ORN-WAT: Oncology Research Nurse – Workload Assessment Tool

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Clinical Research

- Time Consuming and Laborious
- Multidisciplinary Team
  - Principal Investigator
  - Research Nurse
  - Clinical Research Coordinator
  - Pharmacist
  - Regulatory Specialist
- Highly Specialized
What do research teams do?

- Paperwork, paperwork, paperwork
- Regulatory work
- Correspondence with the IRB
- Enroll and manage study participants
- Highly technical requiring a broad expertise and skill set
Identifying Tasks

- Gwede: Role Identification
- Canada Clinical Trials Group
- Moffitt

→ high burnout
→ high turnover

How To Quantify Workload?

- Inherent Tasks
- Protocol Acuity Scoring System
- “workload is an ever evolving municipality that requires flexibility, especially within clinical trials”
- Activity Based Costing (ABC) methodology

Soenen 2006; Fowler 2003
ABC in Healthcare

- Flexibility
- ABC in Clinical Settings
- ABC for Research in Africa

Soenen 2006; Fowler 2003; Demeere 1992; Chou 2007
ABC in Clinical Trials

- Clinical Trial Tasks
- Complex Factors
  - Disease
  - Acuity of Underlying Illness Related to Disease
  - Phase of Study
  - Sponsor
  - Study Team Structure
- Team Member Roles: The Oncology Research Nurse (ORN)

Ehrenberger 2004; ONS 2010; Castro 2009; Gwede 2001; Roche 2002
Oncology Research Nurse

- Research Nurse
- Research Coordinator
- Clinical Research Coordinator
- Oncology Research Nurse
- Oncology Research Nurse Coordinator

Gwede 2001, 2008; Roche 2002; Schmidt 2008; Ocker 2000; Thompson 2005
Defining the Role

- CTN SIG 2004: Dimensions of an Oncology Research Nurse
- 2010: Clinical Trials Nurse Competency
- Castro and NIH

Ehrenberger 2004; ONS 2010; Castro 2009; Biron 2007
Nursing Role Effectiveness Model

- Structure-process-outcomes
- Role delineation

Organizational Variables

Oncology Research Nurse

Patient

Nursing

Irvine 1998
ORN-WAT (Oncology Research Nurse – Workload Assessment Tool)

- Itemize Tasks
- Quantify Time for Task
- Flexible Tool
- Budget
- Workload Organization
- Workload Allocation
Objectives

- Test the feasibility of completing the ORN-WAT
- Measure how much time respondents were spending on identified tasks
- Time to completion of survey
What’s in the ORN-WAT?

- 94-item questionnaire
  1) Non-identifiable Demographics (5 questions)
  2) Protocol Management (40 questions)
  3) Eligibility and Entry (13 questions)
  4) Treatment (22 questions)
  5) Follow-Up and Final Stage (7 questions)
  6) Time to Complete (1 question)
  7) Acceptability E-Scale (6 questions)

Tariman 2009
Pilot test of the ORN-WAT

- Dana-Farber/Harvard Cancer Center (DF/HCC)
- 70 Oncology Research Nurses at Dana Farber/Harvard Cancer Center Institutions
- Survey methodology utilizing Survey Monkey®
- Time and Task
- 48 Responses (69% response rate)
Respondents:

Survey Participation by Institution

- Beth Israel Deaconess Medical Center (BIDMC) 31%
- Dana Farber Cancer Institute (DFCI) 50%
- Massachusetts General Hospital (MGH) 9%
- Nonresponder 10%
Level of Experience

Number of years as a research nurse:
- Less than 2 years
- 2-5 years
- 6-10 years
- 11-15 years
- Greater than 16 years

Number of years as oncology research nurse:
- Less than 2 years
- 2-5 years
- 6-10 years
- Greater than 16 years

Research Experience

DANA-FARBER CANCER INSTITUTE
Protocol Management (40 questions)

- > 90% do not do any Regulatory Work
- Only 10% Budget Review/Negotiation
- > 60% do not spend time working on correspondence with SRC/IRB
- 80% spend < 5 hours on Drug Order Templates
- 25% of time: Sponsor Required Meetings
- Research Team Supervision
- Low % Preparing for Audit
Eligibility and Entry (13 Questions)

- **Assessing Participant Eligibility:** 11-20 hours
- **Consenting:** ~10 hours
- **Education of Participant/Family:** 50% greater than 10 hours per month
Treatment (22 Questions)

- Scheduling Research Related Exams and Visits: 89% reported 5-40 hours
- Education of Clinical Care Staff: 66% 1-10 hours
- Providing Research Related Care: 53% 1-10 hours
- Toxicity Assessment/Management: > 60% more than 20 hours
- Violations/Deviations/Adverse Events: 65% spend less than 5 hours
Follow Up and Final Stage (7 Questions)

- Minimal Involvement
  - 80-90% respondents did nothing in this category
  - Surprising
## Acceptability E-Scale (6 Questions)

<table>
<thead>
<tr>
<th></th>
<th>Number (N)</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>How Easy</td>
<td>37</td>
<td>1.9</td>
</tr>
<tr>
<td>How Understandable</td>
<td>37</td>
<td>1.6</td>
</tr>
<tr>
<td>How Much Enjoy</td>
<td>37</td>
<td>2.9</td>
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<tr>
<td>How Helpful</td>
<td>36</td>
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<tr>
<td>Time Acceptable</td>
<td>37</td>
<td>1.8</td>
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<tr>
<td>Overall Satisfaction</td>
<td>36</td>
<td>2.3</td>
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</tbody>
</table>
How Long Did it Take?

Survey Completion Time

- 0.0%
- 10.0%
- 20.0%
- 30.0%
- 40.0%
- 50.0%
- 60.0%

- less than 15 minutes
- 15-30 minutes
- 30-45 minutes
- 45-60 minutes
- greater than 60 minutes
The Next Step:

- Test Reliability
- Broaden the Sample Size
- Simpler Tool
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Questions…
Thank You
Gwede CK, Johnson D, Trotti A. Tools to study workload issues. Applied Clinical Trials. 2000 January:9(1)
References Continued…


