Assessing Clinical Trial Associated Workload

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Learning Objectives:

• Explain the importance of assessing clinical trial associated workload
• Describe a clinical trial workload assessment tool
Today’s Discussion

• Background
• ASCO efforts
  – Current tools
  – Workload Assessment Project
• Future direction
Assessing Clinical Trial Associated Workload

• Many challenges associated with managing clinical trials
• Today’s trials heterogenic and increasing in complexity while funding less
  – Need to work efficiently and effectively
  – Turnover and burnout high
  – Data management and quality negatively affected
Why Develop a Workload Assessment Tool?

- Workload is an important issue!
  - Rated in Top 4 in an ASCO Community Research Forum needs assessment survey

- Benchmarking – Compare one research program to others
  - Determine how many patients one research nurse/CRA can manage
  - Provide validation for the need for more staff
  - Justify budget (for grant applications and/or in-house)

- Staff management
  - Assess and redistribute workload
  - Staff-specific issue accruing patients
  - Data submission delinquency levels monitored
  - Annual performance review
Implications for Workload Assessment

- Compare to national metric
- More trial options / Higher accrual
- Improved quality / Timeliness
- Balanced among staff
- Staff satisfaction

Clinical Trial Workload Assessment
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

• Key steps taken:
  – 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 (Research Practitioner)</td>
<td>2003</td>
<td>Points assigned to protocol tasks. Time in hrs/protocol task X # points = score</td>
<td>500 – 750 points/coordinate 3 – 7 trials 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; Standard complexity = 0 pts; Mod complexity = 1 pt; High complexity = 2 pts</td>
<td>None reported</td>
</tr>
<tr>
<td>US Oncology Research Study Clinical Coordination Grading</td>
<td>2009</td>
<td>Points assigned to each of 21 grading criteria. Complexity based on number of points (↑ points = ↑ score)</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 # of contact events, type of trial</td>
<td>None reported</td>
</tr>
<tr>
<td>University of Michigan – Research 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; 25-30% = non-trial (vacation, mtgs, etc); 72% of DM effort -&gt; opening studies; 25% effort -&gt; not yet open/closed</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>* Yrly average Acuity Score per nurse: Tx=30.6; CC=37.8; Off S=15.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* Yrly average Pts per nurse: New enrollments=69; On S=103; Off S=97</td>
</tr>
</tbody>
</table>
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
Wichita CCOP Model

A CLOSER LOOK
1999 Wichita CCOP: Need for Workload Metric

- Unequal distribution of clinical trial workload
- 1983 – 1999: Followed NCI formula: 1 FTE=40 credits
  - Does not reflect individual trial differences related work nor post-enrollment associated work
- Literature search: 1979 publication (Giovannetti)
  - Group pts into categories reflecting magnitude of nursing care required
  - Acuity system = scoring system in which each pt care requirement associated with a score
- 1980’s – Patient Classification Systems
  - Nursing units commonly used patient classification systems based on patient acuity
Wichita CCOP Patient Classification

• Patients *On Study/Active treatment*
  – Treatment trials
  – Cancer control trials

• Patients in *Off Treatment* follow-up
  – *On Study/Off Treatment*: Treatment completed; in regular follow-up required by study
  – *Off study*: no longer following protocol; vital status only
Protocol Acuity Elements

- Complexity of treatment
- Protocol specific lab/testing requirements
- Toxicity potential
- Data forms required (complexity and number)
- Degree of coordination required
- Number of randomizations/steps
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)
Calculating Acuity

• On monthly basis
  – Generated lists of patients per nurse by protocol
  – Lists categorized into:
    • On active treatment
      – Treatment
      – Cancer control
    • Off Treatment Follow-Up
      – On study & off study
  – Accounted for days worked per week
  – Each nurse provided
    • Individual acuity level + team average
## Calculation Example

**On Active Treatment**

<table>
<thead>
<tr>
<th>Study</th>
<th>Acuity</th>
<th>#Patients</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1496</td>
<td>3</td>
<td>X 2</td>
<td>6</td>
</tr>
<tr>
<td>E2997</td>
<td>3</td>
<td>X 4</td>
<td>12</td>
</tr>
<tr>
<td>E3999</td>
<td>4</td>
<td>X 2</td>
<td>8</td>
</tr>
<tr>
<td>N9831</td>
<td>3</td>
<td>X 5</td>
<td>15</td>
</tr>
</tbody>
</table>

Total: 41

Divide by # days/wk worked: (5)

Total On Active Treatment Acuity: 8.2
Other Variables Evaluated

• Patients:
  – Actual patients per category
  – Patients screened per month

• QA-Associated:
  – Queries
  – Overdue initial forms submissions
  – Overdue follow-up data submissions
Treatment Trials: # of Patients in Relation to Acuity Scores
Cancer Control Trials: # Patients in Relation to Acuity Scores

- Average Cancer Control Acuity Scores
- Average # New Enrollments/Cancer Control Nurse FTE
- Average # Cancer Control Patients On Active Treatment per Cancer Control Nurse FTE
How Acuity Information Utilized

• Balanced workload between staff
  – Monthly individual scores + team average
• Provided validation to increase staff
• Management assessment tool
  – Nurse specific issue accruing patients
  – Data submission delinquency levels
  – Annual performance review
Now

BACK TO ASCO EFFORT
Next Steps:

1. Modified / Clarified Wichita CCOP scoring criteria

2. Developed Protocol Acuity Score Assignment Worksheet
   Tested among:
   - Working Group members
     - Reviewed 6 Cooperative Group trials
     - 100% congruence
   - ASCO Community Research Forum and CCOP/MBCCOP PI & Administrator Meeting attendees
     - Reviewed 3 SWOG Trials
     - 80 to 100% agreement for treatment trials
     - 60 to 64% agreement for cancer control trial

3. Designed and conducted ASCO Clinical Trial Workload Assessment Tool Project
   - Developed web-based/electronic data capture tool
   - Goal = Test tool in multiple community-based research sites
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 (beginning June 2013/providing May 2013 data)
  - 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)
      o On Study/Off active treatment
      o Off Study

• Nurse/CRA Acuity Score
  • Calculation
    protocol acuity score x number of patients
    Individual Nurse/CRA FTE
### Protocol Acuity Scoring Worksheet

**STEP 1** Evaluate the protocol for workload-related elements:
- 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.

**STEP 2** Assign a score utilizing a range of 1 – 4 as follows:

<table>
<thead>
<tr>
<th>Score</th>
<th>Scoring Criteria</th>
</tr>
</thead>
</table>
| 1     | • Observational/Registry trial  
       | • Patients in follow-up status only |
| 2     | • Testing oral agents with minimal toxicity  
       | • Tests/procedures considered standard of care  
       | • Data forms require basic information easily captured from medical record  
       | • Requires minimal coordination with outside and/or ancillary staff  
       | • Non-randomized or single randomization  
       | (May include standalone laboratory/correlative science studies, cancer control symptom management trials and hormone therapy trials) |
| 3     | • Testing chemotherapy and/or radiation therapy regimen (may include high toxicity potential oral agents)  
       | • Increased toxicity potential when compared to a score of “2”  
       | • Involves non-standard of care "research" tests/procedures  
       | • Data forms more complex and higher in number  
       | • Requires coordination with 1 - 2 other disciplines/ancillary departments  
       | • Single time point, randomized Phase II or III  
       | (Includes the majority of randomized phase II & III treatment trials) |
| 4     | • Very complex  
       | • Multiple drug regimens  
       | • High degree of toxicity potential  
       | • Involves multiple non-standard of care "research" tests/procedures  
       | • Data forms more complex, daily to weekly data collection required and higher in number  
       | • Requires coordination with > 2 disciplines/ancillary departments  
       | • Multiple randomizations and/or steps  
       | (e.g., bone marrow transplant, leukemia, lymphoblastic lymphoma, myeloma trials) |
Entering Data into the Tool

<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-on study treatment</td>
<td>5</td>
</tr>
</tbody>
</table>

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
Project Update

• Over 100 sites expressed interest
• 52 completed data collection over 6 months
  – June through December 2013
• Data limited to patient centered research personnel
• Findings available in Summer/Fall 2014
• Tool to be available to public through ASCO in Summer/Fall 2014
Location of Participating Sites
Conclusions

• Clinical trial-associated workload is significant issue
  – Current project will answer important questions
    • Initial benchmarking data coming soon!!
Future Directions

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

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

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• All participating sites!!
Questions?