Clinical Trials: Is Your Staff Competent?

What fundamental skills and knowledge should clinical trials nurses have? In response to questions from its members about how to measure qualified staff, ONS developed the Clinical Trials Nurse (CTN) Core Competencies. In this session, you’ll learn how these competencies have been implemented by your peers, as well as how they were developed.

Content Area: Education

Content Level: Intermediate

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Objectives:
At the end of this session, participants will be able to:
1. Determine behavioral indicators that could be used in assessing CTN competencies.
2. Analyze various ways the CTN competencies can be used in practice.

Content Outline:
I. The ONS CTN Competencies
   A. Background
   B. Mission and core values
   C. List of core competencies
II. Behavioral indicators
   A. Definition of
   B. In relation to the CTN Competencies
III. Applications to practice
   A. Orientation programs for novice oncology CTNs
   B. Competency checklists to delineate performance expectations
IV. Future applications
   A. Evaluation of OCN CTN Competencies
   B. Basis for the development of an oncology CTN certification

Bibliography:


The CTN Competencies: Background on “Why”

- Great variability in CTN position titles, role implementation and educational background
- Expressed need for comprehensive curriculum
- Need for role clarification and standardization
- To validate nurse’s contribution to clinical trials
- Lack of literature defining oncology CTN role

Literature on CTN Role

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

\(^{1}\)Ehrenberger and Lillington, 2004  \(^{2}\)Napel, Gender & Bonner, 2008
\(^{3}\)Catania et al, 2008  \(^{4}\)Klimaszewski et al, 2008

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

Mission and Core Values

- To delineate the core values, knowledge, and expertise required to be proficient as an oncology CTN
- 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 added value that professional nurses and the nursing process contribute to the successful conduct and outcomes of clinical trials

List of Core CTN Competencies

- Protocol Compliance
- Communication
- Informed Consent process
- Management of participants on trial
- Documentation
- Participant recruitment
- Ethical Issues
- Financial Implication
- Professional development

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 investigational devices or drugs
### 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

### Informed Consent
- Initial and ongoing consent process performance and documentation
- Initial and ongoing patient education about pertinent clinical trial
- Addressing barriers to effective informed consent

### Management of Clinical Trial Participants
- 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

### Management of Clinical Trial Participants
- Need for treatment or dose modifications based on adverse events
- Disease response data collection and evaluation
- Patient adherence
- Management of vulnerable patients

### 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

### Participant Recruitment
- Recruitment plans and individual eligibility
- Addressing barriers to recruitment
- Identifying resources
Ethical Issues
- Advocacy for ethical care and clinical trials
- Protections for vulnerable populations
- Data and scientific integrity

Financial Implications
- Identifies key budget components and resources
- Differentiate between routine care and research-related costs
- Ensures timely submission to facilitate recovery of costs
- Ensures that stipends to pts are disclosed

Professional Development
- Education to increase knowledge about clinical trials and role
- Updates on oncology treatment and nursing practice issues

Oncology CTN Behavioral Indicators
- Definition: behaviors/indices conducive to the practice of clinical trials nursing. CTNs are expected to bring certain inherent skills to the role including:
  - Effective communication
  - Effective interpersonal skills
  - Teamwork orientation
  - Autonomy
  - Critical thinking/problem solving
  - Organizational skill/attention to detail
  - Priority setting ability
  - Strong Computer skills

Behavioral Indicators
- Professional Indicators:
  - Practice-based
    - Oncology practice experience
    - Oncology certification
  - Educational
    - Human Subjects Training
    - ONS Chemo/Biotherapy course
    - Clinical Trials Nursing 101
    - Clinical Trials Awareness on a Global Level

Applications to Current Practice
- Job Description
- New CTN Orientation Skills Check-list
- Fundamentals of Clinical Research Course
- Performance Evaluation Tool
- Annual Competency Assessments
Orientation Skills Checklist

- Compare existing skills checklists to the Competencies
- Re-organize essential CTN skills by Competency category
- Develop skills checklists based on and organized by Competency category

Competency Assessments

- Define competence in relation to CTN responsibilities
  - Essential building blocks that shape the CTN’s work
  - Allows CTN to demonstrate how they meet increasingly challenging levels of competence
- Develop competency skills assessment
  - Example: Research Billing, consenting competency

Performance Evaluation Tool

- Review current evaluation/appraisal form against competencies
- Work with organization to incorporate

Future Applications

- On-going evaluation of OCN CTN Competencies
  - Living document to mirror the standards of practice
- Basis for developing of oncology CTN certification
- May be adapted by non-oncology CTNs

Reason for Action

- Variation on Job title and Duties
- Clarification of roles and responsibilities
- Update Current Job Description
- Need to develop yearly evaluation for Clinical Research Nurse (CRN) role
- Need to Standardize orientation process and to validate skills competency.

Job Description: Nurse Coordinators

- Vague and Generic
- Used for all Nurse Coordinators:
  - Hematopoietic Cell Transplant Nurse Coordinators
  - Clinical Research Nurses
  - Clinic Nurses
  - Others
Review of Orientation Process

- Lacked Standardization
- Inadequate tools to assist preceptor
- Lacked focus
- Nurses worked in disease clusters
  - Practice varied
  - Roles and Responsibilities varied

Review of Evaluation Process/Form

- Generic Nurse Coordinator
- Did not reflect the Competencies of CTN
- Same Evaluation used for:
  - Hematopoietic Cell Transplant Nurse Coordinators
  - Clinical Research Nurses
  - Clinic Nurses
  - Others

Article/Policy Review

- Literature varied in defining “nurse coordinator/research/trial nurse”
- Most literature did not specify clinical trial nurse role competency
- COH Policy needed revision
- Clinical Trial Network Best Practices: Great resource for tools, templates and training
- ONS Clinical Trial Nurse Competencies (2010) identified basic knowledge, skills and proficiency needed for CTN function

What did City of Hope do?

- Developed new Job Description
- Modified existing Competence Evaluation Form
- Created Practical Orientation Form
- Designed role specific detailed skills inventory list: Skills Matrix Tool
- Administered Self Skills Assessment Evaluation Survey

Annual Evaluation

Practice Standard focused on 5 Competency Categories:

1. Study Initiation
2. Screening and Consenting
3. Management of Patient on Clinical Trials
4. Communication and Documentation
5. Protocol Compliance and Management

Comparison of ONS and COH Competency Categories

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<th>City of Hope Competency Categories</th>
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<td>Clinical Trials-Related Communication</td>
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Oncology Nursing Society, 2010
5 Competency Categories and 42 Skills Competencies/Inventory

1. Study Initiation (9 Skills Competencies)
2. Screening and Consenting (6 Skills Competencies)
3. Management of Patient on Clinical Trials (13 Skills Competencies)
4. Communication and Documentation (8 Skills Competencies)
5. Protocol Compliance and Management (6 Skills Competencies)

Self Assessment Survey

Self-assessment survey was developed to review gaps in practice
- Reviewed current skills and competence
- Utilized Novice to Expert Rating Scale
- Administered via online survey
- Individual results were documented on Skills Matrix
- Will be utilized to develop future education/skills competency validation

Novice to Expert

Novice
- Beginner with no experience
- Ex. “Tell me what I need to do and I’ll do it.”

Advanced Beginner
- Demonstrates acceptable performance
- Has gained prior experience in actual situations to recognize recurring meaningful components

Competent
- Gains perspective from planning own actions based on conscious, abstract, and analytical thinking and helps to achieve greater efficiency and organization

Proficient
- Perceives and understands situations as whole parts
- Learns from experiences what to expect in certain situations and how to modify plans
- No longer relies on principles, rules, or guidelines to connect situations and determine actions

Benner, 1982

Skill Competency Matrix Tool Utilization

- Gap Analysis
- Hiring New Staff
- Assigning New Work
- Identifying Development Needs
- Selecting Preceptor/Coach

Impact

- CRN job description and newly created evaluation form is part of defining COH CRN coordinator’s role.
- ONS CTN Core competencies guided to create CRN individualized practical orientation form and Skills Matrix Tool.
- CRN skills competency self-assessment survey will be utilized:
  - to determine gaps in CRN skills
  - to develop CRN educational program

In Development:

- Review of Skills Matrix Tool
- Education plan:
  - Review of Good Clinical Practice
  - Clinical Research Nurse Role specific in-services
  - Development of SOPs and Standard Work
  - Role Specific Orientation Binder/References
COH Skills Categories Inventory

Study Initiation
1. Understands Process Creating SRO in collaboration with IDS Pharmacy
2. Demonstrate ability of defining CRC expectations with CRC
3. Collaborates in creating eligibility checklist
4. Participate in site qualification visit and site initiation visit
5. Create database for tracking patients
6. Assure all regulatory study documents submitted to IRB
7. Participate in subject evaluation appointment
8. Set up study chart
9. Advocates for the safety and care of clinical trial patients

Screening & Consenting
1. Complete eligibility forms completely
2. Confirm subject eligibility and assure study registration
3. Reviews consent with patient/family
4. Obtains subject signature accurately on consent
5. Obtains required HIPAA documents
6. Accession consent and HIPAA into clinical trials database

Management of Clinical Research Patients
1. Coordinates scheduling of protocol required appointments
2. Writes orders for study diagnostic tests per standardized procedure
3. Assures treatment orders are written per standard research order
4. Completes checklist before sending orders to Investigational Drug Services (IDS)
5. Maintain research chart
6. Maintain case report forms with CRC
7. Demonstrates ability to resolve patient or protocol issues
8. Collaborates with PI for single subject exemptions
9. Assess and determine Serious Adverse Event (SAE)
10. Assess toxicity, Adverse Events, using toxicity taxonomy (CTCAE)
11. Assures drug accountability and patient compliance for oral agents
12. Maintain research databases
13. Ongoing review of Concomitant & prohibited medications

Communication and Documentation
1. Documents Toxicity in medical records and research chart
2. Documents toxicity using toxicity taxonomy (CTCAE)
3. Reports SAE and documents SAE in chart
4. Document and Educates patient & family regarding protocol
5. Educates others regarding protocol
6. Documents findings in medical record and research chart
7. Instructs others for obtaining study specimens
8. Documents concomitant & prohibited medications
Protocol Compliance & Management

1. Participates in discussions regarding feasibility of protocol implementation
2. Actively Participates in Monitoring & Auditing visits
3. Advocates for Patient's ethical care while on protocol
4. Participates in on-going Sponsor required meetings, on & off site
5. Protects patient, protocol, and scientific confidentiality by ensuring security of research data and PHI.
6. Complies with the IATA and institutional policies for shipping and receiving specimens, agents