Clinical Trials Nurse Competencies

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Objectives

• Describe the process used in developing competencies for the novice oncology clinical trial nurse.
• Discuss how the clinical trial nurse competencies can be implemented in practice.
Why Draft Competencies for CTNs?

• Great variability in CTN position titles, role implementation and background
• Need for role clarification and standardization
• Need to validate the unique contribution that nurses bring to clinical trials
• Lack of literature defining the role of the oncology CTN
Literature on CTN Role

- Most literature on CTN role anecdotal
- Clinical Trials Nursing Questionnaire (CTNQ)
  - Developed and validated in 2004\(^1\)
  - Translated to Italian and validated in 2008\(^2\)
  - Used to study the clinical research nurse role pediatric oncology\(^3\)
- ONS Manual for Clinical Trials Nursing\(^4\)

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\(^1\) Ehrenberger and Lillington, 2004  
\(^2\) Catania et al, 2008  
\(^3\) Nagel, Gender & Bonner, 2008  
\(^4\) Klimaszewski et al, 2008
Charge for CTN Competency Development

• ONS believes that oncology nurses are essential to the effective conduct of cancer treatment and prevention trials\(^1\)
• Consistent feedback from the ONS membership, especially the CTN Special Interest Group, about need for resources
• In 2007, ONS leadership called for the development of clinical trials competencies.

\(^1\)ONS Position on Cancer Research and Clinical Trials, 2009
CTN Competency Development Team

• Five ONS members currently working in oncology clinical trials
• Chosen based upon experience with clinical trials and defining competencies/job descriptions in diverse practice settings

  Penny Daugherty, RN, MS, OCN
  Linda Schmieder, MSN, RN, CCRC
  Marjorie Good, RN, BSN, MPH, OCN
  David Leos, RN, BSN, MBA, OCN, CCRA
  Patricia Weiss, RN, MSN, OCN, CCRP
  Barbara Lubejko, RN, MS (ONS staff)
Competency Development Process

• Three step process
  – Initial competency draft
  – Field review
  – Expert review
• Consistent with process and format used for the ONS Clinical Nurse Specialist and Nurse Practitioner competencies
• Focus on novice CTN
Oncology CTN Competencies - Definition

- Oncology clinical trials nurse core competencies include 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) assure that scientific integrity is maintained through data reliability and strict adherence to regulatory mandates.
Mission and Core Values

• **Project Team Mission:** To delineate the core values, skills, knowledge, and expertise required to become proficient as an oncology CTN, highlighting the unique contribution that nurses, and the nursing process, bring to clinical trials practice.

• **Core Values of CTN 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.
Development of Draft Competencies – Resources Reviewed

- Published articles on CTN role
- ONS Manual for Clinical Trials Nursing\(^1\)
- Position descriptions from a variety of institutions
- Education modules on the ONS CTN SIG Virtual Community
- Research management curricula from schools of nursing
- Training manual outlines from cancer cooperative groups

\(^1\)Klimaszewski et al, 2008
Development of Draft Competencies: Questionnaire

• Two questions
  – Demographic data
  – Open ended question: *Please list the essential knowledge, skills and expertise required of an oncology clinical trials nurse. For each item, please indicate whether it is a basic or an advanced competency.*

• Sent to random sample of ONS members who identified themselves as oncology clinical trials nurses.

• 90 surveys were sent with 19 returned (21% response rate).

• Respondents:
  – Average 12 years experience
  – All phases and types of trials
  – Variety of work settings
Initial Draft Competencies

• 11 functional areas with general goal statements
• 109 competency statements focused on expected behaviors
• Focus:
  – Reasonable expectations of a novice CTN nurse
  – Apply across a wide variety of settings.
Field Review

• Each competency statement evaluated on the three points
  – Represents an essential function of the clinical trials nurse in a wide variety of settings.
  – Is clearly written to facilitate consistent interpretation and implementation across practice settings.
  – I support inclusion of this competency in the final document.
  – Other comments
Field Review Responses

• 1,617 surveys sent out with 247 responses received (15% response rate).
• Respondent demographics
  – From all regions of the country (44 states)
  – Wide variety of practice settings
  – 61% having more than six years of experience as a CTN.
  – Significant diversity in educational preparation.
  – 74% ONCC certified
  – 34% SOCRA or ACRP certified
  – Involved in all types and phases of oncology clinical trials from cooperative groups, industry, and individual institutions.
Edits After Field Review

- Reduced number of competency statements to 68
- Removed competencies that were not core or were beyond the role of most novice CTNs
- Reduced duplication
- Clarified other statements
Expert Review

• Two parts
  1. Overall competency document
     • Flow
     • Competency category appropriateness
     • Comprehensiveness or redundancy of competency listing
     • Reflection of nursing’s contribution
  2. Review of individual competency statements
     • Appropriateness for novice CTN
     • Clarity
     • Comments
Expert Review Outcomes

• Reduced Competency Categories to 9
  – Protocol Compliance (incorporated Study Design)
  – Clinical Trials-Related Communication
  – Informed Consent Process
  – Management of Clinical Trials Patients
  – Documentation (incorporated Research-Related Technology)
  – Patient Recruitment
  – Ethical Issues
  – Financial Implications
  – Professional Development

• Ended up with a total of 54 competency statements
Oncology CTN Nursing Competencies: Protocol Compliance

- Adherence with protocol requirements, regulations, guidances and policies
- Ensuring confidentiality and validity of research results
- Assessment of protocol feasibility
- IRB compliance and communication
- Monitor and auditing visits
- Proper use of and accountability for experimental devices or drugs
Oncology CTN Nursing Competencies: Clinical Trials Related Communication

- Research team communication
- Providing research related information to other staff
- Developing relationships to facilitate compliance and accrual
- Patient education
- Advocacy for clinical trials and patients enrolled
Oncology CTN Nursing Competencies: Informed Consent Process

• Initial and ongoing consent process performance and documentation
• Initial and ongoing patient education about pertinent clinical trial
• Addressing barriers to effective informed consent
Oncology CTN Nursing Competencies: Management of Clinical Trial Patients

- Assurance of eligibility criteria
- Adherence to protocol activities and assessments
- Assessment for protocol and non-protocol related side effects
- Evidence-based symptom management
- Grading, documentation and reporting of adverse events
Oncology CTN Nursing Competencies: Management of Clinical Trial Patients

• Need for treatment or dose modifications based on adverse events
• Disease response data collection and evaluation
• Patient adherence
• Management of vulnerable patients
Oncology CTN Nursing Competencies: Documentation

- Collection and documentation of source data
- Education of research team and clinical staff about documentation needs
- Abstraction and recording of data into clinical trial case report forms/systems
- Regulatory documents
- Clinical and research-related technology
Oncology CTN Nursing Competencies: Patient Recruitment

- Recruitment plans and individual eligibility
- Addressing barriers to recruitment
- Identifying resources
Oncology CTN Nursing Competencies: Ethical Issues

- Advocacy for ethical care and clinical trials
- Protections for vulnerable populations
- Data and scientific integrity
Oncology CTN Nursing Competencies: Financial Implications

• Identifies key budget components and resources
• Differentiate between routine care and research-related costs
• Ensures timely submission to facilitate recovery of costs
Oncology CTN Nursing Competencies: Professional Development

- Education to increase knowledge about clinical trials and role
- Updates on oncology treatment and nursing practice issues
Full version of the Oncology Clinical Trials Nurse Competencies:
http://www.ons.org/media/ons/docs/publications/ctncompetencies.pdf
Tackling Implementation

• Core Competencies document released 2010
  – Circulated to
    • Human Resources
    • Office of Clinical Research
    • Section Chief
    • Clinical Trials Nurse
    • And anyone else who would read it!
Organized Approach

- Establish a team
- Select a model
- Review the literature
- Solicit staff suggestions
- Network with peer institutions
Model for Process Improvement

- **Plan** Develop a plan for improving quality at a process
- **Do** Execute the plan, first on a small scale
- **Study** Evaluate feedback to confirm or to adjust the plan
- **Act** Make the plan permanent or study the adjustments
Areas for Implementation

• Job Description
• New CTN Skills Check-list
• Fundamentals of Clinical Research Course
• Performance Evaluation Tool
• Annual Competency Assessments
• Integration with Shared Governance Model as a Magnet recognized facility
• Career Ladder
Job Description

• Re-design of staff, non-union compensation was already in progress
• Extensive resources had been already devoted to updating job families that defined career paths and promotional opportunities
• Created
  – Standard position summary
  – Required Competencies
Orientation Skills Checklist

• Reviewed skills checklist in comparison to competency publication
• Re-organized essential CTN skills by competency category
Competency Assessments

• Current competency assessment tools for a CTN focus on clinical aspects of care
• Needed to define competence in relation to CTN responsibilities
  – Essential building blocks that shape the CTN work
  – Allows CTN to demonstrate how they meet increasingly challenging levels of competence
• Next Steps
  – Develop competency skills assessment
    • Example: Research Billing Competency
Didactic Coursework

- Fundamental of Clinical Research Course
  - Interactive lecture
  - Comprehension Assessment (post-test)
  - Q/A
  - Contact Hours earned
  - Certificate awarded at completion
Modules

• Successful Navigation of Research Infrastructure at UC
• Research Background
• Clinical Trials: From Concept to Consent
• IRB Overview
• *Informed Consent Process*
• Federal Regulations & Guidelines for Clinical Research
• *Research Documentation*
• Audits & Monitoring
• Introduction to Research Billing: What you really need to know
• Comprehensive Review
Performance Evaluation Tool

• Current appraisal form is non-specific
  – Job knowledge
  – Accountability/Dependability
  – Quality/Quantity of work
  – Service orientation
  – Initiative
  – Interaction with others

• Opportunity exists to craft a CTN appraisal tool based on key competencies
Shared Governance Model

A model in which nurses are formally organized to make decisions about clinical practice standards, quality improvement, staff and professional development and research

1American Nurses Credentialing Center. The Magnet Model Components and Sources of Evidence, 2008.
Shared Governance Model
What’s In It For CTN’s?

• All nurses can have a voice in improving clinical practice
• Promotes Evidence Based Practice
• Improves nursing satisfaction, which leads to improved patient satisfaction
• Allows nurses to network with peers, other departments & management to achieve organizational goals
Shared Governance Model

• Next Steps
  – Form Unit-Based Council
  – Form Local Practice Council
    • Oncology CTN’s
    • Infusion Therapy Special Procedure Nurses
    • Oncology Collaborative Nurses
    • Oncology Clinic Nurses
Career Ladder

• Currently only 2 steps in career ladder
  – Research Nurse
    • Need to establish ladder
      – Novice
      – Experienced
      – Senior
  – Cluster Leader
Lessons Learned

• Change takes time
• Persistence is needed
• Start small for an early win
• Use that early win to get noticed
• Scale up when ready
• Support from leadership critical
Bibliography

• American Nurses Credentialing Center. (2008). The Magnet Model Components and Sources of Evidence, Silver Spring, MD.


