Clinical Research Optimization:
The Expanded Role of Nursing in the Delivery of Clinical Trials

Dorothy Dulko, Ph.D., RN, AOCNP, CCRP
Assistant Vice President, Nursing
Administrative Director, Clinical Trials

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

…today’s standard of care therapy was the clinical trial of yesterday …
OUR MISSION

- To conduct clinical trials upholding the highest ethical standards in accordance with established federal and international standards while ensuring the safety of each research participant.

OUR VISION

- To provide access to new and innovative treatments to cancer patients in South Florida, the Caribbean and Latin America.
MCI Clinical Trials Office

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

MCI Clinical Trials Office
Organizational Structure
Nursing and Clinical Research

• Historically, two basic roles:
  • Nurse researcher/scientist
    – Leads discovery
  • Clinical nursing
    – Assess, test, apply, and adopt practices based on research evidence
      (evidence-based practice)

• Nursing as a profession has given little attention over the past 30 years to the roles and impact of nurses who practice in the clinical research setting
  – Confusion related to nursing roles and disparate responsibilities with respect to coordination of research protocols
    • Research Nurse turnover
    • Difficult to recruit positions
    • Inability to fully integrate and standardize professional nursing role in delivery of clinical trials

Current Research Nurse Model: Emphasis on Clinical Care

Clinical Research Nurse

Protocol Development and Approval

Patient Accrual

Informed Consent/Randomization
Research Plan
Research Intervention/Data Collection
Endpoint Data/Data Safety and Monitoring
Follow-up Data Collection Plan

Initial Assessment
Multidisciplinary Care Plan
Treatment
Patient Monitoring and Evaluation
Discharge/Transfer
Data Analysis
Dissemination of Results
Future Direction: Deeper Integration into Research Teams

Nursing care delivery parallels clinical trial implementation

Phase I Trials: It takes a village

- Complex treatment schedules/extended hours
- More research lab/tests, investigational imaging
- Greater need for nursing specialization
- Increase data management expectations
Tumor Targets:
The future of oncology innovation

<table>
<thead>
<tr>
<th>Oncogene</th>
<th>Targeted Therapeutic</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCR-ABL</td>
<td>imatinib, dasatinib, nilotinib</td>
</tr>
<tr>
<td>HER2</td>
<td>trastuzumab, lapatinib</td>
</tr>
<tr>
<td>c-KIT</td>
<td>imatinib, sunitinib</td>
</tr>
<tr>
<td>PDGFR</td>
<td>imatinib, sunitinib</td>
</tr>
<tr>
<td>EGFR</td>
<td>gefitinib, erlotinib, cetuximab</td>
</tr>
<tr>
<td>mTOR</td>
<td>everolimus, temsirolimus</td>
</tr>
<tr>
<td>MET</td>
<td>crizotinib</td>
</tr>
<tr>
<td>BRAF</td>
<td>vemurafenib</td>
</tr>
<tr>
<td>EML4-ALK</td>
<td>crizotinib</td>
</tr>
<tr>
<td>AR</td>
<td>enzalutamide</td>
</tr>
</tbody>
</table>

A Success Story

ER/PR+, HER2 non-amplified, ERBB2 V777L Breast Cancer

Courtesy MSK Phase I
MSK Developmental Therapeutics
Referral Team Pilot:
An Exemplar of Integration

Background and Significance

• Obtaining molecular analysis is important in matching patients with available trials as treatments may be more or less effective against tumors with certain mutations

• Efficient review of clinical information, including tumor mutations, to determine eligibility is imperative

• Virtual assessment offers enhanced trial matching and may ease the burden of multiple clinic visits for patients
  – Historically, many of these appointments resulted in hopeful patients found to be ineligible on more detailed screening in clinic

• Oncology nurses are integral to coordination between referring physicians and research team in ensuring accurate evaluation of eligibility
A pilot evaluation of virtual trial eligibility screening was planned for August 1, 2014 through January 30, 2015

The Referral Team was created
- Three oncology research nurses
- A clinical trials operations manager
- A medical oncologist from the Developmental Therapeutics Center (DTC).
  - Other DTC principal investigators were consulted during the pilot as needed for specific trial eligibility questions.

Referrals for trial were made via computerized physician order entry by patients’ primary oncologist.

In collaboration with Information Systems (IS) key data elements were identified and collated into an automated report including co-morbidity, performance status, labs, and specific tumor mutations. This allowed a near “real-time” evaluation of patient information.
- A daily electronic list of referred patients was provided to the Referral Team by Information Systems (IS).

Methods

During the pilot patients referred for trials were not required to complete a physical visit before being considered for trial participation.

At the time of referral, if molecular profiling had not been performed, a research nurse advised the referring physician that tumor genomics could increase the number of trials for which their patient might be eligible.

Virtual assessment was performed by research nurses; confirmed by the study principal investigator. Once a patient met initial eligibility review, the research nurse communicated with the referring physician via email.

The patient was offered the opportunity of a clinic visit, trial consent consideration, and formal eligibility assessment.

A limited waiver from the Institutional Review Board was obtained to allow for screening.
The Referral Process

1. Patient's Physician Places a DTC/ITC Referral
2. Referral Team Replies to Referring Physician
3. Research Project Coordinator (RPC) Enters and Reviews Patient Data for Referral Lists
4. Patients and Available Spots are Discussed Throughout the Week and at Weekly Meetings with Research Nurse and MD
5. Patient is Assigned a Spot and Receives a DTC or ITC Appointment
6. Patient Signs Consent, Screens, and Enrolls to a Clinical Trial

Auto generated referral list

- Generated daily
- Supplements eligibility review and matching

Courtesy of Stu Gardos, Information Systems
Referral Trend Data

Number of Patient Referrals, Visits and Enrollment in the DTC

Referral Year, Referral Month

Referral → Visit → Consent → Treatment

Average Days Per Task, Seen by DTC

Referral Year, Referral Month
Summary

- There were 320 referrals placed from August 1, 2014 through January 30, 2015 resulting in 197 clinic visits (61% of referrals) as compared to 207 visits for 219 referrals during the prior six months (95% of referrals).

- Pilot data revealed that despite the reduction in number of visits, there was an increase in the number of patients who had a DTC visit and went on to start protocol during the referral team pilot when compared to the prior six months 49% versus 37%.

- Post pilot data continues to display effective virtual screening with average of 51% of referrals proceeding to clinic visit and more than half of those patients consenting and starting on trial.

- The average number of days from first DTC visit to consent as well as consent to starting treatment on protocol has steadily decreased.

Key Takeaways

- Clinical Research Nurses (CRN) are pivotal members of the clinical research enterprise
  - Not only do they provide clinical insight and patient care expertise, they are well positioned to optimize interdisciplinary communication and streamlined eligibility screening

- Integration with non-clinical research team is essential
  - Collaboration with leadership and stakeholders
    - Appropriate assignment of responsibilities
    - Clearly articulate the unique resource of research nurses
      - Maintain quality patient care, research integrity

- Integration of CRNs not limited to academic centers, must evaluate in other healthcare settings and community centers