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 clinical 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...
clinical research. 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). 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. 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.

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. 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

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.

### 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. 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.

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. 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. The questionnaire has also been translated and validated in Chinese with slight modifications for both a nurse and nonnurse study coordinator role. 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.

Clinical Trials Nurse Competencies

The ONS embarked upon defining the core values, skills, knowledge, and expertise required to be an oncology CTN. 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.

The resulting competencies, available in 2010, were divided into nine categories [Table 3] and included 54 competency statements. 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.” 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. 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]. 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.

| 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 |
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). 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. 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. In 2009, seven forward thinking nurse managers created the IACRN and the consortium merged with IACRN.

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.” 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. 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.

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]. The association is currently developing a core curriculum and CRN certification.

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

There are no conflicts of interest.

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