The Evolving Role of Nurses in Early Phase Research

Clare Hastings, RN, PhD, FAAN
Chief Nurse Officer, Clinical Center
April 27, 2012
Disclosure Statement:

• Nothing to disclose
Goals for session

- Define the Domain of Practice that differentiates Clinical Research Nursing as a specialty

- Describe the unique features of early phase research in terms of the requirements for nursing care

- Discuss considerations when staffing a clinical research unit for early phase work
Clinical Research: A System Under Stress

- National calls for increase in the pace of translation
- Focus on severe and chronic conditions as well as rare diseases
- Explosion in the amount of genetic and biologic information available
- Greater need and greater constraint in resources
- Challenges of globalization
Top Minds are Focused on Us
What is the Challenge to Clinical Pharmacology Units?

• Be prepared for a rapid response to a new opportunity with expert staff and infrastructure

• Expand capability to study first-in-human applications of new drugs and devices in healthy participants as well as patients with the condition proposed for treatment
  ➢ Provide clinical treatment during research participation
  ➢ Prepare to balance the demands for clinical vs. research activities
NIH Clinical Center: America’s Research Hospital

- Supports intramural clinical research conducted by the Institutes and Centers of the NIH

- Creates and disseminates standards and innovations for conducting clinical research

- Creates and demonstrates models for clinical research training and career development for all disciplines
Unique Capabilities of the NIH Clinical Center

- 240 bed research hospital and clinics
- Staff and infrastructure dedicated to clinical research
- Close proximity of multiple disciplines
- No payment by patients or insurers
- “Bench-to-Bedside” link to support rapid translation of discoveries into practice
Major Emphasis

• First in human with new therapeutics

• Study of patients with rare diseases
<table>
<thead>
<tr>
<th></th>
<th>FY 07</th>
<th>FY 08</th>
<th>FY 09</th>
<th>FY 10</th>
<th>FY 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>68</td>
<td>72</td>
<td>69</td>
<td>67</td>
<td>71</td>
</tr>
<tr>
<td>Training</td>
<td>31</td>
<td>28</td>
<td>25</td>
<td>21</td>
<td>22</td>
</tr>
<tr>
<td>Natural History</td>
<td>642</td>
<td>646</td>
<td>623</td>
<td>580</td>
<td>557</td>
</tr>
<tr>
<td>NH Sample Data Analysis</td>
<td>39</td>
<td>59</td>
<td>84</td>
<td>120</td>
<td>156</td>
</tr>
<tr>
<td>Pharmacodynamics/Kinetics</td>
<td>5</td>
<td>12</td>
<td>15</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>605</td>
<td>632</td>
<td>635</td>
<td>638</td>
<td>691</td>
</tr>
<tr>
<td>Phase 0 (micro-dose, first-in-humans)</td>
<td>6</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Phase 1 (toxicity)</td>
<td>204</td>
<td>209</td>
<td>204</td>
<td>198</td>
<td>215</td>
</tr>
<tr>
<td>Phase 1-2 (toxicity and activity)</td>
<td>15</td>
<td>30</td>
<td>46</td>
<td>70</td>
<td>86</td>
</tr>
<tr>
<td>Phase 2(activity)</td>
<td>323</td>
<td>332</td>
<td>325</td>
<td>307</td>
<td>326</td>
</tr>
<tr>
<td>Phase 3 (efficacy)</td>
<td>38</td>
<td>35</td>
<td>38</td>
<td>39</td>
<td>36</td>
</tr>
<tr>
<td>Phase 4 (safety)</td>
<td>19</td>
<td>17</td>
<td>14</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>1390</td>
<td>1449</td>
<td>1451</td>
<td>1443</td>
<td>1513</td>
</tr>
</tbody>
</table>
A Global Agenda to Define and Support the Practice of Nurses in Clinical Research
Clinical research nursing: A critical resource in the national research enterprise

Clare E. Hastings, RN, PhD, FAAN1, Cheryl A. Fisher, RN, EdD2, Margaret A. McCabe, RN, PhD
The National Clinical Research Nursing Consortium3

1 National Institutes of Health Clinical Center, Bethesda, MD
2 Boston Children’s Hospital, Boston, MA

Received 17 August 2009; revised 3 October 2011; accepted 13 October 2011; available online 14 December 2011.

http://dx.doi.org/10.1016/j.outlook.2011.10.003, How to Cite or Link Using DOI
Permissions & Reprints

Abstract

Translational clinical research has emerged as an important priority for the national research enterprise, with a clearly stated mandate to more quickly deliver prevention strategies, treatments and cures based on scientific innovations to the public. Within this national effort, a lack of consensus persists concerning the need for clinical nurses with expertise and specialized training in study implementation and the delivery of care to research participants. This paper reviews efforts to define and document the role of practicing nurses in implementing studies and coordinating clinical research in a variety of clinical settings, and differentiates this clinical role from the role of nurses as scientists and principal investigators. We propose an agenda for building evidence that having nurses provide and coordinate study treatments and procedures can potentially improve research efficiency, participant safety, and the quality of research data. We also consider the opportunities for nurse scientist role development.
Definition of Clinical Research Nursing

Clinical research nursing is nursing practice with a specialty focus on the care of research participants and the process of clinical research.

1. Providing and coordinating clinical care in the context of a research study
2. Assuring participant safety
3. Maintaining ongoing informed consent
4. Managing protocol implementation
5. Assuring accuracy of data collection and recording

Care received by research participants is driven by study requirements and the collection of research data as well as clinical indications.
Care and Research in Clinical Research

Clinical Research Process

Patient Care Process

Protocol Approval

Patient Recruitment

Informed Consent

Admission

Eligibility/Screening

Initial Assessment

Protocol Consent/Randomization

Multi-Disciplinary Plan of Care

Data Collection

Treatment

Patient Monitoring/Evaluation

Plan for Next Level of Care

Dissemination of Results

Data Analysis

F/U Plan Communicated

Discharge/Transfer

Eligibility/Screening

Protocol Consent/Randomization

Data Collection

Data Safety Monitoring

F/U Data Collection Plan

Patient Recruitment

Informed Consent

Admission

Initial Assessment

Multi-Disciplinary Plan of Care

Treatment

Patient Monitoring/Evaluation

Plan for Next Level of Care

Dissemination of Results

Data Analysis

F/U Plan Communicated

Discharge/Transfer

Protocol Approval

Patient Recruitment

Informed Consent

Admission

Eligibility/Screening

Initial Assessment

Protocol Consent/Randomization

Multi-Disciplinary Plan of Care

Treatment

Patient Monitoring/Evaluation

Plan for Next Level of Care

Dissemination of Results

Data Analysis

F/U Plan Communicated

Discharge/Transfer

Discover America's Research Hospital
The NIH Clinical Center
Specialty Definition Steps

• Define practice domain
• Establish practice standards
• Determine core competencies
• Develop tools to assist clinicians, managers and educators (core curriculum, staffing standards, core courses, etc.)
• Develop certification process
Developing and Validating the CRN Domain of Practice at the NIH Clinical Center

- **2007**: “Role Clarity” CRN\textsuperscript{2010} Team collected documents and verbal vignettes reflecting CRN practice in the NIH intramural program
- **2008-2009**: “Domain of Practice” CRN\textsuperscript{2010} Team conducted national Delphi study to validate taxonomy
- **2009-2010**: “Role Delineation” CRN\textsuperscript{2010} Team conducted survey of nurses within the NIH Intramural Program to profile roles of the Clinical Research Nurse and Research Nurse Coordinator across practice settings
- **2011**: Applied CRN Domain of Practice in the development and testing of Clinical Research Nursing competencies (competency implementation in 2012)
- **Next steps**: Conduct national survey to compare roles across settings within the national clinical research enterprise. Support doctoral student projects that test and evaluate the Domain of Practice as a conceptual framework.
Our Practice Domain Taxonomy

Domain
Specialty Practice Area

Dimension
Distinctive Categories within the Domain

Activities
Specific Job Descriptors within each Dimension
Clinical Research Nursing Specialty Practice Domain

- Clinical Practice
- Study Management
- Care Coordination and Continuity
- Human Subject Protection
- Contributing to the Science
Clinical Practice

Provision of direct nursing care and support, using the nursing process, to participants in clinical research, their families and significant others. Care requirements are determined by the scope of study participation, the clinical condition of the patient and the requirements and clinical effects of research procedures.
Study Management

Management of clinical and research support activities in order to assure patient safety, address clinical needs and assure protocol integrity and accurate data collection.
Care Coordination and Continuity

Coordination of research and clinical activities to meet clinical needs, complete study requirements and manage linkage with referring and primary care providers.
Human Subject Protection

Facilitation of informed participation by diverse participants in clinical research.
Contributing to the Science

Contribution as a research team member to the development of new ideas for study and explorations of innovations arising from clinical research finding to practice.
Clinical Research Nursing Includes Two Major Roles

- **Clinical Research Nurses** (primary focus: care of research participants)
- **Research Nurse Coordinators** (primary focus: implementation of clinical studies)
Described the nursing roles in clinical research at the NIH

Activity frequency suggests 2 clear nursing roles

- Clinical Research Nurse
  - Direct patient care – clinical practice
- Research Nurse Coordinator
  - More experience and full time
  - Study management and care coordination and continuity
Role Delineation Study

Results

Current Nursing Position
- Clinical Research Nurse: 70%
- Research Nurse Coordinator: 18%
- Nurse Practitioner: 4%
- Other: 8%

Primary Specialty Population
- Oncology: 41%
- Behavioral/Mental Health: 10%
- Medical/Surgical: 41%
- Critical Care: 2%
- OR/PACU: 1%
- Other: 5%
Comparison of Dimension Use: Clinical Research Nurses vs. Research Nurse Coordinators*

CRN

RNC

*From NIH Role Delineation Study
What is Unique About Early Phase Research?

- More unknowns
- Smaller sample sizes
- May or may not involve participants with the condition of interest
- May involve complex research procedures that do not have a clinical goal (pharmacokinetics)
“Phase I Nursing Care”

Nursing implication of “first-in-humans” studies

• Developing “mechanism-based” strategies to promote patient safety
• Developing techniques for managing and evaluating treatment delivery systems that have never been attempted in humans before
• Learning practical clinical implications of new modalities
• Understanding quality of life implications for new treatments for advanced or incurable disease
• Developing strategies for informed consent and patient education
How is the Domain of Practice Different in Phase 1 Work?

- Clinical Practice
- Study Management
- Care Coordination and Continuity
- Human Subject Protection
- Contributing to the Science
Staffing Decisions When Planning a Study

• Regulatory requirements
  – Licensure (related to medication administration, clinical procedures such as IV management, emergency management)
  – Investigator delegation and supervision
• Risk management
  – What “could happen”
  – Critical thinking and clinical judgment needs
• Education and Coordination needs
  – During research procedures
  – After leaving the research center
• Cost
• Efficiency
Most Important Consideration in Early Phase Research

Patient Safety
How Do We Justify the Need for Nurses?

Currently – anecdotally:

- Responses from participants
- Study implemented “more smoothly”
- “Fewer errors”
- Investigators able to “implement and complete studies more rapidly”
- “Sponsor needs met” (Coordination, information sharing, processing of data and specimens, coordination of regulatory documents)
Outcome Measurement is our Next Challenge…
# Measuring the Contribution of Clinical Research Nurses

<table>
<thead>
<tr>
<th>Contribution Area</th>
<th>Potential Outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention design and implementation planning within the clinical setting</td>
<td>Efficiency; intervention fidelity</td>
</tr>
<tr>
<td>Participant recruitment and consenting</td>
<td>Study accrual; adherence to human subjects protection standards</td>
</tr>
<tr>
<td>Participant education and support regarding self managed study procedures and evaluation</td>
<td>Participant safety; treatment fidelity; efficiency; subject retention; data quality</td>
</tr>
<tr>
<td>Direct administration of study treatments and evaluations</td>
<td>Participant safety; treatment fidelity; efficiency; data quality</td>
</tr>
<tr>
<td>Participant monitoring for response and adverse events</td>
<td>Participant safety; adherence to human subjects protection standards; data quality</td>
</tr>
<tr>
<td>Data preparation and management</td>
<td>Data quality; human subjects protection; efficiency; speed of dissemination</td>
</tr>
</tbody>
</table>
