gov/nursing/crn/DOP_document.pdf. [Last accessed on 2020 Mar 30].
34. Nagel K, Gender J, Bonner A. Delineating the role of a cohort of clinical research nurses in a pediatric cooperative clinical trials group. Oncol Nurs Forum 2010;37:E180-5.
35. Poston RD, Buescher CR. The essential role of the clinical research nurse (CRN). Urol Nurs 2010;30:55-63, 77.
36. Oncology Nursing Society. Oncology Clinical Trials Nurse Competencies; 2010. Available from: https://www.ons.org/sites/default/files/ctncompetencies.pdf. [Last accessed on 2020 Mar 30].
37. Royal College of Nursing Research Society. Competency Framework for Clinical Research Nurses; 2011. Available from: https://cambridge.crf.nihr.ac.uk/wp-content/uploads/2015/04/Research_Nurse_Competency_Framework_-_Version_2_-_Full_-_Oct_20111.pdf. [Last accessed on 2020 Mar 30].
38. Lubejko B, Good M, Weiss P, Schmieder L, Leos D, Daugherty P. Oncology clinical trials nursing: Developing competencies for the novice. Clin J Oncol Nurs 2011;15:637-43.
39. Catania G, Poirè I, Bernardi M, Bono L, Cardinale F, Dozin B. The role of the clinical trial nurse in Italy. Eur J Oncol Nurs 2012;16:87-93.
40. Wilkes L, Jackson D, Miranda C, Watson R. The role of clinical trial nurses: An Australian perspective. Collegian 2012;19:239-46.
41. Gibbs CL, Lowton K. The role of the clinical research nurse. Nurs Stand 2012;26:37-40.
42. Hastings CE, Fisher CA, McCabe MA; National Clinical Research Nursing Consortium, Allison J, Brassil D, *et al*. Clinical research nursing: A critical resource in the national research enterprise. Nurs Outlook 2012;60:149-560.
43. Yoshida Y, Zhang Y, Yoshida Y, Ma D, Wang P. Current situation of clinical trials in Bejing, China. Contemp Clin Trials 2012;33:583-8.
44. Clouson C, Grane A. Developing clinical research nurses. Nurs Times 2012;108:23-5.
45. Jones CT, Wilson LL. Role perceptions of nurse clinical research coordinators. Nurs Res Rev 2013;3:133-9.
46. Brinkman-Denney S. An international comparison of the clinical trials nurse role. Nurs Manag (Harrow) 2013;20:32-40.
47. Sonstein S, Seltzer J, Li R, Jones C, Silva H, Daemen E. Moving from compliance to competency: A harmonized core competency framework for the clinical research professional. Clin Res 2014;28:17-23.
48. Irish Research Nurses Network. Clinical Research Nurse Competency Pack; 2015. Available from: https://irnn.ie/wp-assets-irnn/uploads/2019/11/IRNN-Clinical-Research-Nurse-Competency-Pack.pdf. [Last accessed on 2020 Mar 30].
49. Kao CY, Huang GS, Dai YT, Pai YY, Hu WY. An investigation of the role responsibilities of clinical research nurses in conducting clinical trials. Hu Li Za Zhi 2015;62:30-40.
50. Hyland D, Clarke Moloney M. Spotlight on clinical research nursing. World Irish Nurs 2016;24:52-3.
51. Oncology Nursing Society. Oncology Clinical Trials Nurse Competencies; 2016. Available from: https://www.ons.org/

sites/default/files/2018-10/Oncology_Clinical_Trials_Nurse_Competencies.PDF. [Last accessed on 2020 Mar 30].
52. Choi IJ, Park HJ. Validation of a questionnaire to delineate the clinical trial nursing roles in Korea. Cancer Nurs 2018;41:E30-7.
53. Fujiwara N, Ochiai R, Shirai Y, Saito Y, Nagamura F, Iwase S, *et al*. Qualitative analysis of clinical research coordinators' role in phase I cancer clinical trials. Contemp Clin Trials Commun 2017;8:156-61.
54. Monas L, Toren O, Uziely B, Chinitz D. The oncology nurse coordinator: role perceptions of staff members and nurse coordinators. Isr J Health Policy Res 2017;6:66.
55. Purdom MA, Petersen S, Haas BK. Results of an oncology clinical trial nurse role delineation study. Oncol Nurs Forum 2017;44:589-95.
56. Tinkler L, Smith V, Yiannakou Y, Robinson L. Professional identity and the clinical research nurse: A qualitative study exploring issues impacting on participant recruitment in research. J Adv Nurs 2018;74:318-28.
57. Sonstein SA, Jones CT. Joint task force for clinical trial competency and clinical research professional workforce development. Front Pharmacol 2018;9:1148.
58. McCabe M, Behrens L, Browning S, Vessey J, Williams MJ. Original research: The clinical research nurse: Exploring self-perceptions about the value of the role. Am J Nurs 2019;119:24-32.
59. Lavender V, Croudass A. The role of the nurse in supporting canner clinical trials. Br J Nurs 2019;28:S14-7.
60. Backman Lönn B, Olofsson N, Jong M. Translation and validation of the clinical trial nursing questionnaire in Swedish – A first step to clarify the clinical research nurse role in Sweden. J Clin Nurs 2019;28:2696-705.
61. Zhu W, Zhao Q, Zhu H, Zhang J, Han J, Qing R. The validation of a questionnaire to delineate clinical research coordinator roles in China. Perspect Psychiatr Care 2020; doi: 10.1111/ppc.12478.
62. Klimaszewski AD, Aikin JL, Bacon MA, DiStasio SA, Ehrenberger EH, Ford BA. Manual for Clinical Trials Nursing. Pittsburgh (PA): Oncology Nursing Society; 2000.
63. Klimaszewski AD, Bacon, MA, Eggert JA, Ness E, Westendorp JG, Willenberg K. Manual for Clinical Trials Nursing. 3rd ed. Pittsburgh (PA): Oncology Nursing Society; c2016. p. 628.
64. Lindberg M, Lundström-Landegren K, Johansson P, Lidén S, Holm U. Competencies for practice in renal care: A national Delphi study. J Ren Care 2012;38:69-75.
65. Nathan DG, Nathan DM. Eulogy for the clinical research center. J Clin Invest 2016;126:2388-91.
66. About IACRN. Available from: https://www.iacrn.org/aboutus. [Last accessed on 2020 Mar 30].
67. IACRN Committees. Available from: https://www.iacrn.org/committees. [Last accessed on 2020 Mar 30].
68. IACRN Chapters. Available from: https://www.iacrn.org/Local-Chapters. [Last accessed on 2020 Mar 30].