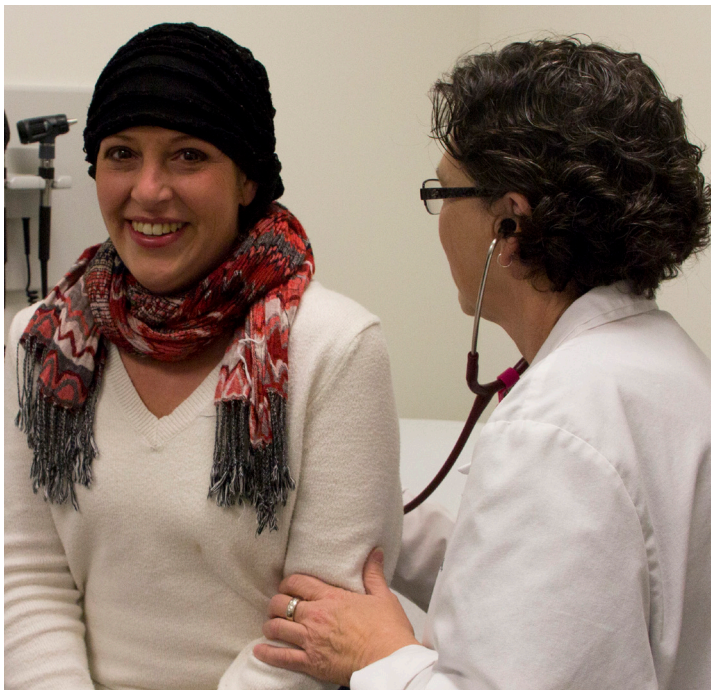
ONS
Oncology Nursing Society

2016 Oncology Clinical Trials Nurse Competencies



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Introduction

Nurses play many roles in clinical trials, most commonly as direct care providers or study coordinators. The direct care provider's primary responsibility is clinical care for patients on research studies. Their responsibilities with clinical trials can vary widely but may include reinforcement of the informed consent process by providing patient and caregiver education, finding information about clinical trials for patients, advocating for ethical care for research participants, administering investigational drugs, collecting biospecimens, and monitoring for side effects.

The oncology clinical trials nurse (OCTN) is a subspecialty nursing role that focuses on the coordination of clinical trials and the management of patients on those trials. The OCTN practices in diverse settings and may be referred to by other job titles such as clinical trials coordinator, clinical research nurse, research nurse coordinator, and protocol coordinator. In some research settings, the OCTN may also provide direct care. Although research regulations refer to a research participant as a human subject, the term *patient* will be used throughout this document. This denotes that the patient (i.e., subject) is under the specialized care of an OCTN or in a specific relationship with the OCTN based on clinical trial requirements.

Background

The effective conduct of cancer clinical trials requires the involvement of a variety of personnel. The specific types of personnel involved at an individual institution (i.e., research site) depends on the requirements of the trials and the resources of the institution. A growing number of Oncology Nursing Society (ONS) members identify clinical research as their primary job focus. With the dominant influence of clinical research in oncology, clinical trials nursing has developed a mainstream standing in oncology, perhaps more than in other disease areas. Today's oncology nurse clinicians have insight into the clinical trial process as it pertains to the patients for whom they care. Those same clinicians may decide to enter the research subspecialty and impart an added value to the research team by applying the basic nursing tenets of clinical and critical-thinking skills, bedside experience, care coordination, interpersonal skills, and patient advocacy.

ONS supports the role of the OCTN and believes that coordination of clinical trials can most effectively be performed by an OCTN with oncology nursing experience. As a licensed professional nurse, the OCTN brings a background of scientific knowledge, critical-thinking skills, and understanding of individual and group behavior. In particular, the OCTN brings the ability to:

- Anticipate physiologic and psychosocial problems and prepare for them using evidence-based nursing expertise.
- Recognize the potential impact of study outcomes on standards of oncology care.
- Assess for protocol-related needs and identify applicable resources.
- Recognize at-risk groups and individuals.
- Incorporate the nursing process into holistic patient care, including clinical assessment to identify needs and problems experienced by patients and their caregivers.
- Understand how scientifically based interventions work.
- Provide patient, caregiver, and colleague education.
- Advocate for patients and help them navigate through complicated systems.
- Form and maintain productive collegial relationships with all research team members, recognizing the value that each contributes to the successful execution of clinical trials.
- Interact with nurse navigators, discharge planners, and referral agencies using nursing knowledge of healthcare systems to facilitate transitions between care settings and home.

Since the first edition of the oncology OCTN core competencies in 2010, literature has been increasing surrounding competencies for nurses in disease specialties (Lindberg, Lundström-Landegren, Johansson, Lidén, & Holm, 2012) and in clinical research (Jones et al., 2012; Sonstein et al., 2014), specifically nurses in clinical research (Bevans et al., 2011; Castro et al., 2011; Royal College of Nursing Research Society, 2011). To ensure that the competencies reflect the current state of clinical trials and OCTN practice, ONS undertook a process to evaluate and update them.

Process of Development and Updating

Competency Development

The development of competencies by ONS (e.g., the Oncology Nurse Generalist Competencies in 2016, Oncology Nurse Navigator Core Competencies in 2013, and Leadership Competencies in 2012) typically follows a three-step consensus-building process led by a team of experts in the field. This process includes a review of the literature, field review, and expert review to identify key competencies to include in the final competencies. The same process was utilized during this revision.

Step 1: Develop Revised Competencies

The OCTN competency revision project team consisted of four members from the original OCTN competency project team (three ONS members and one ONS staff member) with the addition of two members who are experienced in clinical trials (one an OCTN and the other a clinical trial educator). The update process began with a review of the literature and

requests from the ONS Clinical Trials Nursing CTN Community (formerly known as a special interest group) members. Based on an analysis of the information collected, the project team decided that two major changes were needed to the original competencies. The first change was the development of two levels of competencies: one for the novice OCTN (level 1) and one for the OCTN with more experience (level 2). In addition, review of the original competencies revealed that some were knowledge based and not a skill or behavior. To clarify what the OCTN should be able to do in practice, the team decided that each category would be divided into three sections: required knowledge, competency behaviors, and resources. This allowed the revision to focus on the observable behaviors the OCTN would need to perform in the role as a novice or experienced OCTN.

Next, each team member was assigned two competency categories to review and revise, assessing for redundancy within and across all categories, identifying the knowledge required, editing and adding to the level 1 skills, developing level 2 skills, and developing a list of suggested resources. After several brainstorming sessions for the first round of edits, the team decided to remove one category (communication) as it was adequately addressed in other categories. Another category (documentation) was divided into (a) documentation and document management and (b) data management and information technology, given the importance of information technology in the OCTN role. A second round of revisions of the competencies by the team led to the development of definitions for level 1 or level 2 to ensure that the parameters were clear (see Figure 1).

Step 2: Field Review

In the second step, feedback on the draft competencies was requested from all ONS CTN SIG members as well as other ONS members who listed their primary position as an OCTN. These field reviewers were asked to comment on the clarity of the revised competency statements, whether the knowledge required was appropriate, if other competencies should be added to each level, and if additional resources were needed. Of the 5,165 surveys sent out, 81 responses were received (1.6% response rate). The respondents represented various regions of the country (30 states) and practice settings. They varied in experience level, with 83% having more than six years of experience as an OCTN. Diversity also existed in educational preparation, ranging from diploma program graduates to doctorally prepared nurses, with 75% holding either a BSN (48%) or master's (27%) as their highest nursing degree. They reported involvement with all types and phases of clinical trials.

Overall, the comments from the field reviewers were supportive of the updates to the competencies. Based on the field reviewers' responses, a number of edits were made to the behavioral competency statements: A few competencies were removed as they were deemed not applicable in enough settings; edits were made to the wording of some competency statements to clarify them; additional competencies were added based on field reviewer recommendations; and others were moved between level 1 and level 2.

Step 3: Expert Review

Eleven expert reviewers were identified and agreed to complete a review of the revised OCTN competencies. These experts were chosen based on their years of experience and leadership roles in clinical trials nursing. The expert reviewers were asked to comment on the flow, clarity, completeness, and appropriateness of the overall categories and skills for both levels 1 and 2, and comment on whether the competency statements accurately reflect nursing's unique contribution to clinical trials. Based on the feedback of the expert reviewers, the project team developed the final version of the OCTN competency listing found in this document.

Figure 1. Oncology Clinical Trials Nurse (OCTN) Skill Levels

Level 1 behaviors reflect what someone with two years or less of experience as an OCTN should be able to achieve.

Level 2 behaviors reflect what someone with more than two years of experience as an OCTN should be able to achieve. Performance at level 2 assumes that competence at level 1 has been reached.

OCTN Model and Framework

The competencies describe behaviors that demonstrate achievement of the fundamental knowledge and skills required to proficiently coordinate clinical trials and manage research participants at the novice and more experienced levels. This is achieved through demonstration of behaviors that fall into nine categories as depicted in the model in Figure 2.

Knowledge

At the core of the competencies lies the knowledge that is needed for OCTNs to effectively perform in their role. For each behavior identified in the competencies, related knowledge is identified.

Behaviors

The wedges represent the nine competency categories delineated for the OCTN competencies. Each category contains

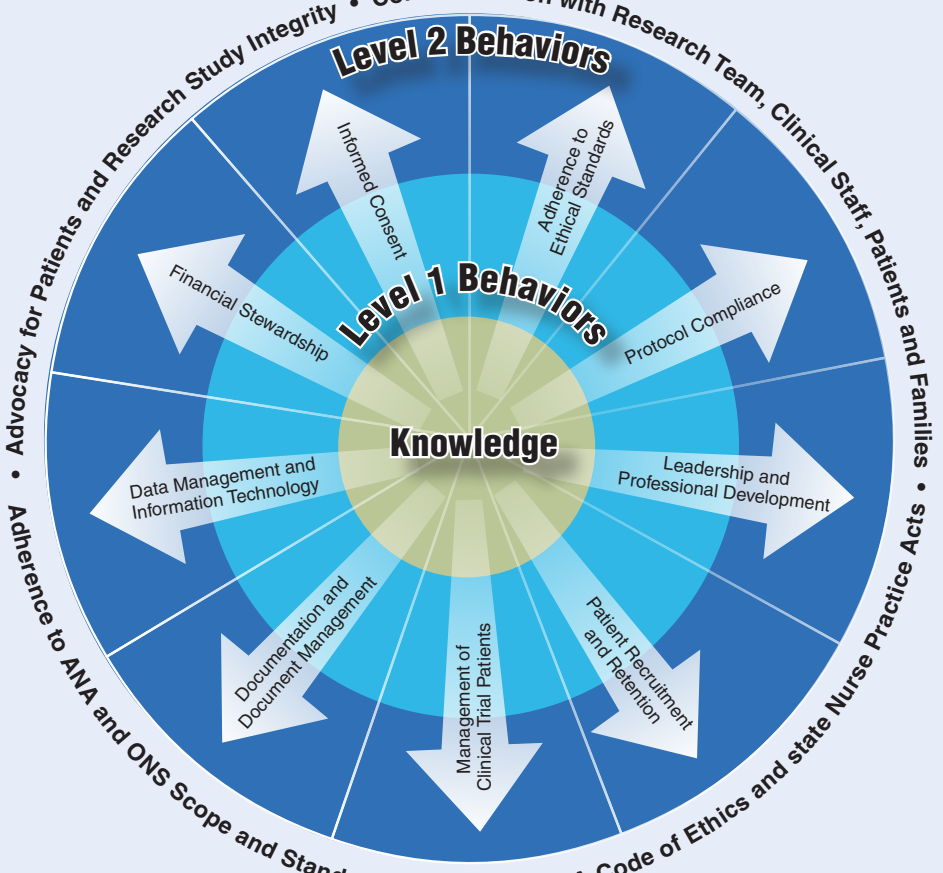
behavior statements that describe the observable actions that OCTNs need to be able to effectively perform and competently function as an OCTN. Behaviors were chosen (instead of skills) because they not only demonstrate the ability to perform a skill but also reflect the OCTN's ability to critically think and determine the most appropriate action in each situation.

The two concentric rings surrounding the knowledge ring represent two levels of behavior in which OCTNs with different levels of knowledge and experience may engage. The inner ring represents level 1 behaviors. The outer ring represents level 2 behaviors.

The two levels of OCTN practice are intended to be used as a framework for advancement in the role. Although those new to the OCTN role are anticipated to spend about two years functioning at level 1, achievement of level 2 may take more or less time depending on opportunities provided in the work environment, participation in continuing education, and commitment to professional development. In addition, as they grow in their career, OCTNs will at times be performing at level 2 in some competency categories and level 1 for others.

Figure 2. Oncology Clinical Trials Nurse Competency Model

ANA—American Nurses Association; ONS—Oncology Nursing Society



Three major principles underlie the OCTN competencies. These are concepts and role responsibilities that cross-cut the categories and are required for safe, competent, and effective practice.

- *Advocacy for patient safety and protocol integrity:* The OCTN must balance the needs of each person enrolled in a clinical trial with the requirements of the protocol. As a nurse, the OCTN has the responsibility to understand the unique needs and challenges experienced by each individual and identify issues that may interfere with his or her ability to comply with protocol requirements.
- *Adherence to nursing standards:* Although they practice in a different role than most oncology nurses, OCTNs must be aware of and abide by all standards that govern oncology and general nursing practice such as the American Nurses Association (ANA) Nursing: Scope and Standards of Practice, the ANA Code of Ethics for Nurses, the ONS Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice, and the nurse practice act for the state(s) within which they are employed.
- *Communication:* Effective communication, both verbal and written, is essential for the effective conduct of clinical trials and quality patient care. Whether within the research team setting or when interacting with clinical staff, patient participants and their caregivers, sponsors, or regulatory bodies, the OCTN must ensure that all communication is clearly conveyed, understood, and effective.

In addition, each competency category has a list of recommended resources. These resources are intended to assist the OCTN in gaining the knowledge and skill necessary for competent performance of the role responsibilities.

TABLE 1. Use of Oncology Clinical Trials Nurse Competencies in Practice (N = 81)

Competency	%
Integrated into our position descriptions	31
To guide orientation	40
To develop the content of our orientation	26
To guide the skills portion of our orientation	33
To identify individual learning needs	37
To structure or as a part of clinical trial nurse performance appraisal	15
Integrated into our clinical ladder or to help evaluate for promotion	16
I don't use them at all.	31
Other[a]	10

[a] Included using the competencies as a general guide for practice, to evaluate personal practice, and to compare current organizational practice with other institutions

Implementation Into Practice

The OCTN competencies were developed with the intent of more clearly defining the knowledge and skills required by OCTNs but also to facilitate the development of other tools to educate, evaluate, and foster professional growth. With the addition of a second level for more experienced OCTNs, further opportunities to define career development now exist.

Because OCTNs work in a wide variety of practice settings, each organization should use the competencies to develop their own indicators for measuring an OCTN's ability to effectively function in the position. These competencies are considered a baseline, and each organization can add to them for individual needs.

Since the release of the original OCTN competencies in 2010, many organizations and individuals have used the competencies in practice. As part of the field review conducted for the update of the OCTN standards, participants were asked how they have used the ONS clinical trials nurse competencies in their practice setting. The data indicated that almost 70% of participants have used the competencies in some way (see Table 1).

Other opportunities for use of the OCTN competencies in practice include:

- Development of continuing education curricula and other resources for novice and experienced OCTNs
- Development of clinical ladders based on the two levels of competency to provide OCTNs with suggestions for professional development and job advancement
- Promoting and educating others about the value of the role of OCTNs in an organized format.

Summary

Since the release of the first competencies in 2010, the role of the OCTN has become more mainstream and recognized as a subspecialty of oncology nursing. At the same time, the OCTN's role has evolved to meet the demands of personalized health care and a growing research enterprise, including new trial methodologies, response measurements, monitoring techniques, and regulatory requirements. More than ever, oncology nurses who enter the research subspecialty are contributing added value to the research team by applying their clinical and critical-thinking skills, bedside experience, care coordination, interpersonal skills, and patient advocacy.

Based on an analysis of the information collected, the project team made significant changes to the format and contents of the OCTN competencies. First, the competency statements were reworked so that they focus on observable behaviors to make them easier to measure and implement in practice. In addition, a second level of competencies was added to provide a framework for advancement in the OCTN role. It is hoped that individual OCTNs and their employing organizations will adopt the OCTN competencies as a model for practice to provide guidance and consistency to the role across settings.

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Competency Category A: Adherence to Ethical Standards

The oncology clinical trials nurse demonstrates leadership in ensuring adherence to ethical practices during the conduct of clinical trials to protect the rights and well-being of patients and the collection of quality data.

Required Knowledge

- American Nurses Association (ANA) Scope and Standards
- ANA Code of Ethics
- Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
- The Belmont Report
- Definitions
  - Research integrity definition
  - Research misconduct definition
  - Clinical equipoise
- Conflict of interest regulations and institutional policies
- Federal and state clinical research laws and regulations
- Good clinical practice

Level 1 Behaviors

a. Performs clinical trials duties in accordance with standards of nursing practice and the Code of Ethics.
b. Promotes ongoing compliance with the key ethical concepts of respect for individuals, beneficence, and justice.
c. Ensures that members of vulnerable and other special needs populations enrolled in clinical trials are identified and that their rights are addressed.
d. Maintains awareness of what constitutes falsification of data or other research misconduct.
e. Adheres to federal and institutional requirements for research misconduct reporting.
f. Adheres to conflict of interest regulations and institution-specific policies.

Level 2 Behaviors

a. Continuously assesses and reports situations that can lead to research misconduct.
b. Works with a principal investigator (PI) and/or research program to develop and implement interventions to provide education about misconduct to mitigate risk.
c. Works with a PI and/or research program to develop and reinforce a culture that facilitates compliance with reporting research misconduct.

Resources

- ANA Professional Practice Standards
- ANA Code of Ethics
- U.S. Food and Drug Administration (FDA) regulations
  - Code of Federal Regulations Title 21 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54)
- FDA guidance
  - Financial Disclosure of Clinical Investigators (www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf)
- U.S. Department of Health and Human Services Office of Research Integrity (https://ori.hhs.gov/)
- Office for Human Research Protections YouTube video: Research Involving Vulnerable Subjects (www.youtube.com/watch?v=SqRw6FevuXg&index=11&list=PL5965CB14C2506914)
- ONS *Manual for Clinical Trials Nursing,* 3rd ed., chapter 12
- Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
- The Belmont Report (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

Competency Category B: Protocol Compliance

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

Required Knowledge

- Clinical trial study designs
- Clinical trial protocol contents
- Roles and responsibilities of the research team, including the patient participant
- Federal and state clinical research laws and regulations
- Good clinical practice
- International Air Transport Association requirements for shipping and receiving biologic specimens
- Institutional policies and procedures for human subject protection and clinical research
  - Event reporting to the institutional review board (IRB)
  - Electronic IRB management system
- Privacy and confidentiality (Health Insurance Portability and Accountability Act [HIPAA], Certificates of Confidentiality)
- Institutional and sponsor policies for shipping and receiving experimental agents and drug accountability process
- Institutional polices related to protocol feasibility
- U.S. Food and Drug Administration (FDA) and National Institutes of Health requirements related to registration and results reporting for clinical trials
- Drug development process
- Corrective and preventive action plan

Level 1 Behaviors

a. Identifies primary and secondary study objectives and outcome measures
b. Uses the nursing process to identify patient care needs in the context of the study design
c. Adheres to applicable federal, state, and institutional regulations, policies, and procedures related to clinical research
d. Complies with processes and procedures required by different types of sponsors (e.g., private industry, federal agency, investigator)
e. Contributes to discussions regarding feasibility of protocol implementation with a specific focus on clinical issues, available resources, study coordination, patient safety, and data quality
f. Identifies facilitators and barriers to protocol compliance
g. Identifies the IRB of record for each protocol and adheres to IRB policies, including preferred method of contact
h. Participates in providing timely, informative, and accurate communication to the IRB
i. Collaborates with principal investigator, pharmacy, and other appropriate personnel to ensure proper use of and accountability for study drugs, biologics, and devices
j. Provides education about specific protocols and process changes to clinical staff caring for patients on clinical trials
k. Communicates with the interdisciplinary team to ensure protocol compliance and timeliness of protocol-related procedures
l. Facilitates and participates in the preparation for and conduct of meetings with sponsors, monitors, and auditors
m. Provides timely, accurate, and complete reporting of adverse events, unanticipated problems, deviations, violations, and noncompliance to the IRB and sponsor
n. Contributes to development of corrective and preventive action plans for unanticipated problems, deviations, violations, and issues of noncompliance

Level 2 Behaviors

a. Assists in developing clinical research and protocol-specific standards of practice (SOP).
b. Develops, implements, and assesses process improvement strategies for compliance with applicable regulations and SOPs.
c. Develops and institutes a nursing feasibility review process to assess the ability to implement the protocol within local nursing care practices and standards.
d. Develops methods to overcome institutional and external barriers to protocol compliance.
e. Collaborates with the principal investigator to finalize, ensure implementation, assess efficacy, and revise corrective and preventive action plans.
f. Participates in the preparation of reports for appropriate regulatory agencies and monitoring bodies or boards.

Resources

- FDA Regulations (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm): 21 Code of Federal Regulations (CFR) Parts 11, 50, 54, 56, 312, 314, 610, 612, 812
- FDA guidance documents (www.fda.gov/regulatoryinformation/guidances)
- ICH good clinical practice guidelines (www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html)
- Institutional HIPAA training
- FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond online course (http://fdadrugregulations.e-paga.com/)
- Office for Human Research Protections (OHRP) regulations
  - 45 CFR Part 46 (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

Competency Category B: Protocol Compliance *(Continued)*

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

- OHRP guidances (www.hhs.gov/ohrp/policy/index/index.html)
- OHRP YouTube videos
  - Research Use of Human Biological Specimens and Other Private Information (www.hhs.gov/ohrp/education/training/ded_video.html#researchuse)
  - Reviewing and Reporting Unanticipated Problems and Adverse Event (www.hhs.gov/ohrp/education/training/ded_video.html#unanticipatedproblems)
  - IRB Membership (www.hhs.gov/ohrp/education/training/ded_video.html#irbmembership)
  - IRB Records (www.hhs.gov/ohrp/education/training/ded_video.html#irbrecords)
  - IRB Records II (www.hhs.gov/ohrp/education/training/ded_video.html#irbrecords2)
- Human subjects protection training, such as from National Institutes of Health or Collaborative Institutional Training Initiative
- ONS *Manual for Clinical Trial Nursing,* 3rd ed., chapters 2, 8, 9, 10, 11, 16, 40, and 41
- ONS Clinical Trials Nurse Community (http://clinicaltrial.vc.ons.org/1885240)

Competency Category C: Informed Consent

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

Required Knowledge

- Historical perspective of ethical research and informed consent
- Federal and state laws, regulations, and guidances, including informed consent for non-English–speaking subjects and vulnerable populations
- Elements of an informed consent document
- Informed consent regulations and guidance documents for assent
- Elements of an assent document
- Difference between clinical care and clinical research
  - Therapeutic misestimation
  - Therapeutic misconception
- Regulatory and institutional requirements for medical record documentation related to the informed consent process
- Methods for delivering informed consent
- Institutional requirements related to Health Insurance Portability and Accountability Act (HIPAA) in clinical research
- Difference between capacity and competency for informed consent
- Evidence-based practices for evaluation of literacy, cognitive capacity, language barriers, and distress

Level 1 Behaviors

a. Identifies and intervenes to address facilitators and barriers to effective informed consent discussions and decision making (e.g., literacy, capacity, language, distress, lack of time, therapeutic misconception)
b. Describes and abides by institutional policy and processes for informed consent
c. Ensures that the most current version of the institutional review board approved protocol consent document is used when consenting a patient
d. Collaborates with the principal investigator to ensure initial and ongoing consent process is performed and documented
e. Assesses ongoing consent through discussions with patients and reinforcement of education
f. Assesses patient's understanding of the information provided during the informed consent process
g. Ensures timely re-consenting as needed
h. Demonstrates understanding of tiered consent process when optional correlative studies (e.g., biospecimen, quality of life, patient-reported outcomes collections) are involved

Level 2 Behaviors

a. Develops, implements, and evaluates processes to address institutional barriers to effective ongoing informed consent
b. Develops supplemental materials for institutional review board approval that assist in the informed consent process
c. Develops and enacts comprehensive process to ensure compliance with re-consenting needs
d. Collaborates with principal investigator to utilize appropriate consent format and content
e. Ensures compliance with consent for correlative studies by tracking the patient's wishes related to collection of associated specimens or data

Resources

- U.S. Food and Drug Administration regulations
  - 21 Code of Federal Regulations (CFR) Part 50 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)
- FDA guidances and other documents
  - Information sheet (www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm)
  - Use of electronic consent (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf)
- ICH Good Clinical Practice Guidelines, Section 4.8 (www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html)
- Office for Human Research Protections (OHRP) regulations
  - 45 CFR Part 46 (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)
- OHRP guidance and other documents (www.hhs.gov/ohrp/policy/consent/index.html)
- OHRP YouTube video: General Informed Consent Requirements (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)
- ONS *Manual for Clinical Trial Nursing,* 3rd ed., chapter 14
- The Belmont Report (www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)
- Health literacy
  - Quick Guide to Health Literacy (http://health.gov/communication/literacy/quickguide/Quickguide.pdf)
  - Informed Consent and Health Literacy (http://nationalacademies.org/hmd/Reports/2015/Informed-Consent-Health-Literacy.aspx)

Competency Category D: Patient Recruitment and Retention

The oncology clinical trials nurse utilizes a variety of strategies to enhance recruitment and retention while being aware and respectful of the needs of diverse patient populations.

Required Knowledge

- Barriers affecting recruitment and retention to clinical trials such as:
  - demographic factors
  - underserved populations
  - institutional, healthcare, and insurance system influences
- Components of a recruitment and retention plan
- Clinical trials registries
- Targeted therapy impact on screening and recruitment
- Cultural impact on recruitment and retention
- Oncology clinical trials nurse responsibilities in recruitment and retention

Level 1 Behaviors

a. Identifies facilitators and barriers to recruitment and retention
b. Works with individual patients to address barriers to recruitment and retention
c. Identifies institutional or community-based resources or groups that can assist in achieving recruitment goals
d. Develops relationships and communication pathways with referring physicians, clinical staff, and ancillary departments to facilitate compliance with recruitment and retention to clinical trials
e. Applies recruitment strategies to promote timely accrual
f. Follows protocol-specific recruitment and retention plan, if available

Level 2 Behaviors

a. Identifies trends, facilitators, and barriers in recruitment and retention
b. Develops recruitment and retention plans
c. Assists the principal investigator and subinvestigators in the effective coordination of recruitment and retention efforts
d. Develops, implements, and assesses interventions to overcome identified recruitment and retention challenges
e. Evaluates and determines resources required to implement recruitment and retention plan
f. Consistently recognizes physician investigators and research staff for recruitment and retention efforts

Resources

- Center for Information and Study on Clinical Research Participation (www.ciscrp.org)
- AccrualNet™
- Five Steps to Enhance Patient Participation in Clinical Trials, Guide and Workbook (www.enacct.org/sites/default/files/ENACCT 5 Steps Guide 11 01_0.pdf)
- ONS *Manual for Clinical Trial Nursing,* Section IV
- Points to Consider about Recruitment and Retention (www.nimh.nih.gov/funding/grant-writing-and-application-process/recruitment-points-to-consider-6-1-05_34848.pdf)

Competency Category E: Management of Clinical Trial Patients

The oncology clinical trials nurse 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.

Required Knowledge

- Oncology disease process, including biology, staging, treatment, oncology emergencies, and symptom management
- The research protocol: organization and contents
- Common Terminology Criteria for Adverse Events (CTCAE)
- Patient-reported outcomes (PROs)
  - PRO-CTCAE
  - Role of quality-of-life assessments
- Response Evaluation Criteria in Solid Tumors (RECIST), Immunologic and Hematologic Response
- Resources available to patients with cancer (e.g., psychosocial, financial)
- Investigator's brochure, investigational new drug safety reports
- Rules and regulations related to the collections and processing of specimens

Level 1 Behaviors

a. Collaborates with the investigator to ascertain study patient eligibility for a clinical trial, including documentation of criteria specified in the protocol
b. Educates the patient and family regarding protocol participation, clinical condition, and/or disease process
c. Coordinates, schedules, and ensures timely completion of protocol-required events and other requirements (e.g., pharmacokinetics or -dynamics, scans, study visits, quality of life, PROs)
d. Identifies patients who require increased nursing assessment and management in addition to the clinical trial requirements and collaborate with other members of the healthcare team to ensure patient safety
e. Assesses individual patients for physical, psychosocial, and financial factors that could impact adherence with study requirements and implement interventions as necessary
f. Evaluates patient's adherence to and documentation of self-administered protocol agents and the return of such agents
g. Assesses adverse events and ensures evidence-based symptom management as permitted by the protocol
h. Collaborates with the investigator to determine if any treatment schedule or drug dose modification is necessary and communicates findings to the study team and other care providers
i. Collaborates with the investigator to determine disease response as defined by the protocol and communicates findings to the study team and other care providers
j. Ensures appropriate communication between research and clinical staff related to patient-specific care needs

Level 2 Behaviors

a. Develops study-specific materials for patient education and ensures institutional review board and sponsor approval, as required
b. Ensures protocol clarity in treatment modification guidelines
c. Assesses for and addresses trends that affect patient adherence to protocol-specific activities
d. Develops, implements, and assesses necessary interventions to address issues related to the patient population on a clinical trial
e. Collaborates with the interdisciplinary team to develop nursing practices that have the potential to improve patient outcomes
f. Provides guidance to participating sites related to patient management per protocol requirements
g. Facilitates accurate communication between research sites
h. Assesses for and addresses changes that increase the acuity of assigned protocols and that adversely affect protocol management abilities
i. Identifies and implements workload assessment tools and processes to ensure patient safety and data integrity

Resources

- CTCAE (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm)
- Cancer Therapy Evaluation Program-Adverse Event Reporting System (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm)
- National Comprehensive Cancer Network Guidelines (www.nccn.org/professionals/physician_gls/f_guidelines.asp)
- National Cancer Institute (www.cancer.gov/)
- ONS Clinical Trials Nurse Community toolkit: Patient Management (www.clinicaltrialtools.vc.ons.org/190168)
- ONS Putting Evidence Into Practice: evidence-based symptom management (www.ons.org/practice-resources/pep)
- *ONS Manual for Clinical Trial Nursing,* 3rd ed., chapters 10, 15, and 28
- PRO-CTCAE
- RECIST Criteria (http://clinicaltrialtools.vc.ons.org/file_depot/0-10000000/0-10000/1338/folder/1119270/RECIST_EORTC_NCI_AACR_OCtober_2008$5B1$5D.pdf)
  - Article 1 (www.eortc.be/Recist/documents/RECISTGuidelines.pdf)
  - Article 2 (http://clinicaltrialtools.vc.ons.org/file_depot/0-10000000/0-10000/1338/folder/1119270/RECIST+2000.pdf)

Competency Category E: Management of Clinical Trial Patients *(Continued)*

The oncology clinical trials nurse 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.

- Response assessment resources
- Slides: Clinical Trial Protocol Development (http://clinicaltrialtools.vc.ons.org/file_depot/0-10000000/0-10000/1338/folder/1119268/Protocol_development.pdf)
- Rules and regulations related to the collections and processing of specimens
- Tip sheet: Processing and shipping of specimens (http://clinicaltrialtools.vc.ons.org/file_depot/0-10000000/0-10000/1338/folder/8022/Quick_Guide_Specimens1.doc)
- Workload assessments
  - AccrualNet™ search workload
  - American Society of Clinical Oncology (ASCO) workload tool (https://workload.asco.org/user)
- 2013 ASCO/ONS Chemotherapy Biotherapy Guidelines (www.ons.org/practice-resources/standards-reports/chemotherapy)

Competency Category F: Documentation and Document Management

The oncology clinical trials nurse provides leadership to the research team in ensuring accurate source documentation and maintaining essential documents that validate integrity in the conduct of the clinical trial.

Required Knowledge

- State practice act
- American Nurses Association Standards of Practice
- Definitions
  - Source document
  - Essential documents
- Contents of a regulatory file or binder
- Institution's electronic medical record or electronic health record
- Record retention requirements at federal, state, and local level

Level 1 Behaviors

a. Documents all patient encounters in the legal medical record per licensure and institutional requirements
b. Obtains documents from outside providers or laboratories that are needed as part of the research data
c. Educates other research team members and clinical staff regarding appropriate and accurate source documentation for patients in clinical trials
d. Assesses documentation for discrepancies and ensures that inaccurate or discrepant documentation is addressed in the medical record or other source documents
e. Maintains the privacy and confidentiality of patients' source documents
f. Maintains essential documents in a regulatory file or binder per good clinical practice guidelines
g. Retains all research-related records according to regulations, guidelines, and institutional-specific policies

Level 2 Behaviors

a. Participates in the development of approved source documents, templates, or forms
b. Implement a plan to address identified trends related to noncompliance or deficiencies with source documents
c. Participates in the preparation of reports for appropriate regulatory agencies and monitoring bodies or boards

Resources

- American Nurses Association Standards of Practice (http://nursingworld.org/MainMenuCategories/ThePracticeofProfessionalNursing/NursingStandards)
- ICH Good Clinical Practice guidelines, specifically glossary and Section 8 (www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf)
- ONS Clinical Trials Nurse Community Documentation toolkit (www.clinicaltrialtools.vc.ons.org/190179)
- ONS *Manual for Clinical Trials Nursing,* 3rd ed., chapters 37 and 39
- Health Insurance Portability and Accountability Act guidelines (www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/research.html)

Competency Category G: Data Management and Information Technology

The oncology clinical trials nurse provides leadership in the collection of data and demonstrates basic information technology and computer skills to ensure data quality and patient confidentiality.

Required Knowledge

- Understand definitions
  - Data management plan
  - Clinical data management system
  - Clinical trial management system
  - Remote data capture
  - Quality control
  - Quality assurance
  - Quality improvement
  - Source document
  - Data queries or clarifications
  - Data sharing
- Basic computer skills
  - Word-processing applications
  - Spreadsheet applications
  - Use of local electronic medical record
- Sponsor-specific remote data capture systems
- Case report form (CRF) purpose, development, and relationship to protocol
- Components of a protocol-specific data management plan
- Protocol-specific data submission requirements
- How to correct data entry errors on paper CRFs

Level 1 Behaviors

a. Adheres to the data management plan developed for each clinical trial
b. Assists in troubleshooting data entry issues whether CRF is paper or electronic
c. Ensures that relevant data from source documents are abstracted and recorded on the protocol-specific CRFs in a timely and accurate manner
d. Ensures that all data recorded on CRFs can be verified within the source documents
e. Participates in quality control activities to ensure data integrity, including timely responses to database or sponsor queries
f. Protects patient, protocol, and scientific confidentiality by ensuring security of research data and personal health information
g. Enters data into electronic data capture systems, as applicable

Level 2 Behaviors

a. Assists the principal investigator in developing data management plans for each clinical trial
b. Develops quality improvement plans to ensure data integrity
c. Uses information management and computer technology to support clinical data management activities
d. Assists in developing CRFs for multisite trials if coordinating center

Resources

- U.S. Food and Drug Administration (FDA) Regulations
  - 21 Code of Federal Regulations Part 11 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
- FDA Guidance
  - Part 11 Electronic Signatures and Documents (www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm)
- Data Management course (www.coursera.org/course/datamanagement)
- ICH Good Clinical Practice Guidelines (www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html)
- Nursing Informatics Competencies user self-assessment (http://nursing-informatics.com/niassess/users.html)
- ONS *Manual for Clinical Trials Nursing,* 3rd ed., chapter 38
- Data-sharing resources
  - National Institutes of Health (NIH) sharing policies and related guidance on NIH-funded research resources (https://grants.nih.gov/policy/sharing.htm)
  - National Academies of Sciences (NAS) discussion framework for clinical trial data sharing: guiding principles, elements, and activities (www.nationalacademies.org/hmd/Reports/2014/Discussion-Framework-for-Clinical-Trial-Data-Sharing.aspx)
  - NAS sharing clinical trial data: maximizing benefits, minimizing risk (www.nationalacademies.org/hmd/Reports/2015/Sharing-Clinical-Trial-Data.aspx)
  - Pharmaceutical Research and Manufacturers of America (PhRMA) principles for responsible clinical trial data sharing (http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf)
  - PhRMA principles on conduct of clinical trials and communication of clinical trials results (www.phrma.org/principles-and-guidelines-clinical-trials)

Competency Category H: Financial Stewardship

The oncology clinical trials nurse identifies the financial variables that affect research and supports good financial stewardship in clinical trials.

Required Knowledge

- Rules for billing requirements
- Coverage analysis
  - Routine care versus research-specific costs
  - Regional Medicare or Medicaid contractor and requirements for billing compliance
  - Qualifying studies
  - Billing noncompliance risk-reduction processes
  - Billable versus nonbillable costs
  - Impact on the informed consent document
- Budget management
  - Key components of a study budget
  - Research site resources
- Research site billing process
  - Organization's key players for clinical trial billing compliance
  - Oncology clinical trials nurse's role related to research billing
- Research site patient compensation process
- Impact of state laws on clinical trials insurance coverage

Level 1 Behaviors

a. Facilitates accurate billing for study-required procedures by referring to each protocol's coverage analysis
b. Assists patients in identifying the financial impact of the study on them and makes appropriate referrals
c. Reports protocol-specific insurance coverage issues to lead study organization for possible consideration of protocol amendment
d. Verifies that routine care versus research-related cost descriptions in the protocol document match the consent document and vice versa
e. Ensures that the informed consent document identifies that stipends to patients for protocol-related activities are disclosed
f. Provides information needed for the appeal process when a payer declines coverage for patients on clinical trial
g. Ensures timely submission of specified items (e.g., completed case report forms, specimens) to facilitate prompt recovery of protocol-related activity costs

Level 2 Behaviors

a. Assists the principal investigator and/or finance personnel in determining when protocol requirements or revisions will affect the cost of protocol management
b. Assists in the assessment and/or development of the coverage analysis and has the ability to determine "qualified" clinical trial status
c. Analyzes a protocol to identify routine care versus research-related costs and how each is being covered by local Medicare contractor
d. Develops a quality assurance process for tracking submission of specified items (e.g., completed case report forms, specimens) to facilitate prompt recovery of protocol-related activity costs

Resources

- Medicare Benefit Policy Manual, chapter 14
- National Coverage Determination for Routine Costs in Clinical Trials 310.1 Clinical Trial Policy
- Patient Protection and Affordable Care Act
- Health Care Reform and Education Act
- Training Manual for Clinical Trials Billing Compliance (http://aegis-compliance.com/trainingmanual.html)
- ONS *Manual for Clinical Trial Nursing,* Section III
- ONS Clinical Trials Nurse Community financial implications toolkit (www.clinicaltrialtools.vc.ons.org/190189)

Competency Category I: Leadership and Professional Development

The oncology clinical trials nurse utilizes leadership skills to inspire and motivate the clinical research team toward the common goal of conducting quality clinical research to enhance cancer care across the continuum and takes responsibility for his or her ongoing professional development.

Required Knowledge

- American Nurses Association (ANA) professional practice standards
- Research site culture, structure, vision, and mission
- Qualities of an effective team and project leader
- Professional portfolio
- Evidence-based practice and levels of evidence

Level 1 Behaviors

a. Identifies gaps in knowledge and skill related to the role as an oncology clinical trials nurse (OCTN) and develops, evaluates, and revises own professional goals to address these gaps
b. Participates in educational opportunities to address identified knowledge and skill gaps related to role as an OCTN
c. Utilizes strong communication and collaboration skills with research team members and others involved in clinical research

Level 2 Behaviors

a. Pursues opportunities to participate in local or national research-related activities (e.g., professional nursing and/or research organizations, institutional committees)
b. Provides mentorship to new clinical trials nurses, research team members, and other healthcare providers
c. Defines the role of the OCTN at an institution by developing tools (e.g., job descriptions, competency assessment that delineates OCTN responsibilities)
d. Demonstrates the ability to inspire and motivate OCTNs and others involved in clinical research
e. Advocates for clinical trials by participating in community outreach efforts to provide general clinical trials education when opportunities arise
f. Disseminates information about the impact of new treatments on cancer care and nursing practice
g. Participates in the development of publications related to clinical trials with focus on patient management and impact on current or future nursing practice

Resources

- ANA professional practice standards
- Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
- ONS leadership competencies (www.ons.org/sites/default/files/leadershipcomps.pdf)
- ONS *Manual for Clinical Trials Nursing,* Section X
- Professional journals (e.g., *Journal of Nursing Management, The Monitor, SoCRA Source, Oncology Nursing Forum, Clinical Journal of Oncology Nursing*)
- ANA Leadership Institute (www.ana-leadershipinstitute.org/Doc-Vault/About-Us/ANA-Leadership-Institute-Competency-Model-pdf.pdf)
- Nursing Times Leadership Skills for Nurses (www.nursingtimes.net/Journals/2011/08/24/j/n/i/Leadership-Skills-for-Nurses.pdf)

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