Assessing Clinical Trial-Associated Workload
Marge Good, RN, MPH, OCN
Nurse Consultant
Division of Cancer Prevention
National Cancer Institute
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Today’s Discussion
• Background
• Literature review
  – Published and unpublished CT workload assessment efforts
• ASCO involvement and subsequent project
• Future directions

Background
• Many challenges associated with managing clinical trials
• Today’s trials heterogeneous and increasing in complexity while funding less
  – Need to work efficiently and effectively
  – Turnover & burnout high
  – Data management quality negatively affected
• How many patients can one research nurse/CRA manage?
Implications for Assessing Clinical Trial-Associated Workload

ASCOResearchForum

ASCOClinical Trial Workload Assessment

Compare to national metric
Balanced among staff

Staff satisfaction
Improved quality / Timeliness
More trial options / Higher accrual

ASCO Community Research Forum Membership Survey

• Conducted in Spring 2011
• Goal – Assess needs related to conduct of clinical trials
• "How helpful would various research-related projects be if developed by ASCO?"
  – Ranked 4th out of 12 → Workload Assessment Tool
• ASCO’s Community Research Forum convened a Workload Assessment Working Group

Workload Assessment Working Group

Goals:
1. Develop a tool that is simple, reproducible, and usable in the long term
   - Implement within community research programs
   - Establish clinical trial workload metrics or benchmarks
2. To help research sites assess staff workload based on:
   - Complexity of research protocols
   - Number of patients assigned to each research nurse and CRA
Workload Assessment Working Group Preliminary Efforts

- Review of literature
  - Six tools examined
- Comparison of tools
  - Common elements
  - Diversity
  - Complexity
  - Feasibility for use in community practice setting

Literature Review Summary

<table>
<thead>
<tr>
<th>Name</th>
<th>Pub Year</th>
<th>Model/Focus/Metric</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fowler &amp; Thomas Acuity Rating Tool</td>
<td>2003</td>
<td>Points assigned to protocol tasks. Time spent = protocol task X 5 points + score</td>
<td>200–700 points/protocol task X 3 – 7 tasks per coordinator</td>
</tr>
<tr>
<td>NCI Trial Complexity Elements &amp; Scoring Model</td>
<td>2009</td>
<td>Points assigned for each of 10 elements. Complexity: 0 pts = low, 1 pt = moderate, 2 pts = high complexity</td>
<td>None reported</td>
</tr>
<tr>
<td>US Oncology Research Study Clinical Coordination Grading Criteria</td>
<td>2009</td>
<td>Points assigned to each of 21 grading criteria. Complexity based on number of points.</td>
<td>None reported</td>
</tr>
<tr>
<td>Ontario Protocol Assessment Level (OPAL)</td>
<td>2011</td>
<td>Score of 1–8 assigned based on 8 of contact events, type of trial</td>
<td>None reported</td>
</tr>
<tr>
<td>University of Michigan – RETA Effort Tracking Application (RETA)</td>
<td>2011</td>
<td>Staff logged daily time spent per protocol tasks.</td>
<td>70-75% staff time = trial-related tasks, 20-30% = other tasks, 5% = non-trial tasks</td>
</tr>
<tr>
<td>Wichita CCOP Protocol Acuity Tool (WPAT)</td>
<td>2013</td>
<td>Trials ranked 1–4 based on 6 complexity elements.</td>
<td>Data collected over 10 years. Tx=38.5; CC=37.8; Off S=15.9.</td>
</tr>
</tbody>
</table>

Literature Review
**Fowler & Thomas Acuity Ranking Tool - 2003**

- Time in hours per each protocol task × number of points = score per task
  - Scores and time summed resulting in a total score and number of hours/patient/trial
  - Time to complete 1 participant through 1st year of study

- Results - Comparison of two studies:
  - Study 1 = 47 acuity points; required 8.5 hours for each patient
  - Study 2 = 84 acuity points; required 29.5 hours per patient
  - Workload ranged from 500-750 points per coordinator;
    number of protocols per coordinator ranged from 3–7
  - Most significant differences in 2 trials
    - Number of assessments and CRFs

**Fowler & Thomas Example**

<table>
<thead>
<tr>
<th>Task</th>
<th>Time in hours for procedure</th>
<th>Points</th>
<th>Score</th>
<th>Total time per pt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient recruitment &amp; enrollment</td>
<td>0.5</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Outpatient recruitment &amp; enrollment</td>
<td>0.5</td>
<td>1</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Lab processing – each</td>
<td>0.45</td>
<td>1</td>
<td>6</td>
<td>2.7</td>
</tr>
<tr>
<td>EKG – each</td>
<td>0.5</td>
<td>1</td>
<td>6</td>
<td>3.0</td>
</tr>
<tr>
<td>Assessments – each</td>
<td>0.5</td>
<td>1</td>
<td>6</td>
<td>3.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>19</strong></td>
<td><strong>9.2</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NCI Trial Complexity Elements & Scoring Model – 2009**

- CT Working Group Operational Efficiency Initiative – reimburse for trial complexity
- Points assigned for each of 10 elements (most time consuming & complex for sites)
  - Standard complexity = 0 points
  - Moderate complexity = 1 point
  - High complexity = 2 points
- Findings: Not reported

NCI Trial Complexity Elements & Scoring Model

<table>
<thead>
<tr>
<th>Element #</th>
<th>Study Element</th>
<th>Standard (0 points*)</th>
<th>Moderate (1 point*)</th>
<th>High (2 points*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Study Arms</td>
<td>1 or 2 study arms</td>
<td>3 or 4 study arms</td>
<td>&gt;4 study arms</td>
</tr>
<tr>
<td>2</td>
<td>Informed Consent Process</td>
<td>Straightforward</td>
<td>One step randomization/registration</td>
<td>Trials involving multiple steps/randomizations or complex Central Pathology Review prior to randomization</td>
</tr>
<tr>
<td>3</td>
<td>Registration or Randomizations Steps</td>
<td>One step</td>
<td>Separate registration/registration</td>
<td>Complex Central Pathology Review prior to randomization</td>
</tr>
<tr>
<td>4</td>
<td>Complexity of Investigational Treatment</td>
<td>Outpatient single modality</td>
<td>Combined modality treatments</td>
<td>Treatments with potential for increased toxicity (i.e. gene transfer, investigational bone marrow/ stem cell transplant, etc.)</td>
</tr>
<tr>
<td>5</td>
<td>Length of Investigational Treatment (tx)</td>
<td>Regimens with a defined # of cycles</td>
<td>Routine or standard hormonal therapy (i.e. 5 yrs. of tamoxifen or AI for breast cancer)</td>
<td>Extended administration of investigational rx</td>
</tr>
</tbody>
</table>

Varying number of points assigned to each of 21 grading criteria

Complexity measure based upon points:
- Level 1 = 1 - 20
- Level 2 = 21 - 35
- Level 3 = 36 - 50
- Level 4 = 51 - 65
- Level 5 ≥ 66

Findings: Not reported

US Oncology Research Study Clinical Coordination Grading – 2009

US Oncology Example
Ontario Protocol Assessment Level (OPAL) – 2011

- Canadian: Ontario Institute for Cancer Research & 27 research sites
- Score of 1 - 8 assigned based on number of contact events, special procedures, central processes, phase of trial, type of trial (treatment vs. non-treatment vs. imaging and/or exercise)
  - Optional considerations — inpatient treatment, on site monitoring, ≥3 surveys/questionnaires
- Findings: Not reported

University of Michigan: Research Effort Tracking Application (RETA) – 2011

- Staff logged daily time spent per protocol tasks
  - Tasks standardized and grouped by job role
  - Took 10-15 minutes per day/staff person
- Findings:
  - 70 - 75% staff time trial-related tasks
  - 25 - 30% time non-trial related activities (vacation time, sick time, team and office-wide meetings)
  - 72% of data management effort committed to open studies
  - 25% of effort reserved for studies not yet open or closed to enrollment.
### RETA Example

<table>
<thead>
<tr>
<th>User</th>
<th>All Logged Effort Task (Qty)</th>
<th>Hours</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doe, Jon</td>
<td>Communications</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DSM Reports</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other, Specify</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient Enrollment</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient Screening</td>
<td>8.8</td>
<td>15.8</td>
</tr>
<tr>
<td>Yates, Diane</td>
<td>Queries/Data Clarifications</td>
<td>15.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SAE/FU reports</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Training/Education</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Role Subtotal</td>
<td></td>
<td></td>
<td>16.5</td>
</tr>
<tr>
<td>Role Subtotal</td>
<td></td>
<td></td>
<td>31.8</td>
</tr>
</tbody>
</table>

### Wichita CCOP Protocol Acuity Tool

#### Protocol Acuity Elements
1. Complexity of treatment
2. Protocol specific lab/testing requirements
3. Toxicity potential
4. Data forms required (complexity and number)
5. Degree of coordination required
6. Number of randomizations/steps

### Wichita CCOP Protocol Acuity Tool

#### Acuity Score Rankings
1 = Observational/registry trial; follow-up only
2 = Oral agents (minimal toxicity), lab only study
3 = Chemotherapy and/or XRT regimen; increased number of elements including toxicity potential & higher associated workload than #2
4 = Very complex; multiple drug regimens; high degree of toxicity potential; majority of workload elements apply (i.e., BMT, leukemia, lymphoblastic lymphoma, myeloma)
Wichita CCOP Protocol Acuity Tool 1999 to 2010

- Findings (per research nurse):
  - Yearly average acuity score:
    - Treatment trial: 30.6
    - Cancer control trial: 37.8
    - Off study: 15.9
  - Yearly average number of patients:
    - New enrollments: 69
    - On study: 103
    - Off study: 97

Unpublished. Personal communication.

Treatment Trials:
# of Patients in Relation to Acuity Scores

Cancer Control Trials:
# Patients in Relation to Acuity Scores
ASCO Working Group Determinations

- Literature increasing
- Workload measurement tools are being developed
- Still no validated measures or recommended maximum metrics (i.e., number of research participants-to-staff ratio)
- Selected Wichita CCOP model

Next Steps:

1) Modified/Clarified Wichita CCOP scoring criteria
2) Developed Protocol Acuity Score Assignment Worksheet
3) Designed Clinical Trial Workload Assessment Tool Project
   - Developed web-based electronic capture tool
   - Limited to patient centered research personnel
   - Goal: test tool in multiple community-based research sites

Protocol Acuity Score Assignment Worksheet

- Tested among
  - Working Group members
    - Reviewed 6 NCI Cooperative Group trials
    - 100% congruence
  - ASCO Community Research Forum and CCOP/MBCCOP PIs & Administrator Meeting Attendees
    - Reviewed 3 SWOG Trials
    - 80 to 100% agreement for treatment trials
    - 60 to 64% agreement for cancer control trials
Protocol Acuity Scoring Worksheet

Complexity of treatment,

Trial specific laboratory and/or testing requirements,

Treatment toxicity potential,

Data forms required (consider complexity and number of forms),

Degree of coordination required (involvement of ancillary departments, outside offices/sites and/or disciplines),

Number of randomizations/steps.

Objectives of the Project

1) Determine the feasibility of utilizing a common clinical trial workload assessment tool
2) Gather information regarding average acuity levels per research staff
3) Compare number of patients per research staff FTE to acuity levels for various types of trials
4) Refine the tool
5) Determine screening-related data collected

Site Recruitment/Participation

- Community-based oncology research programs
- Goal to obtain 25 – 30 participating sites
- Recruited from:
  - ASCO Community Research Forum
  - NCI CCOPs & MBCCOPs
  - NCI NCCCPs
  - ONS CTN SIG
  - Sarah Cannon Research Institute
  - US Oncology Network
Research Program Eligibility

- Community-based research program
- Currently accruing to industry and/or NCI-funded cooperative group trials
- Ability to produce electronically generated lists of enrolled patients by specified categories
- Willing to collect and enter required data in ASCO web-based workload tool in timely manner
- Willing to participate in scheduled training, planning and evaluation conference calls

Participating Site’s Responsibility

- Participate in web-based training
- Assign acuity scores to each active trial
- Enter data into the web-based tool
  - Monthly for 6 months
  - Verify any changes to staffing and protocol information before each phase of data collection
- Complete Follow-up Surveys
  - Online survey (5 - 10 minutes) completed each month and at completion of data collection
  - Provide feedback about using tool

Two Acuity Metrics

- Protocol Acuity Score
  - Scored 1 to 4 (Per Protocol Acuity Scoring Worksheet)
    - On Study/On active treatment
    - Follow-up (assumed 1)
      - On Study/Off active treatment
      - Off Study
- Nurse/CRA Acuity Score
  - Calculation
    - protocol acuity score x number of patients
    - Individual Nurse/CRA FTE
Entering Data into the Tool

1) Nurse/CRA ID
   • Staff initials
     - Only staff with direct patient contact!
2) Site ID
   • Research programs with multiple sites
3) Study ID
   • Includes sponsor + protocol number + patient status
     - Provided during registration
4) Number of patients
   • Number of patients on staff member’s workload

<table>
<thead>
<tr>
<th>Nurse/CRA ID</th>
<th>Site ID</th>
<th>Study ID</th>
<th>#Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>Yellowknife</td>
<td>NCCTG-N0543-</td>
<td>on study treatment</td>
</tr>
</tbody>
</table>

Participating Sites

• 51 completed 6 months of data collection
  – May through November 2013

Lots of Work!!

• Multiple webinars:
  – Training webinars
  – Interim update/compliance webinars
• Data collection/cleaning/query resolution
• Definitions/processes clarified
  – Data limited to patient centered research personnel
  – Team options
Analyses and Findings

- Analyses are nearing completion
- Participating sites reports this Fall
- Publications in 2015

Bottom line: Clinical trial-associated workload is significant issue!
- Findings will answer important questions
  - Initial benchmarking data coming soon!!
  - We know more work needs to be done
    - e.g., screening, regulatory, etc

Tool Available on ASCO Website

ASCO Clinical Trial Workload Assessment Tool is now available! Go to www.workload.asco.org.
It's free but you need to register to use it.

Features

- Reports and graphs
- Assess staff workload:
  - Per protocol
  - Per individual staff person
  - Compare to other staff
- Effectively and efficiently monitor and manage research staff
- Monitor performance
- Compare productivity
- Export data
Data Entry View

Report View

Available Graphs – Overall Average Acuity Score per Staff
Available Graphs:
Acuity Score per Individual Staff Over Time

Future Directions

• Accessible workload assessment tool
  • Utilize within broader ASCO membership & oncology research field

• Further tool evaluation
  • Within academic settings
  • Other areas of clinical trial associated workload
    • Regulatory
    • Screening
    • Credentialing, etc
Acknowledgements

For their contribution:

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  • Rogerio Lilenbaum, MD – Cleveland Clinic Florida
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  • Nicholas Robert, MD – Virginia Cancer Specialists
  • Teresa Stewart, MHA - New Mexico Cancer Alliance
  • Connie Szczepanek, RN, BSN – Grand Rapids Clinical Oncology Program/Grand Rapids, MI

• Last but not least!! -> All participating sites!!!

Questions?