Staffing and Workload Management Strategies

Introduction
Marge Good, RN, MPH
National Cancer Institute

Topics to be Covered
- ASCO Clinical Trial Workload Assessment Tool
- Levine Workload/Staffing Assessment Tool
- Diversified Workforce in Research
- Career Ladders
- Staffing and Retention Strategies

ASCO Clinical Trial Workload Assessment Tool
Marge Good, RN, MPH
National Cancer Institute

Assessing Staffing Mix and FTEs Over Time: An Example

<table>
<thead>
<tr>
<th>Year</th>
<th>Oncology Service Line Director</th>
<th>CCOP Manager</th>
<th>Secretary/Assistant</th>
<th>Regulatory Specialist</th>
<th>CRA - Treatment Focused</th>
<th>CRA - Cancer Control</th>
<th>Research Nurse - Treatment Focused</th>
<th>Research Nurse - Cancer Control</th>
<th>Total FTE</th>
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Early years
- Primarily supported with research nurses
- Adjuvant treatment trials
- Minimal biospecimen collection/submission
- Cancer control primarily symptom management
- Everyone cross-trained

2001 - 2006
- Prevention trials introduced

Later years
- Acuity increased across all categories (number of patients and trial complexity)
- Fewer oncology nurses available
- Non-nurse CRAs hired - work redistributed/teams
- More biospecimen (kit room required)
- Insurance issues
Why Assess Clinical Trial Workload?

- Have actual metrics of research staff effort (not just statements “I’m overwhelmed”)
- Provide validation of need for more staff
- Budget justification (institution, grant applications, etc.)
- Tool for staff management
- Assess and ensure equal distribution of work
- Change in metrics over time / Signals indicating reaching maximum effort
- Staff-specific issues (accruing patients, knowledge gaps, etc.)
- Monitor data submission delinquency
- Interim and annual performance reviews

Implications for Assessing Clinical Trial-Associated Workload

Consistent Workload Assessment
Balance between staff
Staff Satisfaction
Quality data
More trial options
Higher accrual rates
Increased funding
Consistent Workload Assessment

ASCO Research Community 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 Research Community Forum convened a Workload Assessment Working Group

Literature Review Summary

<table>
<thead>
<tr>
<th>Name</th>
<th>Publication Year</th>
<th>Model/Focus/Metric</th>
<th>Findings</th>
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</thead>
<tbody>
<tr>
<td>Fowler &amp; Thomas</td>
<td>2003</td>
<td>Acuity Rating Tool</td>
<td>Points assigned to protocol tasks. Time in hrs/protocol task X # points = score</td>
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<tr>
<td>NCI Trial Complexity</td>
<td>2009</td>
<td>Elements &amp; Scoring Model</td>
<td>Points assigned for each of 10 elements. Standard complexity = 0 pts, Mod complexity = 1 pt, High complexity = 2 pts</td>
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<tr>
<td>US Oncology Research</td>
<td>2009</td>
<td>Study Clinical Coordination Grading</td>
<td>Points assigned to each of 21 grading criteria. Complexity based on number of points (↑ points = ↑ score)</td>
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<tr>
<td>University of Michigan</td>
<td>2011</td>
<td>Research Effort Tracking Application</td>
<td>Staff logged daily time spent per protocol tasks. 70-75% staff time = trial-related tasks, 25-30% = non-trial tasks</td>
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<td>Wichita CCOP Protocol</td>
<td>2013</td>
<td>Acuity Tool</td>
<td>Trials ranked 1-4 based on 6 complexity elements. Data collected over 10 years. Yrly average Acuity Score per nurse: Tx=30.6; CC=37.8; Off S=15.9</td>
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</table>
Two Acuity Metrics

- **Protocol Acuity Score**
  - Scored 1 to 4 (Per Protocol Acuity Scoring Worksheet)
  - On Study/On active treatment
  - Follow-up (assumed 1)
  - Off Study

- **Nurse/CRA Acuity Score (Patient Centered Effort)**
  - Calculation: protocol acuity score x number of patients
  - Individual Nurse/CRA FTE

Conclusions

- ASCO tool intuitive/simple and usable
  - Collecting data from across multiple sites was complicated, but achievable
  - Applicable to academic and community settings
  - CT Workload Benchmark data now available
  - Assessing workload requires time and commitment
  - More work needs to be done
  - e.g., screening, regulatory, etc.

Tool Available on ASCO Website

- ASCO Web-Based Workload Tool
  - As of August 15, 2019
  - Total Registrants: 403 unique sites
  - United States: 371
  - International: 32
    - Australia, Brazil, Canada, Chile, China, India, Ireland, Italy, South Korea, Spain, Saudi Arabia, Thailand, United Kingdom, Switzerland
  - Community-based: 253
  - Academic: 116
  - Other (e.g., government, etc.): 34

ASCO Web-Based Workload Tool

- **Tool Available on ASCO Website**
  - Go to www.workload.asco.org
  - It’s free but you need to register to use it!
What we are doing?

- Evaluating protocol complexity
- Understanding the make-up of our teammates experience and what this resourcing available capacity consists of
- Analyzing the level of actual work effort occurring
- Forecasting our actual and pending trial accruals
- Benefits of reviewing capacity for work life balance and organizational process improvements

Evaluation of Protocol Complexity

- Evaluation is based upon protocol driven criteria as well as LCI processes
- Some of the key drivers for patient and protocol management are:
  - # of sites
  - # of modalities
  - Are there PKs and if so, how many and what is the frequency
  - Are there specimens to be collected
  - Any fresh bio-specimens
  - Are there patient diaries, QOLs, self-assessments using a tablet
  - Imaging requirements, frequency, central reads
  - Screening
  - Visit frequency
  - Follow-up frequency
  - Estimated rate of accrual based upon patient population and past history

Understanding Resourcing for Research Nurses & CRAs

- Developed a theoretical Work Unit (WU) capacity value for each FTE
- Created ranges for expected WU's based on the level of experience as defined below
  - 0-8 months – 12 WU's
  - 9-18 months – 24 WU's
  - 18 months – 36 WU's
- Assess the level of workload an FTE can undertake for the positions of research nurses and CRAs
- Experience is updated monthly
- Cap FTE capacity at 80%

Theoretical WU capacity for each FTE is used to assess available WU capacity for patient management

- FTE WU values based upon the management of 12 active patients from low to high complexity protocols (12 – 36)
- Ability to aggregate theoretical WU capacity for each role to forecast potential shortfalls of workload

The more experienced people we have, the more patients we can serve!
Department Workload

- All staff workload is reviewed for the department
- Workload for the roles of clinical research nurse and CRA’s are aggregated separately to determine overall capacity for each
- Workload can be compared for each staff member over time to look at trends based upon assignments
- This helps to guide us directionally over time to determine if we have future resourcing needs based upon the type of protocols and number of patient's we are accruing

Forecasting Active and Pending Trial Accrual

- A report is generated looking at ongoing accruals by protocol
- The number of total accruals per protocol is broken down into a monthly accrual number based upon the length of time the protocol has been open to accrual (OTA)
- This monthly accrual number is multiplied by the protocol complexity to calculate the forecasted number of WU’s
- The forecasted number of WU’s is aggregated for all OTA protocols and compared to our available WU’s of our staff

Forecasting Active & Pending Trial Accrual

- This helps us define if we will have any potential gap in the ability to accrue patients for existing OTA protocols
- The monthly accrual estimate for pending trials is determined by the PI which is multiplied by the protocol complexity to determine what the expected WU will be when the protocol is OTA
- Biweekly meetings are held where all pending trials are reviewed with the latest status for the start-up meeting, budget, contract, IRB submission, SIV, and target OTA date
- The target OTA date is used as a placeholder to forecast WU’s and these WU’s are added to the monthly estimated OTA protocols

What’s next? What do you do with this data?

- All the calculations and reports do not help if you do not pressure test them with your staff through ongoing workload discussions

Meetings

- Weekly resourcing meetings are held where our managers review workload to determine if there are any resourcing needs within teams and across the department
- One on one meetings between managers and their staff are held to review individual workload
- Examine trends over time and outliers
- Review any over capacity to determine if it is necessary to make any workload adjustments

The Other 20%

- 20% protected time accounts for the below areas
  - Administrative Time – Defined as internal meetings, not protocol specific, professional development, training not protocol specific, project work
  - Time off
  - Site travel time – less frequent to more frequent
  - Monitoring visits – include if more frequent visits are occurring
  - Data locks – include when occurring
  - Serving as PC/PCRA
  - Different treatment plan intervals – volume of patients in the higher acuity part of the trial at the same time
What else does a capacity model allow you to do?

- Use workload capacity to justify existing FTEs and for new FTE requests helping to reduce staff attrition
- Review of time and effort (T&E) data to assist in validating protocol complexity
- Use protocol complexity to aid the budgeting process
- Include pre-screening T&E percentages in workload capacity review
- Use workload capacity to make smarter assignments across the department and develop alternate work patterns for work-life balance
- Utilize capacity model to create stretch assignments to support career advancement opportunities aligned with our career ladder.

Going Forward

- Do not overcomplicate and maintain simplicity in the model
- Knowing that review of protocol complexity criteria can be somewhat subjective, use past reviews to inform future evaluations
- Continue 1:1 meetings with staff to understand different treatment plan intervals – if of patients in the higher acuity part of the trial at the same time
- Continue to understand when staff have multiple patients on the same protocol at different timepoints in their treatment plan
- Continually evaluate internal processes to determine if more available capacity exists for patient management activities

Diversified Workforce in Research Career Ladders Staffing and Retention Strategies

Renee Rakvica, RN, BSN, OCN
US Oncology Research, Oncology Hematology Care, Inc.

Research Responsibilities

Job Diversification

Research Responsibilities
**Other Job Roles**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td>Data Coordinator</td>
<td>Collection, coordination, processing and quality control of clinical trial data, maintaining research protocol and other research files as applicable. Works with clinical staff to meet data entry timelines and communicate any concerns about the data. SIV facilitation and Monitor contact.</td>
</tr>
<tr>
<td>Financial Coordinator</td>
<td>Contractor Budget</td>
</tr>
<tr>
<td>Research Regulatory Coordinator</td>
<td>Submission, tracking and maintenance of regulatory documents</td>
</tr>
<tr>
<td>NEW- Data Query Nurse</td>
<td>Involved in resolution of clinical queries</td>
</tr>
</tbody>
</table>

**CAREER LADDERS**

§ Separated Research nurse vs. Research Coordinator
§ Research Nurse Supervisor vs. Research Manager
§ Research Data Coordinator Lead/Supervisor
§ Added Levels:
  - Clinical Research Nurse and CRC: 1, 2, 3
  - DC: 1, 2, 3-Lead
  - Research Assistant 1 and Senior
  - Finance: 1 and Senior level

**RETENTION**

§ Training/Mentoring Program
§ Source and Communication templates
§ Disease program focus
§ Office coverage
§ Staff meetings and one on one with staff
§ MDs available and engaged
§ Recognition
§ Enjoyable environment

**Discussion Questions**

Meet CAR-T Research New Pet
What are ways to address staff turnover?

Do you feel you have an effective research staffing model?
- If yes, what makes it effective?
- If not, why not?
- What are your greatest challenges?

Are there staffing or workload issues that could be a priority for the RCF?

Wrap Up

Share your resources and strategies!

Join the online forum and/or email researchcommunityforum@asco.org