Oncology clinical trials are important in the improvement of outcomes for people with or at risk for cancer. Because of the complexity of oncology clinical trials and the needs of patients with cancer, nurses play a crucial and unique role in the trial setting. However, great variability exists in how the role of the nurse on a research team is defined and implemented.

An Oncology Nursing Society project team set out to identify the core competencies required of a novice oncology clinical trials nurse (CTN) across diverse settings. This article describes the process used to develop core competencies for the novice CTN, presents the final core competencies, and offers examples of how those competencies might be used in practice.

The Oncology Nursing Society (ONS) believes that oncology nurses are essential to the effective conduct of cancer treatment and prevention clinical trials. In particular, ONS has taken the position that the coordination of clinical trials (e.g., coordination of clinical sites, development of standardized treatment orders, symptom management, patient education and advocacy, facilitation of informed consent, assistance with participant accrual and retention) is accomplished best by RNs who have been educated and certified in oncology nursing (ONS, 2009).

However, the scope and practice of the oncology nurse who coordinates clinical trials has not been well defined. Nurses who are employed in clinical trial programs have a wide variety of job titles, practice in diverse settings, and come with inconsistent educational backgrounds. The lack of clear role definition and awareness of the specific contribution nurses can make to the research process has resulted in the clinical trials nurse (CTN) role being poorly understood.

The literature has just begun to delineate the knowledge and skills required for competent practice as a CTN. Most published descriptions of the CTN role are anecdotal and based on individual experience. In 2000, a workgroup of the ONS CTN Special Interest Group (SIG) developed an instrument to help more formally evaluate the CTN role. The tool, the Clinical Trials Nursing Questionnaire (CTNQ), was found to be valid and reliable (Ehrenberger & Lillington, 2004) and measures the frequency with which specific activities are performed and their perceived importance.

At a Glance
- Wide variability in clinical trials nursing position titles, role implementation, and practice settings has hampered clear definition of core competencies.
- Core competencies were developed following a process of information collection, evaluation, and validation.
- Application of the competencies may lead to role clarity, standardization, and validation, which could increase professional satisfaction for oncology clinical trials nurses.
Additional work to support the CTNQ has been described in the literature. Catania, Poiré, Dozin, Bernardi, and Boni (2008) translated the CTNQ into Italian and showed that the CTNQ was a valid and reliable measure for the CTN role in Italy. Nagel, Gender, and Bonner (2010) used the CTNQ as part of a study to gather descriptive information about the clinical research nurse in pediatric oncology and found consistency between the activities listed on the CTNQ and their respondents’ roles. The authors felt that their results highlighted the benefit to the research team of having access to a nurse’s clinical knowledge, decision making, and critical-thinking skills.

The *Manual for Clinical Trials Nursing* (Klimaszewski, Bacon, Deininger, Ford, & Westendorp, 2008), published by ONS, provides in-depth information on the knowledge needs of the oncology CTN. Although it serves as an excellent resource, it does not provide a concise delineation of competencies required of the CTN or differentiate between knowledge and skills needed at the novice or advanced level.

Based on feedback from the CTN SIG and current literature, the ONS Steering Council recognized the need for development of a core set of CTN competencies to begin to standardize role expectations and highlight the specific contributions of the nurse. That need was particularly great for those new to the CTN role, as they tend to have fewer resources to define and develop their role. The decision was made to create a team of ONS members with expertise in oncology clinical trials nursing to develop competencies for novice CTNs.

Project team members were identified through an application process. ONS members (N = 1,592) who listed their primary position as a CTN or who were current members of the CTN SIG were identified from the ONS membership database. ONS reached out to those members, requesting that they submit a volunteer application if interested in participating in the project. Sixty-one volunteer applications were received.

To identify the strongest project team members, applicants were asked to submit an additional questionnaire that requested details about their type and length of experience in clinical trials, educational background and training related to clinical trials, past project involvement, experience with defining professional competencies, and personal strengths. Of the 61 volunteers, 44 completed questionnaires were returned. A panel of four reviewers rated responses to each item on the questionnaires using a five-point Likert-type scale (ranging from 1 [weak] to 5 [strong]) and then identified their five strongest candidates. Five project team members were chosen based on the ratings in addition to diversity in clinical trials expertise, practice settings, and educational backgrounds.

**Project Initiation and Process**

The project team was tasked with determining the essential components of the CTN role, with a particular focus on the knowledge and skills that reasonably can be attained by a novice CTN. The novice CTN was defined as a nurse who has been in a CTN role for up to two years and is building on his or her academic preparation, nursing knowledge, and oncology experience to develop expertise in the role. In addition, the team focused on the unique contributions that nurses can make to clinical trials.

Oncology nurses impart added value to the research team by applying their clinical and critical-thinking skills, bedside experience, interpersonal skills, and patient advocacy expertise.

The oncology CTN core competencies were developed using a three-step process that included drafting an initial list of core competencies, refining through field review, and validating by expert review. That process, identified through literature review, was chosen for consistency with the processes used for the development of the ONS (2008) *Oncology Clinical Nurse Specialist Competencies*, the ONS (2007) *Oncology Nurse Practitioner Competencies*, and the American Nurses Association (2005) *Essential Nursing Competencies and Curricula Guidelines for Genetics and Genomics*. To more clearly conceptualize the steps to be taken in developing the competencies, an initial definition of oncology CTN core competencies, a project mission statement, and core values for the CTN role were drafted (see Figure 1).

**Initial Competency Draft**

To develop an initial draft of competencies for the novice CTN, the project team reviewed the literature and other resources. In addition to published articles, the project team reviewed the *Manual for Clinical Trials Nursing* (Klimaszewski et al., 2008), position descriptions from a variety of institutions, the education modules posted on the ONS CTN SIG Virtual Community, research management curricula from schools of nursing, and training manual outlines from cancer cooperative groups. In addition, an open-ended questionnaire was sent to a sample of ONS members who identified themselves as oncology CTNs. Ninety surveys were sent, with 19 returned (21% response rate). Those who responded indicated employment in multiple clinical settings, practice settings, and educational backgrounds.

**Definition of Oncology Clinical Trials Nursing Core Competencies**

The fundamental knowledge, skills, and expertise required to proficiently

(a) identify and care for participants in clinical trials with a past, current, or potential diagnosis of cancer,

(b) manage oncology clinical trials in diverse settings,

(c) ensure protection of subjects enrolled in clinical trials, and

(d) ensure that scientific integrity is maintained through data reliability and strict adherence to regulatory mandates.

**Project Mission Statement**

To delineate the core values, skills, knowledge, and expertise required to become proficient as an oncology clinical trials nurse, highlighting the unique contribution that nurses and the nursing process bring to clinical trials practice.

**Core Values of the Clinical Trials Nurse Role**

(a) Advocate for patient safety and trial integrity

(b) Advance evidence-based oncology care through scientifically sound research

(c) Recognize the unique value that professional nurses contribute to the successful conduct and outcomes of clinical trials.

**Figure 1. Definition, Mission Statement, and Core Values of Clinical Trials Nurse Competencies**

settings for clinical trials, including small office practices, large institutions, cooperative groups, pharmaceutical companies, and governmental agencies.

After reviewing the collected data and individual experience in clinical trials nursing, the project team defined 11 key functional areas and 109 associated behaviors. Particular focus was paid to behaviors that were reasonable expectations of a novice CTN and that could apply to a wide variety of settings.

Field Review

A field review then was performed to evaluate how well the draft competencies reflected current CTN practice. To gain a broad perspective, all members of the ONS CTN SIG, as well other ONS members who listed their primary position as a CTN, were included in the population surveyed.

A field review survey was developed, focusing on the draft core competency statements. It sought to identify the extent to which the competency statements reflected skills appropriate for the novice CTN. More specifically, each competency statement was evaluated as to how closely it represented an essential function of the CTN in a variety of settings and whether it was written clearly enough to facilitate consistent interpretation and implementation across practice settings. The survey also collected reviewer demographic information (see Table 1) and opinions related to the importance of specific background requirements and training for new oncology CTNs.

Of the 1,617 surveys sent out, 247 responses were received (15% response rate). The respondents represented all regions of the country (44 states) and a variety of practice settings. They varied in experience level, with 61% having more than six years of experience as a CTN. Significant diversity also existed in educational preparation. In addition, 74% of respondents were certified by the Oncology Nursing Certification Corporation (OCN®, AOCN®, AOCCNS®, AOCNP®, or CPON®), and 34% were certified by the Society of Clinical Research Associates (CCRP) or the Association of Clinical Research Professionals (CCRA or CCRC). They reported involvement with all types and phases of oncology clinical trials from cooperative groups, industry, and individual institutions.

The field reviewers’ ratings of each statement and individual comments were used to edit the CTN core competencies. Individual statements were clarified, redundancy was reduced, and competencies that were deemed beyond the scope of novice CTNs were eliminated.

Expert Review

The remaining 68 competency statements then were reviewed by CTN experts. Eleven expert reviewers were selected based on their years of experience and leadership roles in clinical trials nursing. The reviewers were asked to comment on the flow, clarity, completeness, appropriateness, and applicability of the overall competency listing as related to a novice CTN. In addition, the experts provided feedback about the flow and organization of the overall document, whether the specific competency categories reflected all major CTN role areas, and whether the individual competency statements reflected all core competencies and nursing’s contribution to the process of clinical trials.

The project team used the expert review feedback to further clarify the competency functional areas and statements and develop the final version of the oncology CTN core competency listing. The final ONS CTN core competency document included 9 functional areas and 54 competency statements (see Figure 2). The full ONS oncology CTN competencies document can be found on the ONS Web site at www.ons.org/media/ons/docs/publications/ctncompetencies.pdf (Daugherty et al., 2010).

Table 1. Demographic Characteristics of Field Review Respondents

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td>Years of experience in clinical trials</td>
<td></td>
<td></td>
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<tr>
<td>Less than 2</td>
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</tr>
<tr>
<td>11–15</td>
<td>43</td>
<td>17</td>
</tr>
<tr>
<td>More than 15</td>
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<td>23</td>
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<tr>
<td>No response</td>
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<td>&lt;1</td>
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<td>Diploma</td>
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<tr>
<td>Associate</td>
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<tr>
<td>Master’s</td>
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<td>Doctoral</td>
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<tr>
<td>No response</td>
<td>3</td>
<td>1</td>
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<tr>
<td>Practice setting</td>
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<td></td>
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<tr>
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<td>17</td>
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<tr>
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<td>4</td>
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<td>2</td>
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<td>9</td>
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<tr>
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<td>&lt;1</td>
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<td>Most commonly reported job titles</td>
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<tr>
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</tr>
<tr>
<td>Director or manager of research</td>
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<td>7</td>
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<td>Clinical research associate</td>
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</tr>
<tr>
<td>Research program manager</td>
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<td>3</td>
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<tr>
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<tr>
<td>Other</td>
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<tr>
<td>Types of trialsa</td>
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<td>Treatment: antineoplastic agents</td>
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<td>Quality of life</td>
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<td>13</td>
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<tr>
<td>Otherb</td>
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<td>19</td>
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<tr>
<td>Sponsor of trialsa</td>
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<td></td>
</tr>
<tr>
<td>Industry</td>
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<td>83</td>
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<tr>
<td>Cooperative group</td>
<td>196</td>
<td>79</td>
</tr>
<tr>
<td>Institutional initiated</td>
<td>148</td>
<td>60</td>
</tr>
</tbody>
</table>

N = 247

a Participants could choose multiple responses.

b Targeted therapy, gene and immunotherapy, stem cell transplantation, symptom management, supportive care, or cancer control

Note. Because of rounding, not all percentages total 100.
I. Protocol Compliance

The oncology CTN facilitates compliance with the requirements of the research protocol and good clinical research practice while remaining cognizant of the needs of diverse patient populations.

a. Identifies the requirements of various types and phases of clinical trials, including objectives, sample sizes, and patient care needs.

b. Identifies sources for and facilitates adherence to current regulations, guidance, and policies that affect research at the institutional, state, federal, and international levels.

c. Promotes compliance with the varied processes and procedures required by different types of sponsors (e.g., private industry, National Cancer Institute Cancer Therapy Evaluation Program, investigator-initiated).

d. Protects patient, protocol, and scientific confidentiality by ensuring security of research data and personal health information.

e. Participates in discussions regarding feasibility of protocol implementation based on knowledge of institutional capabilities and limitations, therapy, or population of interest.

f. Complies with the International Air Transport Association and institutional policies for shipping and receiving biological specimens, experimental agents, and devices.

g. Collaborates with the research team to implement procedures for maintaining patient study participation from enrollment through completion.

h. Identifies the IRB of record (local, central, or commercial), protocol-related policies of the IRB, and preferred contact method.

i. Participates in providing timely, informative, and accurate communication to the IRB as required.

j. Facilitates and participates in the preparation for and implementation of scheduled and unscheduled meetings with external and internal monitors and auditors, including but not limited to the FDA, Medicare reviewers, the IRB, and quality assurance.

k. Ensures validity of research results by ensuring timely, accurate, and complete data documentation, reporting deviations, violations, and serious adverse events.

l. Collaborates with principal investigator, pharmacy, and other appropriate personnel to ensure proper use of and accountability for experimental devices or drugs as indicated.

II. Clinical Trials–Related Communication

The oncology CTN utilizes multiple communication methods to facilitate the effective conduct of clinical trials.

a. Ensures ongoing formal and informal communication regarding clinical trials with team members.

b. Provides general clinical research as well as trial-specific information to research, clinical, and other organizational staff.

c. Develops relationships with referring physicians, clinical staff, and ancillary departments to facilitate compliance with and accrual to clinical trials.

d. Participates in study initiation meetings.

e. Provides education related to clinical trials to patients and their significant others.

f. Advocates for clinical trials by participating in community outreach efforts to provide general clinical trials education when opportunities arise.

g. Advocates for the safety and care of clinical trial patients as well as for the promotion and integrity of the clinical trial.

III. Informed Consent Process

The oncology CTN demonstrates leadership in ensuring patient comprehension and safety during initial and ongoing clinical trial informed consent discussions.

a. Ensures the initial and ongoing consent process is performed and documented in compliance with FDA, International Conference on Harmonization GCP, institutional, sponsor, IRB, and other applicable regulations, guidelines, and policies.

b. Participates in the education of clinical trial patients about their clinical trial and significant new information that is forthcoming during or after the conduct of the trial.

c. Assesses for barriers to effective informed consent discussions and implements plans to overcome them.

IV. Management of Clinical Trial Patients

The oncology CTN uses a variety of resources and strategies to manage the care of patients participating in clinical trials, ensuring compliance with protocol procedures, assessments, and reporting requirements as well as management of symptoms.

a. Collaborates with the investigator to ascertain study patient eligibility for a clinical trial, including documentation of criteria specified in the protocol.

b. Ensures adherence to the protocol schedule of events and other requirements.

c. Ensures scheduling of all procedures required to assess for adverse events and disease response to the study intervention.

d. Ensures the successful completion of correlative components of the clinical trial (e.g., pharmacokinetic, pharmacoeconomic, and quality-of-life studies).

e. Assesses patients for trial-related and non–trial-related symptoms and ensures evidence-based symptom management while maintaining trial compliance.

f. In collaboration with the investigator, assesses patients for adverse events and then documents and reports these findings per the protocol and FDA, sponsor, and IRB policies.

g. Utilizes adverse event assessment data and clinical judgment to determine if a dose-limiting toxicity has occurred or if any treatment schedule or drug dose modifications are necessary and communicates findings to the study team and sponsors.

h. During phase I/dose escalation studies, collaborates with the principal investigator to determine when the maximum tolerated dose has been achieved based on adverse event assessment data and clinical judgment.

i. Evaluates disease response results and physical assessment data in conjunction with the principal investigator to determine response per the protocol.

j. Supports and evaluates patient adherence to the protocol by utilizing various methods to assist with documentation, patient education, and study agent return.

k. Identifies vulnerable patients who require increased nursing assessment and management in addition to the clinical trial requirements.

(Continued on next page)

Figure 2. Oncology CTN Core Competencies


CTN—clinical trials nurse; FDA—U.S. Food and Drug Administration; GCP—Good Clinical Practice; IRB—institutional review board
V. Documentation

The oncology CTN provides leadership to the research team in ensuring collection of source data and completion of documentation that validate the integrity of the conduct of the clinical trial.

a. Complies with regulations, institutional policies, and sponsor requirements governing source data and documentation.
b. Documents assessment, management, and evaluation in source documents for patients on clinical trials as appropriate to the protocol and role.
c. Educates research and clinical team members regarding appropriate and accurate source documentation for participants in clinical trials.
d. Ensures that relevant data from the source document are abstracted and recorded in the clinical trial case report forms and that every data point can be verified within the source document.
e. Follows appropriate guidelines in making corrections to data entry in clinical records and case report forms as recommended by good clinical practices, standards, or institutional procedures.
f. Ensures that all regulatory documents are processed and maintained per institution, IRB, and GCP regulations.
g. Demonstrates proficiency in the use of clinical and research-related computer programs.

VI. Patient Recruitment

The oncology CTN utilizes a variety of strategies to enhance recruitment while being mindful of the needs of diverse patient populations.

a. Assists in implementation of recruitment plans to identify and assess individuals who might be eligible for clinical trials, taking into consideration the study entry criteria, required procedures, and other potential factors.
b. Identifies and develops processes to overcome barriers to recruitment related to patient demographic factors, underserved populations, and healthcare system influences.
c. Identifies institutional or community-based resources or groups that can assist in achieving recruitment goals.

d. Ensures that every data point can be verified within the source document.
e. Follows appropriate guidelines in making corrections to data entry in clinical records and case report forms as recommended by good clinical practices, standards, or institutional procedures.
f. Ensures that all regulatory documents are processed and maintained per institution, IRB, and GCP regulations.
g. Demonstrates proficiency in the use of clinical and research-related computer programs.

Application of Core Competencies

The ONS CTN core competencies were designed with a focus on assisting novice CTNs in defining their role. The competencies can be used by novice CTNs to identify their strengths, limitations, and learning needs. The competencies also may help novice CTNs track their professional development and provide a tool when advocating for clearer job descriptions and resources.

In addition, individual and organizations may find the CTN competencies helpful in position definition, professional development, and performance appraisal (see Figure 3). Recruitment, education, and retention of qualified research staff can be challenging. A survey of 500 study coordinators found that more than half had been in their current position for fewer than three years (Neuer, 2002). On the other hand, a study that looked at predictive factors for clinical research coordinators’ decisions to leave their positions found that employee development programs could help improve retention (Granda, Duane, Munz, & Cannon, 2009).

Nurses’ role in the implementation of clinical trials can be very challenging. Contributing factors include lack of role clarity, heavy workload, conflict of responsibilities, lack of nursing education in research methodology and procedures, and poor recognition generally awarded to nurses involved in research activities (Johansen, Mayer, & Hoover, 1991). In addition, clinical trial roles are not clearly defined or controlled under nursing licensure.

The use of the core competencies will allow the oncology clinical research community to better define the role of the oncology CTN, which may aide in recruitment, development, and retention. One large oncology institute found an increase in the confidence level of their new oncology CTNs after the implementation of a competency checklist in addition to a formal education plan (Francis et al., 2008). In a broader context, the
CTN core competencies can be used as a starting point for the research community, academia, and professional organizations to standardize the role of the CTN, develop curricula, and design certifications.

Limitations of the Competencies

Wide variability in CTN position titles, role implementation, and practice settings were recurring themes throughout the development of the core competencies, creating challenges for the project team. Because the target audience and, therefore, field reviewers exhibited such a wide variability in role concept, a cohesive review using a consistent set of standards was not possible. Consequently, the team had to tease out a broad spectrum of professional skills and responsibilities that would fit the novice CTN role in most clinical research settings.

Generalization of the oncology CTN core competencies may be limited outside of oncology practice settings and, because they are designed to reflect nursing knowledge and skills, would not be applicable to non-nurses in clinical research roles. Resources used to develop the competencies focused on the oncology research setting and the role of the nurse in clinical trials. In addition, the field and expert reviewers were chosen from the ONS membership, which represents only a portion of oncology research nurses. To be effective, CTNs must achieve balance between patient care and the integrity of the clinical trial.

Conclusion

The role of the oncology CTN has been evolving since the early chemotherapy clinical trials were conducted during the 1960s (Deininger, 2008). Clinical trials nursing differs from staff nursing and other areas of nursing practice, which often are task-oriented (Ermete, 2008). Novice CTNs must learn to apply their nursing knowledge and experience in a new environment of unfamiliar rules and regulations, including an active role in providing direction to other healthcare team members. CTNs must shift their focus from the direct clinical management of patients to a broader focus on coordinating the plan of care for patients on clinical trials. To be effective, CTNs must achieve balance between patient care and the integrity of the clinical trial.

The Oncology CTN Core Competencies provide a common reference point to determine the minimum standards of knowledge, skill, and expertise required of an effective novice oncology CTN. Hopefully, they will provide the groundwork for standardization of the CTN role and a starting point for a certification process. Future studies looking at the impact that the competencies have had on CTN practice and organizational outcomes also will be important.

Progress in cancer care, control, and prevention requires high-quality clinical research, which is accomplished most effectively when CTNs are involved. The growth of and demand for oncology CTNs over the past five decades is testament to the value of the role. The CTN role needs the same nurturing and standards that other nursing specialties have received. The groundwork for the future of oncology CTNs has been laid. Current and future CTNs need to continue to promote and standardize the role for the development of their specialty and to ensure quality, ethical, and safe care for the patients who rely on them.

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References


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