Oncology clinical trials nursing: A scoping review

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ABSTRACT
In the 21st century, cancer is a disease that captures much of our attention for its complexity, and its physical, emotional, and financial impacts on one’s life. Research attention and investment in cancer management has made it the most studied disease in clinical trials globally. Clinical trials nurses are part of the oncology research team and a fundamental factor in trial success. Their direct relationship with research subjects is the key connection in the operation of clinical trials at the front line. The influx and complexity of oncology clinical trials has transformed both oncology nursing practice in general and led to the development of the unique subspecialty of the oncology clinical trials nurse. This scoping review investigated the role and future practice of the clinical trials nurse.

Key words: oncology, clinical trials, clinical trials nurse, nursing

BACKGROUND
The role of the nurse in clinical trials first emerged in the 1950s, with the role evolving significantly since then and using many different nomenclatures (Jenkens & Hubbard, 1991; Medical Research Council Investigation, 1948). Titles describing the role of nurses in clinical trials included: data manager, experimental therapeutics nurse, research nurse, research nurse coordinator, and clinical trials nurse (Carlson et al., 2005; Coulson & Phelan, 2000; Loh et al., 2002; Ness & Royce, 2017). In comparison to research nurse coordinators (RNC) and these other titles focused on protocol implementation, the clinical trials nurse (CTN) role extends to providing direct patient care to study participants (Ehrenberger & Lillington, 2004; Nagel et al., 2010). Additional responsibilities of the CTN include patient and family educator, caregiver, patient advocate, administrator, and researcher (McEvoy et al., 1991). Furthermore, specific CTN practice activities include patient education, such as drug and symptoms management; screening and confirming patient eligibility; advocating for patient inclusion and patient rights while on the study; assisting patients in decision-making; and, obtaining informed consent (Castro et al., 2011; Mueller, 2001). In terms of research-related responsibilities, the CTN keeps accurate records of patient responses and adverse events; facilitates research data collection; and, at times, serves as a liaison between nursing colleagues, staff, patients, and the research team (Castro et al., 2011; Mueller, 2001). The CTN is now specifically recognized as an essential role and resource in clinical trials (Hastings et al., 2012). Practice development within clinical trials nursing has evolved, although not without its challenges. As the composition of a clinical research team may vary in terms of members and health professionals involved, due to the size of the research study and its budget, the roles and responsibilities of each member can dynamically evolve and expand. The roles and responsibilities of nurses working in clinical research settings appear diverse and so, too, are their titles and job descriptions. Additionally, the CTN and RNC may also have overlapping sets of responsibilities. Such diversity in roles, responsibilities, and job title necessitates role clarity, delineation of scope, and the development of practice frameworks.

In recognition of the specialized practice of clinical trials nursing, a conceptual framework depicting CTN practice was developed, based on a four-year project from 2007-2011 (Castro et al., 2011; CRN 2010 Domain of Practice Committee, 2009). The framework includes five practice domains: Clinical Practice, Study Management, Care Coordination and Continuity, Human Subjects Protection, and Contribution to the Science. Bevans et al. (2011) used this model to clarify the overlap between the two roles of CTN and RNC, suggesting that the practice of CTN centers highly on clinical practice activity in comparison to the practice of the RNC, which focuses largely on research coordination, study management, and protocol implementation. While this is an important distinction, in reality, many nurses are hired to assume a dual-role as both a CTN and RNC. With service demands from the clinical research field, the CTN practice continues to grow and professional practice guidelines have been developed. It is now a recognized specialty of oncology nursing, as seen in the establishment of the International Association of Clinical Research Nurses (IACRN) in 2009, the recognition as a practice specialty from the American Nurses Association (ANA), and the development of the Clinical Trial Nursing - Scope and...
Standards of Practice by the ANA and IACRN in 2016. This Scope and Standards of Practice recognizes the unique practice settings of clinical trials and research and thus emphasizes the distinct skills, knowledge, and requisite education needed in the specialized care of clinical trial patients and/or research subjects.

Current data from the International Clinical Trials Registry Platform Search Portal (ICTRP) – World Health Organization (WHO, 2017) show that Canada currently has 24,789 clinical trials, ranking seventh in the world. With a total of 69,745 trials globally, cancer is the most studied disease. The number of cancer clinical trials continues to rise rapidly with more scientific discoveries and nimble technologies in drug design and development, increasing the complexity of cancer clinical trials and the care of study subjects. As a result of these increasing health issues and medical interventions aimed at addressing them, patient care has become increasingly complex, requiring specialized skills for oncology nurses and creating opportunities for specialized nursing roles in the process (Peplau, 2003). Currently, the prevalence of cancer is leading to advancements in cancer research and a high number of cancer clinical trials. This trend is increasing the demands for oncology CTN and hence, the opportunities for the oncology CTN role development and expansion. Oncology CTN (OCTN) qualifications, practice standardization, and workforce planning are essential to meet the increasingly complex needs of cancer patients and the growing number of cancer clinical trials.

Given that clinical trials nursing is an emerging area of practice and that cancer clinical trials are being conducted at an increasing rate, the purpose of this study is to investigate the emergent, current, and future practice of the role of the CTN in oncology settings. The review question was: What is known about the role of the oncology CTN?

**METHOD**

This project utilized a scoping review methodology, following the methodological framework proposed by Arksey and O’Malley (2005). The framework includes six stages: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, (5) collating, summarizing, and reporting the results, and (6) an optional consultation exercise. The results are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension for Scoping Reviews (PRISMA-ScR) guidelines.

**Search Strategy**

Three members of the research team [MH, SS, and KAH (research librarian)] developed the search strategy to identify studies on the role of OCTN. The Cochrane Handbook states that Cochrane Central Register of Controlled Trials (CENTRAL) Medline and Embase are key databases for reviews (Lefebvre et al., 2021). As well, Cochrane suggests searching discipline-specific databases that are relevant to the research question (Lefebvre et al., 2020). Therefore, under the guidance of the research librarian, six relevant databases were selected for searching as they index nursing, clinical sciences, and health-care system and practice journals relevant to our scoping review. OVID databases included: Medline(R) and Epub Ahead of Print, In-Process, and Other Non-Indexed Citations and Daily, EMBASE, PsyClinfo, and Cochrane Central Register of Controlled Trials. Other databases were CINAHL (Ebsco) and Scopus. Four search concepts were identified: oncology, clinical trial, clinical trials nurse/clinical research nurse, and nursing. Both keywords and subject headings were searched for each concept. The mapping of terms was repeated in each database, as subject headings varied in the databases. Key words were the same across all databases. The search was conducted between January and March 2018 and repeated in December 2019 to identify any new relevant studies. The searches were limited to English language and year of publication from 1980 to current, except for the Scopus database, which was searched from 1979 as the year 1980 was not selectable. The reference lists of included studies were scanned to ensure comprehensiveness of the search and exported to Endnote x8.2.

**Eligibility Criteria**

Studies were included if they were published in English and addressed oncology clinical trials nursing and at least one of the following: role, practice guidelines/framework, competency, advanced practice, or practice environment. Editorials, commentaries, conference abstracts, and studies reporting non-oncology settings were excluded.

**Study Selection**

As shown in the PRISMA Flow Diagram (Figure 1), 1,307 records were retrieved. After removing duplicates, 771 titles and abstracts were screened, resulting in 211 articles selected for full-text review. One hundred and eighty-two studies were then excluded for various reasons (see Figure 1), with a final 29 included in this review.

**Extracting and Charting the Results**

One reviewer [MH] completed the extracting and charting of the results. Data extracted from each study article included author, title, year of publication, country of origin, aims/purposes, study population, sample size, participant characteristics (nurse versus non-nurse, oncology versus non-oncology), intervention, and practice setting (inpatient, outpatient). The tabulation of key findings from the extracted data formed a descriptive summary of the results. Guided by the review question and eligibility criteria, themes reflecting the practice of OCTNs were identified and categorized by the first author in close consultation with the authorship team.

**RESULTS**

Twenty-nine studies met the inclusion criteria (Table 1). Themes identified were grouped under the following topic areas: role development (n = 11 studies), competence (n = 3 studies), education and training (n = 5 studies), workload (n = 3 studies), advanced practice (n = 4 studies), and international perspectives (n = 3 studies) (Table 1).

**Role Development**

Themes relevant to the topic area of role development appeared most prominent among others and were further organized into subtopic areas of early role development, role delineation tool development, practice context in pediatric oncology, practice domain development, and professional identity of OCTN.
Early OCTN role development.

Documentation of the OCTN role began in the early 1980s. Roles and responsibilities of OCTN included patient educator, patient advocate, facilitating informed consent, and participation in data collection and analysis (Hubbard & Donehower, 1980). In the early developmental stages, OCTN role descriptions were general with responsibilities ranging from the management of research patients to implementation of clinical trials, and participation in the improvement of patient care via conducting clinical trials research (Hubbard & Donehower, 1980).

Clarifications regarding the OCTN roles and responsibilities became more apparent in the 2000s with the work of Ocker and Plank (2000), when an initiative was undertaken to define the role empirically and further distinguish its focus from other nursing roles. The need to define and delineate the OCTN role was in part a by-product of increasing workforce demands, increased needs of the OCTN, and a growing body of practice evidence (Ocker & Plank, 2000). Direct patient care related to protocol requirements was emphasized as an essential part of the OCTN role. Examination of roles among the OCTNs, clinical nurse specialists, and advanced practice nurses suggested that each was an advanced practice role (Ocker & Plank, 2000).

Clinical Trial Nurse Questionnaire as a tool for role delineation

The Clinical Trial Nurse Questionnaire (CTNQ) was the first tool developed for OCTN role delineation (Ehrenberger & Lillington, 2004). In the early 2000s, a working group of CTNs from the Oncology Nursing Society (ONS) in the United States formed a Special Interest Group. This group conducted a survey that eventually led to the development of the CTNQ (Ehrenberger & Lillington, 2004). The questionnaire was comprised of 12 sections delineating the activities, responsibilities, and various aspects of OCTN practice. It was structured as a self-report instrument depicting roles of the nurses based on performance, frequency, and their perception of importance. Of the questionnaire’s 12 sections, eight focus on the nursing role and include protocol assessment, protocol planning, subject recruitment, informed consent process, investigational product, evaluation and data management, and professional nursing role performance.

The remaining four sections assess aspects of the OCTN role and practice that include nurse’s perception and experience, demographic characteristics, professional characteristics, and employment organization characteristics (Ehrenberger & Lillington, 2004).

The CTNQ added further clarity to the definition of the OCTN role and practice while addressing some of the professional identity and role ambiguity issues at the time. The instrument was well received within the profession, both nationally and internationally. It was subsequently translated into Italian and Korean and has become a standard tool in other CTN role delineation studies (Catania et al., 2012; Catania et al., 2008; Choi & Park, 2018; Nagel et al., 2010). As a result of the positive international response and adoption of the instrument, the emerging practice of OCTN was increasingly recognized as a specialized nursing role on a global level.

OCTN practice in Phase I and II pediatric oncology clinical trials

Clinical trials nursing in pediatric settings was a distinct body of the literature. The pediatric setting formed a unique practice context in relation to informed consent, subject recruitment of vulnerable populations, and the extensive involvement of parents and families in decision-making (Coulson & Phelan, 2000). Phase I clinical trials typically are labour-intensive, particularly with pediatric subjects, where a first-in-human experiment of an innovative therapy is carried out on children. For this young population, the incidence and manifestations of adverse events are diverse due to the study’s relatively small sample size, the developmental stage of subjects, and subjects’ tolerance and capacity, often warranting additional safety assessments and observation (Carlson et al., 2005; Coulson & Phelan, 2000). Due to these reasons, pediatric clinical trials commonly took place in the safety of inpatient hospitals, versus outpatient clinics and academic research centres (Carlson et al., 2005; Nagel et al., 2010).

Early OCTN role development in pediatric oncology was considered a role extension of an oncology pediatric nurse. In the early stages, when few new pediatric clinical trials were available, an effort to maximize resource allocation while

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Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram for the scoping review process.
| Lead Author / Year / Country | Study Design / Objectives | Study Sample | Intervention | Key Findings | Theme |
|------------------------------|--------------------------|--------------|--------------|--------------|-------|
| Hubbard, 1980 US             | Anecdotal                | OCTN         | Differentiating the roles of clinical research nurses from those of primary nurses and nurse specialists | Discussion on the practice context of the oncology clinical trial setting, and the characteristics of phase I, II, and II trials wherein CTN roles are oriented to meet the patient needs; proposals on the role development and role expansion | Role Development |
| Ocker, 2000 UK               | Descriptive Case Study   | OCTN         | Restructure of oncology research program and staff training | An examination of the CTN role and its role boundary with the roles of clinical nurse specialist and advanced practice nurse | Role Development |
| Ehrenberger, 2004 US         | Descriptive cross-sectional | OCTN N = 40 | N/A          | The development of Clinical Trial Nurse Questionnaire | Role Development |
| Coulson, 2000 UK             | Anecdotal                | Pediatric OCTN | N/R         | Identifying the unique features in pediatric clinical trials compared to adult trials; and a description of CTN role in pediatric setting | Role Development |
| Carlson, 2005 US             | Case Study               | Pediatric OTCN | A creation of a new role, a blend between research nurse role and staff nurse; and the implementation of this new role | Based on an argument of the idiosyncrasies of phase I and II trials and the pediatric population, new role of ETN was formed. A role diversity is suggested to encourage professional development and nurse job satisfaction. | Role Development |
| Catania, 2008 Italy          | Psychometrics            | OCTN N = 30  | N/R          | The test confirmed the questionnaire reliability after its translation into Italian. | Role Development |
| Chang, 2008 Canada           | Mixed Methods            | OCTN N = 43  | N/R          | The study surveyed nurses working in phase I clinical trials (pediatric) and no mention of clinical trials nurses. This may suggest that no such role has been developed at this institute and the care of phase I oncology pediatric studies is shared among staff nurses and other (clinical nurse specialist, nurse practitioner, primary care nurse in outpatient clinic, nurse educator, nurse manager). | Role Development |
| Lead Author / Year / Country | Study Design / Objectives | Study Sample | Intervention | Key Findings | Theme |
|-----------------------------|--------------------------|--------------|--------------|--------------|-------|
| **Nagel, 2010**<br>US/Canada | Empirical Quantitative To characterize the role of CRN in cooperative group of clinical trials | N = 85 (Respondents function as both nurse and CRN) | N/R | A characterization of nurses in dual role of CTN and CRC; the value of continuing education in CTN job performance. | Role Development |
| **Catania, 2012**<br>Italy | Empirical Quantitative To delineate the role of the CTN in Italy, with a two-fold focus on (1) role assessment and (2) quality of job performance | OCTN N = 30 working at cancer hospitals | N/R | Italian CTNs are fully aware of being key members of research teams, potentially able to share the common goals of clinical studies, as well as supporting protocol integrity and patient safety. CTN involvement in clinical trial management is low. | Role Development |
| **Purdom, 2017**<br>US | Empirical Quantitative To evaluate the relevance of a five-dimensional model of clinical trial nursing practice | OCTN N = 167 | N/R | Findings indicated the practice domain of CTN in oncology is more complex and that an eight-dimensional model more appropriately reflects the oncology CTN practice. | Role Development |
| **Choi, 2018**<br>Korea | Psychometrics Validation of a questionnaire to delineate the clinical trial nursing roles in Korea | N = 53 clinical research nurses working in clinical cancer centres at five university hospitals | N/R | The Korean version of the CTNQ was tested reliable, valid, and interchangeable with the original CTNQ. | Role Development |
| **Lubejko, 2011**<br>US | Expert Opinion To identify the core competencies required of a novice oncology clinical trials nurse across diverse settings | OCTN | N/R | Competency guidelines for the Novice OCTN | Competence |
| **Oncology Nursing Society (ONS), 2016**<br>US | Expert Opinion An update on the 2011 Oncology clinical trials nursing competencies | OCTN | N/R | The new update expands on practice advancement and activities. | Competence |
| **Scott, 2012**<br>Australia | Descriptive Statistic To develop and test a questionnaire measuring knowledge and skills of cancer clinical trials nurse in Australia; and evaluate the knowledge and skills of CTN in Australia for a better understanding of their educational and training needs | OCTN N = 61 | N/R | (1) Self-reported knowledge is low in areas related to clinical trials methods and conduct; (2) self-reported knowledge was not significantly related to nursing qualification, post-grad qualification, or perceived importance; (3) years of working as CTN were significantly and positively related to self-reported knowledge. | Competence |
| **Arrigo, 1994**<br>Europe (UK, Netherlands, Belgium, France, Spain, Greece) | Descriptive Statistic To survey and identify nurses involved in oncology clinical trials, to describe the extent of their participation, and to document their specific needs | N = 120 RNs from six European countries | N/R | CTNs rank education and training high among other resources for their performance. Nurses felt moderately satisfied with their knowledge. Secondly, the involvement of nurses in clinical trials in European countries is low. | Competence |
| Lead Author / Year / Country | Study Design / Objectives | Study Sample | Intervention | Key Findings | Theme |
|----------------------------|--------------------------|-------------|--------------|--------------|-------|
| Liptrott, 2009 Italy       | Case Study               | N = 2 Ward nurses becoming research nurses | N/R          | The research nurses taking the programme still desired more knowledge at the end. The CTN competency recommendation extracted from the literature did not necessarily reflect the needs of the local institute. | Competence |
| Scott, 2013 Australia      | Survey                   | OCTN N = 61 | N/R          | Majority of participants either hold postgraduate qualifications or are highly interested in taking the education. Postgraduate is recommended to address the educational and training needs of CTNs. | Education / Training |
| Showalter, 2017 US         | Case Report              | OCTN        | The program includes a 4-month orientation followed by 1-2-monthly residency class days during a 12-month period | The curriculum program included training in oncology and clinical trials, re-emphasizing the imperative integration of oncology training in CTN preparation. Initial feedback from RNR participants and the hiring departments has been positive, with much eagerness to bring on additional residents. | Education / Training |
| Herena, 2018 US            | Case Report              | OCTN        | Intervention is an educational course development for new and current clinical research nurses | With the course implementation, there was a decrease in turn-over rate and an increase in retention rate in the first quarter of the fiscal year, after the intervention. | Education / Training |
| Ness, 2017 US              | Case Report              | N/R         | A creation and development of the Office of Research Nursing; promoting nursing leadership among CTNs; reviewing and strengthening CTN competencies via ONS competence | An exemplar of local development of infrastructure of CTN; referencing ONS guideline for CTN competencies. | Advanced Practice |
| Bird, 2005 UK              | Literature Review        | N/R         | N/R          | A potential role for advanced practice and its framework were identified. | Advanced Practice |
| Rosenzweig, 2005 US        | Descriptive              | Nurse coinvestigator | N/R         | An exemplar regarding how nurses in clinical trials can advance their practice and be involved in clinical trials as a study PI. | Advanced Practice |
| Lead Author / Year / Country | Study Design / Objectives | Study Sample | Intervention | Key Findings | Theme |
|------------------------------|--------------------------|--------------|--------------|--------------|-------|
| Winter, 2012 US              | Quantitative             | N = 35 patients with GI cancer | NP-lead clinic | High satisfaction from clinical trials patients with the nurse-led clinic. | Advanced Practice |
| Milani, 2017 Italy           | Workload Measurement    | OCTN N = 7 | N/R          | Workload measurement and tool development of the Wichita Community Clinical Oncology Program (WCCOP) protocol acuity tool | Workload |
| Lee, 2018 Korea              | Quantitative             | N = 70 nurses in clinical trials | Comparing the relative work value difference between oncology, cardiology, endocrinology | Workload measurement tool development; in comparison to the trials of cardiology and endocrinology, oncology clinical trials are more intensive, and requiring more time and work. | Workload |
| Good, 2013 US                | Case Report              | OCTN N/R | To report the acuity-based workload assessment tool that facilitates assessment and a balance of workload among its research nursing staff. | Workload |
| Fujiwara, 2017 Japan         | Qualitative              | N = 15 (13 nurses and 2 pharmacists) | N/R          | The needs of patients in phase I oncology trials were elucidated through the perspective of CRCs. Different patient needs were identified in 3 phases of a study, recruiting and consenting phase, during trial intervention, and posttrial interventions. Patients in this phase require significant psychosocial support, which suggested an area of CRC training. CRCs may have a variety of professional background such as nursing, laboratory, and pharmacology. | International perspectives |
| Matsumoto, 2011 Japan        | Qualitative              | N = 21 a convenience sample of nurses; no CTN and no participants had worked as CRCs or were certified nurse specialists | N/R          | (1) General nursing staff were expected to provide nursing care for patients in phase 1 oncology trials in addition to care for non-trial patients and had difficulties handling both roles. (2) A disconnection between nurses and rest of the clinical trial team while nurses have most contact with research subjects; lack of nursing voice and involvement in clinical trial operation, decision making, as well as the expertise and knowledge of clinical trials | International perspectives |
| Cheng, 1998 Taiwan           | Expert Opinion           | OCTN N/R | CTN role implementation in Taiwan did not have good success in 1998, leaving the practice unsupported and subsequently a high turnover rate of CTNs. | International perspectives |
meeting the rising research needs positioned pediatric oncology nurses in an ideal position to be involved in the care of pediatric patients enrolled in clinical trials. Job titles of nurses assuming the OCTN role were equally ambiguous or inconsistent at the time of the initial role implementation compared to those in adult settings. Professional identity and role confusion were identified as common issues in a pediatric setting as was the case with other areas of clinical trials nursing (Carlson et al., 2005; Chang, 2008; Nagel et al., 2010).

Nagel, Gender and Bonner (2010) conducted a study of the CTN role within the Children's Oncology Group (COG), examining the role with an empirical lens by using the CTNQ instrument. The sample of 85 respondents from United States and Canada, who practised in combined roles of CTN and Clinical Research Coordinator (CRC), completed the questionnaire and provided insight into the role of pediatric OCTN. The findings indicated that the pediatric OCTN role is a specialized role that requires an in-depth knowledge base, cognitive critical thinking skills, and decision-making skills to fulfill the dual requirements of CTN and CRC.

Practice domain and framework

Previous studies on the role of the general CTN classified nurses working in clinical trials into two main groupings—CTN with clinical practice and research focus, and RNC with research coordination and study management focus (Bevans et al., 2011; Castro et al., 2012). However, confusion persisted, as the ONS suggested that the OCTN role encompassed the coordination of clinical trials and the management of patients on trials (ONS, 2010, 2016). The Society acknowledged that the OCTN practice settings and job titles are diverse and could include, but are not limited to, clinical trials coordinator, clinical research nurse, research nurse coordinator, and protocol coordinator. As such, the OCTN may or may not provide direct patient care in some research settings (ONS, 2016).

Purdom, Petersen and Haas (2017) conducted an online cross-sectional survey of oncology nurses working in the roles of study coordinators, direct care providers, and dual role nurses (providing patient care and trial coordination) and reported that OCTN commonly assume a dual role in comparison to CTN in other disease, non-cancer groups. The authors described oncology practice as multi-dimensional, where nurses devote more time to direct patient care, the research processes, and study coordination, and that roles and responsibilities are more complex and diverse in the oncology setting (Purdom et al., 2017).

Purdom et al. (2017) developed a framework describing the OCTN role that includes the domains of Care, Manage Study, Expert, Lead, Prepare, Data, Advance Science, and Ethics. Based on the ONS statement and vision on oncology, the OCTN role, and the practice framework developed by Purdom et al. (2017), oncology clinical trials nursing is recognized as a subspecialty distinguishable from oncology nursing in general and from CTN roles within other disease populations.

Professional identity challenges

The issue of CTN role confusion appears to stem from the inconsistency and discordance of terminologies used in title and job descriptions. Employment and job descriptions are often drafted based on an individual agency’s specific needs and are tailored to the local research programs. Employment of some positions, such as data manager or clinical research coordinator, were not restricted to the profession of nursing, but were open to other professionals (Purdom et al., 2017). Title diversity and role ambiguity were, therefore, not only a challenge related to role clarity but also a challenge in CTN professional identity, branding, and in communicating the role to patients and the public. The term ‘clinical trials nurse’ is common in the nursing literature over the last decade, especially in key studies discussing the OCTN role, competency, education, and practice domain and framework, and thus appears as a title across oncology nursing publications (Ness & Royce, 2017; Purdom et al., 2017; Scott et al., 2013).

Competency

The first core competency guideline for OCTN was developed in 2010 by the ONS, in response to the increased number of OCTNs, the needs for a clinical trials curriculum, and the standardization of the role (Lubejko et al., 2011). The guideline was updated in 2016, integrating new evidence surrounding the scope of practice of this specialized role, and adding recommendations to support and clarify the roles and responsibilities. In nine functional areas, the guideline laid out role expectations and demonstrated the knowledge and skills required of an OCTN (ONS, 2016), at the levels of novice and experienced OCTN. In addition, the 2016 guideline emphasized the leadership role of an OCTN and added a definition of practice advancement. Finally, an objective measurement was developed to assess the skill and experience of advanced practice, rather than the mere number of years working as an OCTN (ONS 2016).

Such new emphasis on leadership and practice advancement are in-keeping with the growing evidence surrounding the advanced practice of oncology clinical trials nursing. Bird and Kirshbaum (2005) proposed an advanced practice framework for the OCTN (Bird & Kirshbaum, 2005). The authors suggested that longevity or years of experience alone may not necessarily translate into a higher level of practice competence but would also need the practitioner’s commitment to professional development to advance his/her own practice. As such, the practitioner manifests the ability to translate the working experience into an advanced level of thinking and demonstrates such knowledge and skills in the everyday practice and his/her body of work (Bird & Kirshbaum, 2005).

Subsequently, the ONS recommended that coordination of cancer clinical trials can most effectively be performed by an OCTN with oncology nursing experience (ONS, 2016). The 2016 ONS guidelines emphasize oncology nursing experience and clinical research competency required of OCTNs in order to meet the unique needs of cancer patients as well as the high number and complexity of cancer clinical trials. Over the years, ONS has further responded to the needs of OCTNs, which has resulted in the development of a tool and competency requirements that further delineate the specialized nature of this role.
Education and Training

Practice frameworks, core competencies, and similar supportive documentations of the role of OCTN are imperative blueprints that help structure and support the education and training for OCTN when they are integrated into curriculum and programs orienting nurses new to the role. Themes of education and training were identified in five studies published from 1994 to 2017 (Table 1). The purpose of these educational and training programs varies, ranging from quality improvement to the recognition of the OCTN role and contribution, to increasing OCTN support, all in light of the increased volume of clinical trials and research participants (Arrigo et al., 1994; Liptrott et al., 2009; Lubejeko et al., 2011; ONS, 2016; Showalter et al., 2017).

Supplemental courses, training, and advanced education were identified as important components, fulfilling needs of OCTN performance and practice (Arrigo et al., 1994). Most programs included both oncology and clinical research training to orient new nurses, although a lack of oncology training is a recurring issue in the literature, compounding the challenges evident in the hiring of non-oncology nurses when oncology nurses are in short supply (Arrigo et al., 1994; Herena et al., 2018). Nurses who received training in both oncology and clinical trials were reportedly more satisfied with their knowledge base and reported strong positive feedback on their performance when compared to their colleagues who had not had this type of education (Arrigo et al., 1994; Liptrott et al., 2009; Showalter et al., 2017). Despite these positive reported outcomes, the OCTN felt the training could be enriched by providing learners with more supplemental materials (Liptrott et al., 2009).

A persistent issue within the literature is a lack of standardization within the OCTN education and training among practice settings. This issue of insufficient standardization was not limited to OCTN education and training but extended to the descriptions of OCTN role descriptions, responsibilities, and performance expectations. As the specialty of clinical trials nursing is becoming more developed with definitions and standards of practice, there is also a growing trend toward standardization through the incorporations of metrics into CTN curriculum development, such as seen in the 2004 Ehrenburger and Lillington CTNQ, the ONS Clinical Trial Nurse Core Competency Guidelines, and the American Nurse Association’s Clinical Research Nursing Scope and Standards of Practice (ANA & IACRN, 2016; Catania et al., 2012, Herena et al., 2018).

Postgraduate education is a growing expectation of OCTNs and in some areas is considered a necessary qualification. In a national study of 61 OCTNs working in cancer clinical trials in Australia, 42 participants (69%), had completed postgraduate education, of which nine had Master’s degrees and 32 had either a postgraduate diploma or certificate (Scott et al., 2013). While postgraduate training is not always a required qualification and educational barriers exist (e.g., out-of-pocket costs, lack of release time, and limited support from employers for career development), most OCTN participants expressed a high interest in postgraduate education. Taking into account the increased complexity of cancer clinical trials; the specialized skills, knowledge, and responsibilities required of oncology CTNs; the gaps in education and training; and an ambiguous career pathway; Scott and colleagues (2013) suggested that not only would postgraduate education address these gaps, but also should be considered a CTN qualification and best practice guideline.

Advanced Practice and Its Potential Within OCTN Role

A theme of leadership and advanced practice of OCTNs was identified in four articles originating from the United Kingdom and United States. Bird and Kirshbaum (2005) analyzed the role of OCTNs and models of advanced practice and suggested a potential framework of practice advancement. The framework appears preliminary and generalized, requiring further development to enhance clarity, specificity and comprehensiveness. However, the framework supports a pathway of practice and career advancement and, in turn, provides career options that may translate into a clear plan for professional development, staff recruitment, and retention (Bird & Kirshbaum, 2005; Scott et al., 2013).

A theme of leadership and advanced practice was also identified in an OCTN-driven initiative in conjunction with a restructuring of the OCTN department at the National Cancer Institute in the United States. The Oncology Nursing Society defined OCTN leadership competencies as skills that inspire and influence, achieving the common goal of quality clinical research and enhancing cancer care across the continuum (Oncology Nursing Society, 2016). Leadership was demonstrated during the establishment of OCTN into a free-standing research unit, under the Office of Research Nursing, at the Center for Cancer Research (CCR), National Cancer Institute, the United States (Ness & Royce, 2017). As a result, OCTN competency levels were evaluated and strengthened following the restructuring.

Several studies demonstrated satisfaction when research collaborations occurred among advanced practice nurses, CTNs, and other healthcare professionals (Rosenzweig et al., 2005; Winter et al., 2012). One example is a randomized controlled trial investigating the effects of erythropoietin on fatigue within metastatic breast patients, where a CTN coinvestigator collaborated with a physician colleague to investigate the drug’s effect on fatigue management (Rosenzweig et al., 2005). Another example is a study of an advanced practice nurse-led clinical trials clinic and CTN collaboration on a study to explore the satisfaction of the clinic (Winter et al., 2012). While these exemplars of CTN leadership and their advanced practice role are few, they highlight the potential leadership role that CTN can play in advancing research.

Challenges of Workload and Measurement

A study comparing clinical trials nursing in endocrinology, cardiology, and oncology showed that the oncology research approaches required more time, effort, and had a higher intensity and workload (Lee & Jeong, 2018). Further, the same study also identified that the inclusion/exclusion criteria in oncology trials are typically more complex, requiring advanced training in the various tests utilized in disease classification,
Metrics measuring OCTNs’ workload were identified in the Wichita Community Clinical Oncology Program (WCCOP) protocol acuity tool (WPAT); the Nursing Time Required by Clinical Trial – Assessment Tool (NTC-TA) from Italy; and the Resource-Based Relative Value Scale for Clinical Research Nurses’ Workload (RBRV scale) from Korea (Good et al., 2013; Lee & Jeong, 2018; Milani et al., 2017). While these tools originated from different countries where the development and regulation of the OCTN’s role and practice may not be uniform, these tools are similar in purpose and measurement indicators. Nursing service, patient care and acuity, research phase, and protocol complexity are the indicators within each of these tools. The score produced indicates not only the individual nurse's workload, but also provides quantifiable, objective data indicating the need for additional hiring, workload support, and re-distribution among staff.

The WPAT measurement is based on the acuity score calculation, a score of patient classification and study protocol classification. Components factored into the score calculation are the patient’s trial status (on study versus off study) and type of study (treatment versus cancer control focus) (Good et al., 2013). The acuity score is used for comparison and workload re-distribution among OCTNs and determines the threshold for increasing staff. The WPAT has been used at its local institution for 11 years, and reportedly has good internal consistency and validity. However, it has not been validated in other institutions, practice settings, or countries (Good et al., 2013).

The NTC-TA was developed based on a computation of standard coefficients of nursing activities. To determine the total working hours required per study, the standard coefficients rate the core activities performed by OCTN and the average complexity of the research phase (Phases I, II, and III) (Milani et al., 2017). The nursing core activities were determined from the review and analysis of literature, expert opinions, and member checking. The activities were timed and coded by an independent external observer before input for standard coefficient computation (Milani et al., 2017).

Lastly, the Resource-Based Relative Value Score (RBRVS) is a workload scoring system intended for use across disease populations of clinical research nursing. It was adopted from a tool used in the service payment calculation for physicians, surgeons, and intensive care nurses, with nursing service or activity being the basic unit for the workload calculation. A nursing activity that is conducted over 98% of the time by an OCTN is selected as a benchmark to evaluate other nursing activities. The intensity of each activity is defined in terms of technical effort (skill), mental effort (professional knowledge and judgment), and stress (the tension assumption of psychological energy that varies with experience) (Lee & Jeong, 2018). The workload score produced reflects nursing activities provided as well as their associated intensity.

**International Perspectives**

The globalization of clinical trials has led to an increase in the number of international and multisite clinical trials being conducted, and a resulting increased recognition of the impact of OCTN practice and workforce development in multicentred international clinical trials. Subsequently, the increasing number of international trials triggered a wave of studies examining OCTN roles in countries wanting to increase their participation in clinical trials. The CTNQ developed by Ehrenberger and Lillington (2004) was translated and validated in Italian and Korean languages (Catania et al., 2012; Catania et al., 2008; Choi & Park, 2018). In Italy, the CTN role has more of a practical focus on direct patient care, in comparison to the dual-role of direct patient care and study management reflected in CTN roles within North America (Catania et al., 2012). Nurses’ involvement in research at the leadership level was reported as low, although the recognition of the advanced practice potential in clinical trial nursing is growing in Italy (Catania et al., 2012). Similarly, two Korean studies reported the importance of the role of OCTN, despite being at an early developmental stage. One of these studies focused on role delineation specifically, aiming to translate and validate the CTNQ tool into Korean (Choi & Park, 2018). A second study, primarily focused on the workload measurement of CTN, as described above, shed further light on the OCTN role in Korea, noting that the intensity of nursing activities is higher in oncology, in comparison to cardiology and endocrinology clinical trial nursing (Lee & Jeong, 2018).

In a Japanese study, findings were reported on the practice of CTN in general versus oncology-specific CTN practice, which is still in its infancy (Matsumoto et al., 2011). The study reported that care for clinical trials patients is typically provided by bedside nurses while clinical research coordinators (CRC), whose professional background may or may not be in nursing, concentrate on study management and facilitation. The authors noted that an embedded challenge of this clinical trials administration model is an apparent lack of communication and connection among the ward nurses, CRCs, and the rest of the research team. Additionally, in relation to CRC-patient relationships, clinical research coordinators were described as playing the role of communication liaison and patient advocate, although the extent of direct patient care is vaguely depicted (Fujiwara et al., 2017).

A Taiwanese study identified the first group of OCTNs being formed in 1989, noting that OCTNs remained a poorly integrated and developed specialty practice area (Cheng et al., 1998). Because of the lack of integration and the infancy of this specialized area, the authors concluded that CTN was perceived as a daunting career pathway and this significantly undermined its development. However, CTN in oncology may have evolved considerably from this nascent state more than 20 years ago, given that the country currently ranks 14th globally in clinical trial participation (WHO, 2017).

**DISCUSSION**

Studies on clinical trials nursing spanning the last four decades indicate a transformation of the practice into a specialty that is now recognized by the American Nurses Association
(ANA & IACRN, 2016). Additionally, throughout the emergence and transformation of clinical trials nursing into a specialized practice area, oncology has been leading in the number of healthcare trials and OCTN practice development, in comparison to other disease populations. From early anecdotal descriptions, the role of OCTN has rapidly evolved and presently continues to be supported with empirical research and practice evidence. Not only has the role expanded to a full scope of practice, but it is now being considered as an advanced practice.

The themes identified in this review suggest the next transformation of the OCTN is into a subspecialized practice area, setting itself apart from general clinical trials nursing. In many ways, the clarion call of Peplau almost fifteen years ago seems to be coming to fruition (1965/2003), namely that: “specialization within a profession tends to be a division of the generic field,... is determined by the avant garde workers who see or sense a great need to move – in depth – in a particular direction.... [and that], the representative workers speaking for and through the professional organization decide the lines along with specialization will develop or be revised” (p. 3-4)

In relation to this specialization in professional nursing, Peplau (1965/2003) further suggested that an influx in knowledge is one of the antecedents to specialization. With the increase in new knowledge, whether basic/applied sciences or technological advancement, practitioners are required to develop complex technological skills and intellectual competencies (Peplau, 1965/2003). Accordingly, with advances in science and technology contributing to the increased activity of cancer research, a subsequent growth in clinical trial numbers and complexity is expected to follow and dictate not only the quantity but the quality of OCTN.

The dynamic nature of cancer biology and genetics makes cancer diagnosis, management, and care increasingly complex and ever changing. Further, cancer patients have unique needs requiring nurses attending to these patients to have specialized knowledge and skills in oncology. Clinically, these biomedical complexities, treatments, and the diverse needs of cancer patients, requires advanced nursing knowledge about the underlying disease and treatment side-effects, in order to safeguard patients and ensure their wellbeing in the process. In short, herein lies the irony of oncology clinical trials and the importance of OCTN being specialized, namely those patients who are receiving potentially life extending innovative therapies, are those patients who are also being subjected to higher levels of risk and uncertainty in regards to the therapies’ impact and efficacy. When one considers the increased complexity of study subject safety and informed consent, in addition to the sensitivity in working with vulnerable populations such as children, seniors, and ethnic minorities, the advanced knowledge and skills of an OCTN become all the more apparent.

The findings from this review indicate that preparation and training in both oncology and clinical research are a crucial element not only for the safety of study subjects but also in terms of OCTN performance, confidence, and satisfaction. Historically, responses from the Oncology Nurse Society have played a significant role in advancing oncology clinical trials nursing along the subspecialty trajectory, producing essential guidelines that have shaped oncology clinical trials nursing practice. Concomitantly, the ONS’ work on OCTN competencies and guidelines was credited with distinguishing oncology clinical trials nursing as separate from clinical trials nursing in general. This distinguishing separation, along with the OCTN framework of Purdom et al. (2017), means oncology clinical trials nursing is increasingly recognized as a subspecialty of oncology nursing.

The themes identified in this review suggest a lack of standardization, particularly in the educational requirements and qualification of an OCTN. As a means to assure quality and accountability, specialized certification of the OCTN is needed. Identifying competencies and a clear role description of the OCTN seems like a logical next step in this process and one that could be easily integrated into local institutions’ practice and policies, if not standardized across practice settings.

As both clinical research education and oncology experience are crucial in role implementation and success of an OCTN, the integration of these requirements in actual training and preparation appears disparate and underdeveloped, requiring the integration of clinical trials nursing into the curriculum of oncology nursing. Similarly, further discussion is needed surrounding postgraduate education and educational preparation at Master’s levels for OCTNs. This would acknowledge the advanced nature of the role and offer a clear career pathway that could positively impact recruitment and retention.

Exploration of advanced practice designations within the OCTN role is at a nascent stage. Although the work of Bird and Kirshbaum (2006) initiated an important dialogue and identified the theoretical foundation of advanced practice in oncology clinical trials nursing, further development of the framework and concepts into an advanced practice role needs to occur as of publication. The roles of the Nurse Practitioner (NP) in clinical trials clinics, nurse coinvestigators in research collaboration with a medical oncologist, and other leadership models are encouraging exemplars of advanced practice that could be adopted to a greater extent into oncology clinical trials nursing. That said, it is still premature to affirm either an advanced practice designation or a clear career pathway in oncology clinical trials nursing without further research. Nevertheless, the recent framework for oncology clinical trials nursing, developed from the Purdom et al. (2017) cross-sectional survey, represents an initial, but important step towards practice standardization and competency development.

Of the 29 studies included in this review, we identified only two involving Canadian CTNs of which one contained a mixed sample of CTN from the United States and Canada (the Cooperative Group of Clinical Trials), and the other was an exclusively Canadian sample. The lack of research in the Canadian context is surprising, as Canada ranks seventh in the world in number of clinical trials (WHO, 2017). The discord between clinical trial involvement and research on the role of CTN was also identified in Taiwan, where research and guidelines on CTN are underdeveloped in comparison to the country’s high involvement in conducting clinical trials. Further,
publication on Canadian clinical trials nursing practice has been largely confined to anecdotal discussions and opinion pieces, revealing a considerable research gap that requires further attention. While clinical trials nursing, within and outside of oncology, has begun to position itself as a unique subspecialty, advancement is impeded by a lack of research to substantiate subspecialty claims and to develop evidence-based guidelines.

From the perspective of advanced practice development of the OCTN, more research is needed to further define the advanced practice aspects and delineate roles. Given the research environment of clinical trials and their research skills, it is apropos and opportune for OCTNs to conduct research on the advancement of clinical trials nursing. Research, publications, and dissemination not only establish the evidence base for advanced practice oncology clinical trials nursing, but also provide evidence to ensure that nursing is recognized equally alongside other professions involved in the research enterprise. The matter is particularly pressing, considering that clinical trials oncology nursing research has been primarily descriptive, lacking in both quality and quantity (Molassiotis et al., 2006).

From an international perspective, clinical trials nursing research appears to be most advanced in developed countries where healthcare systems, health funding, and nursing professions are well-established. With the current rate of economic growth in many developing countries, the rising cancer prevalence on a global scale, and the movement toward multicentre clinical trials in cancer, the role of oncology and clinical trials nursing will need to expand at a similar rate. In order to facilitate this evolution and to advance the OCTN to low resource countries, international standards of oncology clinical trials nursing are needed.

Nursing involvement and scholarship within the clinical research enterprise can occur locally within one’s own practice environment or extend to overseas collaborations and partnerships. Supports from within the profession, government, and/or local research institutions are vital in developing this advanced nursing role. Equally important, OCTNs themselves need to play a crucial role in advocating for the development of advanced practice OCTNs as they function at the epicenter of clinical trials research and possess insider knowledge of the importance, challenges, and complexity of their work.

**Limitations**

This review is not without its limitations. As this review was restricted to studies in English, the global impact of OCTNs may not have been fully captured. Another limitation is that screening and data extraction were conducted by a single reviewer as the study was a Master student’s research project; however, the decision-making process was guided and reviewed by their supervisor, a senior research librarian, and other members of their graduate committee. This limitation was further mitigated by keeping comprehensive documentation of the study processes as well as decisions made in collecting and reporting findings that are open to readers’ scrutiny, enhancing the transparency of the study (Arksey & O’Malley, 2005; Armstrong et al., 2011).

**CONCLUSION**

Innovations in cancer care and therapies have evolved at a remarkable pace over the last 70 years. As part of the research team, OCTNs play an essential role in the scientific advancement of new cancer therapies that allow patients to live longer and with greater quality of life. Patient care, right advocacy, safety, and well-being outcomes are at the core of clinical research, and in safeguarding these qualities to the highest standards, OCTNs facilitate the operation and success of clinical trials. Despite the rapid progress that has been made in clinical trials research in oncology, the specialized role of oncology clinical trials nursing has not been systematically investigated, impeding the development of a standardized approach to this specialized nursing role. This scoping review synthesizes the evolution of the specialized field of oncology and clinical trials nursing, describing the current state of the literature, identifying knowledge gaps and provides recommendations for future directions.

**CONFLICTS OF INTEREST**

No conflicts of interest to declare.

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