Assessing Clinical Trial Associated Workload

January 2018 Consortia Webinar

January 9, 2018

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Objectives

- Why measure clinical trial-associated workload
- Previous literature
- ASCO supported effort

Today’s Clinical Trial’s Arena

- 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 Assess Clinical Trial Workload?

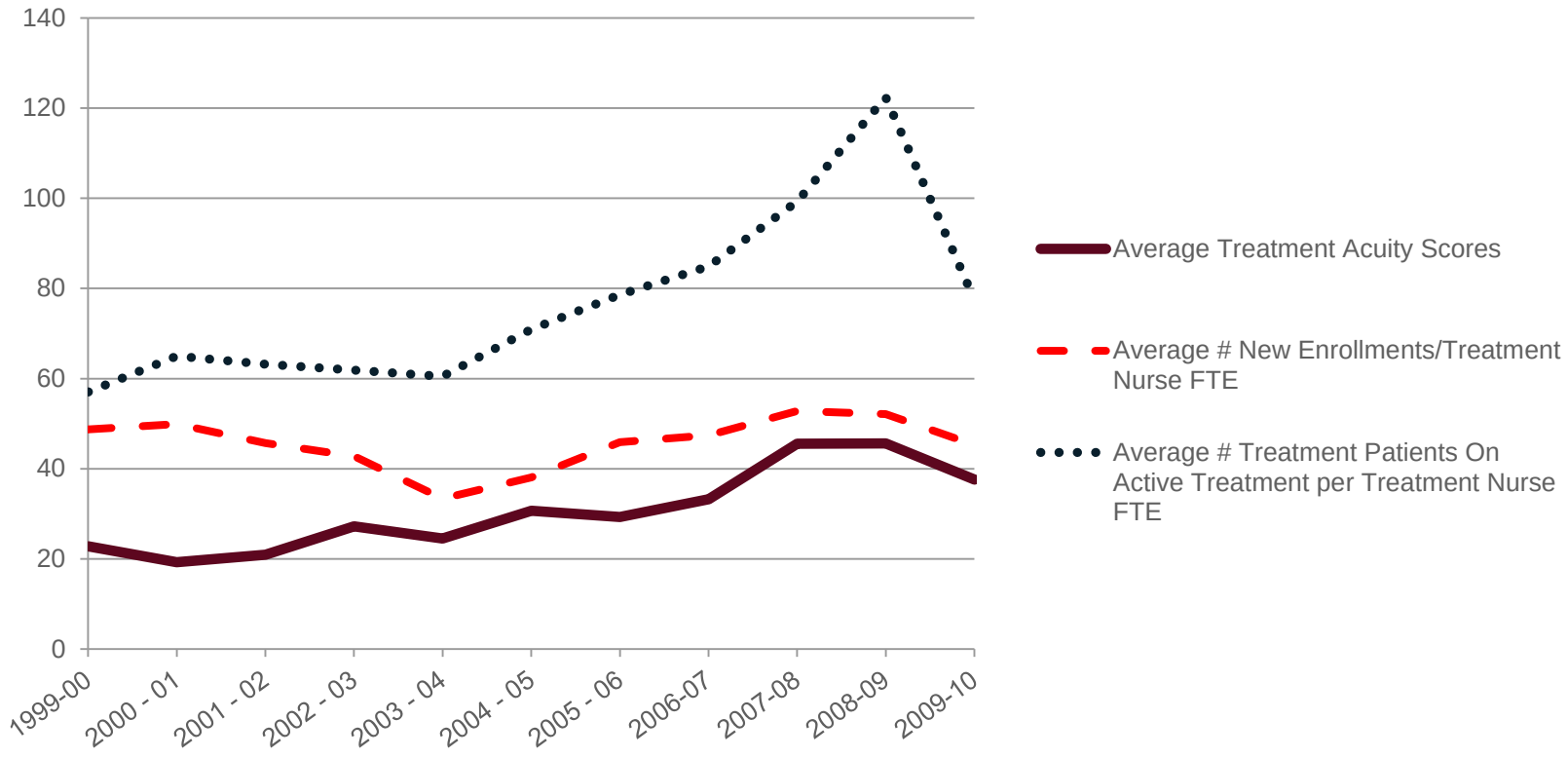
- Determine how program/staff compares to similar program/staff (Benchmarking)
- Provide validation for the need for more staff
- Justify budget (for grant applications and/or in-house)
- Tool for staff management
  - Assess and equally distribute workload
  - Staff-specific issue accruing patients
  - Data submission delinquency levels monitored
  - Annual performance review

Implications for Assessing Clinical Trial-Associated Workload

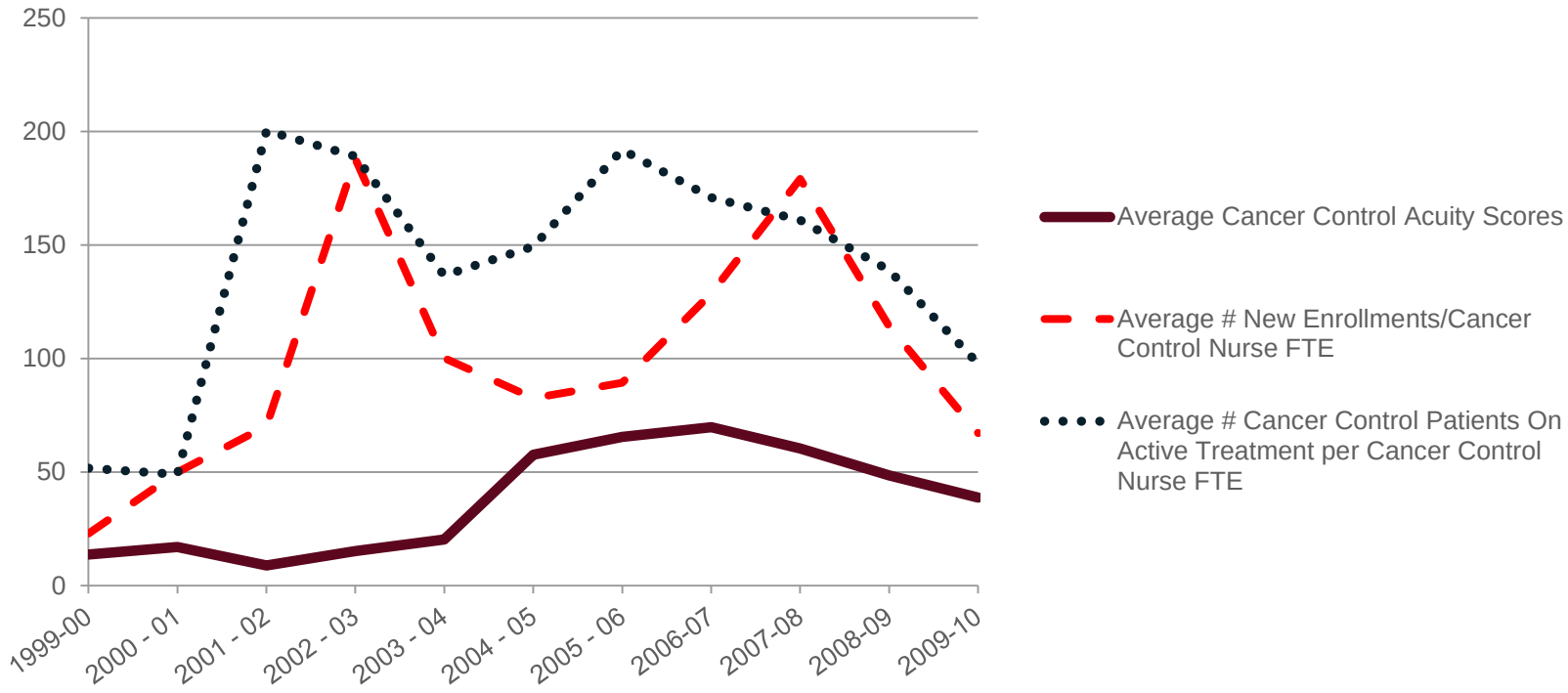
Literature Review Summary

Name	Pub Year	Model/Focus/Metric	Findings
Fowler & Thomas Acuity Rating Tool (Research Practitioner 4(2):64-71. 2003)	2003	Points assigned to protocol tasks. Time in hrs/protocol task X # points = score	500 – 750 points/coordinator 3 – 7 trials per coordinator
NCI Trial Complexity Elements & Scoring Model (http://ctep.cancer.gov/protocolDevelopment/docs/trial_complexity_elements_scoring.doc)	2009	Points assigned for each of 10 elements Standard complexity = 0 pts Mod complexity = 1 pt High complexity = 2 pts	None reported
US Oncology Research Study Clinical Coordination Grading (Unpublished. Personal communication)	2009	Points assigned to each of 21 grading criteria. Complexity based on number of points (↑ points = ↑ score)	None reported
Ontario Protocol Assessment Level (OPAL) (Smuck, et al: JOP 7(2):80-84. 2011)	2011	Score of 1-8 assigned based on # of contact events, type of trial	None reported
University of Michigan – Research Effort Tracking Application (RETA) (James, et al: J of NCCN 9(11):1228-1233. 2011)	2011	Staff logged daily time spent per protocol tasks	70-75% staff time = trial-related tasks 25-30% = non-trial (vacation, mtgs, etc) 72% of DM effort ->opening studies 25% effort ->not yet open/closed
Wichita CCOP Protocol Acuity Tool (WPAT) (Good, et al: JOP 9(4):211-215. 2013)	2013	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 * Yrly average Pts per nurse: New enrollments=69;On S=103;Off S=97

Wichita CCOP - Treatment Trials:
of Patients in Relation to Acuity Scores



Wichita CCOP - Cancer Control Trials:
Patients in Relation to Acuity Scores



ASCO Workload Assessment Tool

Centralized Data Capture

Clinical Trial Workload Assessment Importance Confirmed

- ASCO Research Community Forum Membership
  - 2010 Survey
  - 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
  - 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
   - Evaluate 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

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.

Score	Scoring Criteria
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)*

Two Acuity Metrics

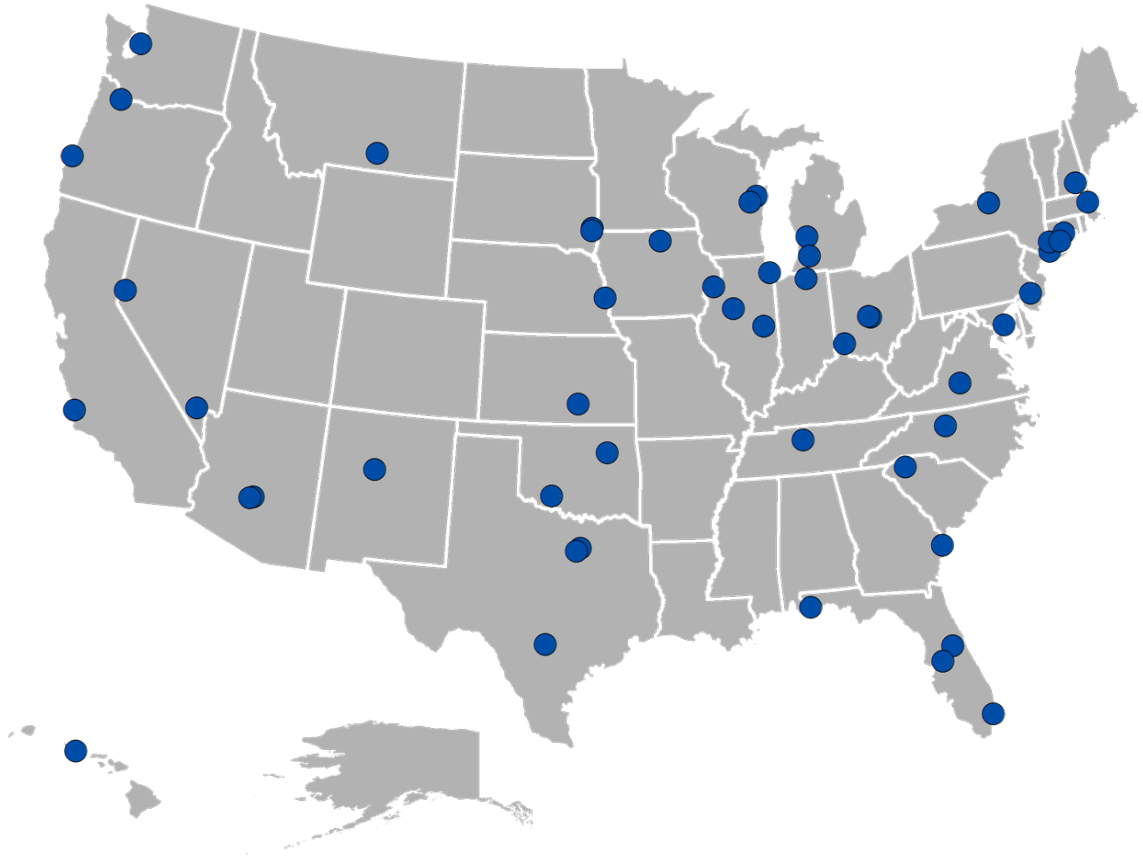
- Protocol Acuity Score
  - Scored 1 to 4 (Per Protocol Acuity Scoring Worksheet)
    - On Study/On active treatment
    - Follow-up (assumed 1)
      - On Study/Off active treatment
      - Off Study
- Nurse/CRA Acuity Score
  - Calculation

$$\frac{\text{protocol acuity score x number of patients}}{\text{number of FTE}}$$

Practical Strategies

- Multiple staff have multiple responsibilities
  - How to measure?
  - Research Nurse sees patient / CRA competes data
    - Data collection workload assessment mixed
- FTE metric
  - Low FTE values impact group score?
  - Time actually spent on activity when part time?

- 51 participating programs completed data collection
  - May through November 2013



Categorization of Research Programs

- 5 Groups based on type and size
  - Group 1: CCOPs/MBCCOPs ≤ 7 FTEs (13)
  - Group 2: CCOPs/MBCCOPs > 7 FTEs (10)
  - Group 3: Community hospitals/NCCCPs (8)
  - Group 4: Non-hospital-based private practice/private research networks (12)
  - Group 5: Hospital-based private practice (7)

Self-Reported Characteristics of Participating Research Programs

Type of Research Program	N (%)
CCOP	16 (31)
MBCCOP – academic-based	3 (6)
MBCCOP – not academic-based	2 (4)
NCCCP and CCOP	2 (4)
NCCCP	1 (2)
Community hospital	7 (14)
Private physician practice, hospital-based, not academic	7 (14)
Private physician practice, not hospital-based	11 (22)
Private research network	1 (2)
Other	1 (2)

Self-Reported Characteristics of Participating Research Programs

Number of Years Conducting Clinical Trials	N* (%)
7 – 13	13 (25)
14 – 25	15 (29)
26 – 30	14 (27)
> 30	9 (18)
Number of Patients Accrued Annually€ (Overall)	N* (%)
6 – 60	14 (27)
61 – 150	13 (25)
151 – 245	11 (22)
> 245	13 (25)
Number of Patients Accrued Annually€ to NCI-Sponsored Trials	N* (%)
0 – 13	13 (25)
14 – 45	13 (25)
46 – 124	12 (24)
> 124	13 (25)
Number of Patients Accrued Annually€ to Industry-Sponsored Trials	N* (%)
0 – 6	13 (25)
7 – 22	13 (25)
23 – 50	12 (24)
> 50	13 (25)

Self-Reported Characteristics of Participating Research Programs

Number of Phase I Trials	N* (%)
0	35 (69)
1-10	12 (24)
> 10	4 (8)
Number of Phase II Trials	N* (%)
0 – 7	13 (25)
8 – 16	15 (29)
17 – 30	11 (22)
> 30	12 (24)
Number of Phase III Trials	N* (%)
7 – 19	14 (27)
20 – 33	12 (24)
34 – 47	12 (24)
> 47	13 (25)

Self-Reported Characteristics of Participating Research Programs

	CCOP/MBCCOP ≤ 7 FTE (13)		CCOP/MBCCOP > 7 FTE (10)		Community Hospital / NCCCP (8)		Private Practice / Research Network (12)		Hospital-Based Private Practice (7)	
	415 trials 63 total staff		451 trials 147 total staff		180 trials 32 total staff		272 trials 55 total staff		139 trials 26 total staff	
	Median	Range	Median	Range	Median	Range	Median	Range	Median	Range
# of Individual Staff	6	1 – 8	15.5	9 – 22	4	2 – 7	3	1 – 14	3	1 - 8
Total # Staff FTEs	5	1 – 7	14.9	8.3 – 20.9	3.25	1.3 – 6.5	2.85	1 – 12	2.7	0.8 – 6.6
# Unique Protocols	69	12 – 150	88	20 – 160	33	9 – 50	27	5 – 75	20	16 - 47

Analysis: Data restrictions

- Point of measurement: Trial-related patient encounters
- Only staff designated as FTE = 1.0 included
  - < 0.5 FTE different workload experience
  - Often had multiple tasks – difficult to define the true amount of time/effort towards patient centered efforts
- Data from one program excluded
  - Uniquely structured program
  - Not comparable to other participating programs

Workload Data Collected

- Of the 51 participating sites
  - 46 (90%) provided data all 6 months
  - 2 provided 5 months
  - 3 provided 2, 3, & 4 months

Workload Data Collected

- 165 unique sponsors
- 963 unique protocols
  - 604 had patients on active study treatment
- 323 staff members
  - Research nurses (49%)
  - CRAs (28%)
  - Research Coordinators (16%)
  - Administrator/managers (1%)

Assigning Acuity Scores

- Congruence
  - Same score assigned to 461 protocols (76%)
  - Difference of 1 point in 120 (20%)
  - Difference of 2 points in 23 (4%)
    - Variability more common in industry trials (36%) compared to NIH/NCI trials (17%)
- Scores assigned (median)
  - Treatment = 3
  - Cancer control = 2
  - Correlative Science = 1.5
  - Observational/Registry = 1

Results

- Acuity scores for staff with patients on study receiving treatment were higher than FU
- Treatment trials had higher acuity than cancer control, observational/registry & prevention
- Industry trials had higher acuity than NIH/NCI, academic and other
- Evidence suggests trial acuity is a better measure of workload than number of patients

Good MJ, Hurley P, Woo KM, Szczepanek C, Stewart T, Robert N, Lyss A, Gonen M, Lilenbaum R. Assessing clinical trial-associated workload in community-based programs using the ASCO Clinical Trial Workload Assessment Tool. *Journal of Oncology Practice,* 2016, 12(5), e536-e546.

Table 2 | Number of Patient Encounters by Variable of Interest and Group Category

Number of Patient Encounters by Variable of Interest and Group Category

	CCOP/MBCCOP ≤ 7 FTE (13)	CCOP/MBCCOP > 7 FTE (10)	Community Hospital / NCCCP (8)	Private Practice / Research Network (12)	Hospital-Based Private Practice (7)
Number of Trials by Sponsor Type	N (%)	N (%)	N (%)	N (%)	N (%)
NIH/NCI Cooperative Group/Research Base	350 (84)	313 (69)	115 (64)	69 (25)	84 (60)
Industry	38 (9)	84 (19)	47 (26)	162 (60)	40 (29)
Academic	6 (1)	28 (6)	9 (5)	5 (2)	4 (3)
Other	21 (5)	26 (6)	9 (5)	36 (13)	11 (8)
Total # Trials	415 (100)	451 (100)	180 (100)	272 (100)	139 (100)
Number of Trials by Type of Trial	N (%)	N (%)	N (%)	N (%)	N (%)
Treatment	345 (83)	379 (84)	145 (81)	237 (87)	110 (79)
Cancer Control	45 (11)	56 (12)	19 (11)	16 (6)	15 (11)
Correlative Science	13 (3)	2	4 (2)	2 (1)	3 (2)
Observational/Registry	12 (3)	12 (3)	12 (7)	16 (6)	11 (8)
Prevention	0	1	0	1	0
Other	0	1	0	0	0
Total # Trials	415 (100)	451 (100)	180 (100)	272 (100)	139 (100)
Type of Research Staff	N (%)	N (%)	N (%)	N (%)	N (%)
Clinical Research Associate	35 (56)	40 (27)	5 (16)	9 (16)	2 (8)
Research Coordinator	1 (2)	37 (25)	5 (16)	4 (7)	6 (23)
Research Nurse	24 (38)	53 (36)	22 (69)	40 (73)	18 (69)
Administrator/Manager	0	1 (1)	0	2 (4)	0
Team	3 (5)	16 (11)	0	0	0
Total # Staff Members	63 (100)	147 (100)	32 (100)	55 (100)	26 (100)

Monthly Staff Acuity Scores & Number of Patient Encounters by Patient Status

		CCOP/MBCCOP ≤ 7 FTE (13)			CCOP/MBCCOP > 7 FTE (10)			Community Hospital / NCCCP (8)			Private Practice / Research Network (12)			Hospital-Based Private Practice (7)		
		N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range
On Study Treatment	Acuity Score	38	27.75	(6-117)	103	17	(2-117.5)	25	8	(1-62)	37	47.5	(3-98.5)	13	23.5	(3-40.5)
	# Patient Encounters		10.5	(2-75)		6	(1-37.5)		3	(1-22)		14.5	(1-31.5)		8.5	(1-17.5)
On Study Off Treatment	Acuity Score	20	11.5	(1-107.5)	68	2.25	(1-49)	15	2	(1-17.5)	33	2.5	(1-9.5)	7	1.5	(1-4)
	# Patient Encounters		11.5	(1-107.5)		2.25	(1-49)		2	(1-17.5)		2.5	(1-9.5)		1.5	(1-4)
Off Study Follow-up	Acuity Score	28	2.75	(1-91)	64	2	(1-35)	14	1.75	(1-5)	26	1.25	(1-4.5)	9	2	(1-4)
	# Patient Encounters		2.75	(1-91)		2	(1-35)		1.75	(1-5)		1.25	(1-4.5)		2	(1-4)

Monthly Staff Acuity Scores & Number of Patient Encounters by Sponsor

		CCOP/MBCCOP ≤ 7 FTE (13)			CCOP/MBCCOP > 7 FTE (10)			Community Hospital / NCCCP (8)			Private Practice / Research Network (12)			Hospital-Based Private Practice (7)		
		N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range
NIH/NCI Cooperative Group/ Research Base	Acuity Score	39	34.5	(8-265.5)	107	14.5	(1-97)	20	8.25	(1-69)	23	2	(1-66)	8	7.75	(2-37)
	# Patient Encounters		18	(3.5-187.5)		7	(1-56.5)		3.5	(1-33)		1.5	(1-26)		3.75	(1-4)
Industry	Acuity Score	14	5.75	(1-27.5)	67	8	(1-110)	14	5.75	(1-22.5)	36	40.5	(2-95)	12	14.25	(1-39)
	# Patient Encounters		3.5	(1-18.5)		2.5	1-27.5		2	(1-17.5)		13	(1-36)		4.5	(1-13)
Academic	Acuity Score	6	3	(1-19)	22	3	(1-24)	8	1.5	(1-25.5)	1	3	-	3	2	(1-5)
	# Patient Encounters		3	(1-19)		2	(1-11)		1	(1-8.5)		3			1	(1-5)
Other	Acuity Score	12	6.5	(1-67)	27	10	(1-30)	7	3	(1-6)	26	2	(1-17.5)	6	4	(1-8)
	# Patient Encounters		3.5	(1-67)		5	(1-15)		2	(1-2)		1.5	(1-7.5)		2	(1-5)

Monthly Staff Acuity Scores & Number of Patient Encounters by Trial Type

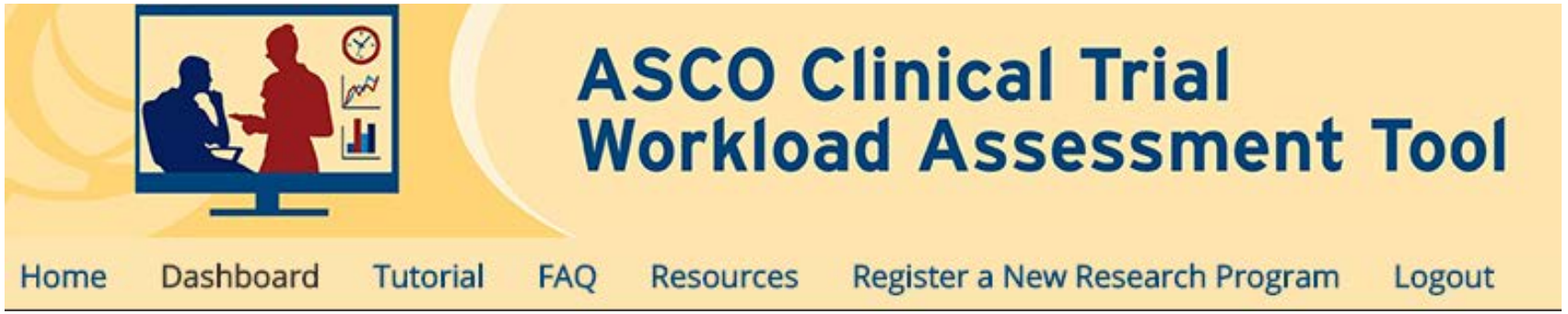
		CCOP/MBCCOP ≤ 7 FTE (13)			CCOP/MBCCOP > 7 FTE (10)			Community Hospital / NCCCP (8)			Private Practice / Research Network (12)			Hospital-Based Private Practice (7)		
		N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range
Treatment	Acuity Score	39	33	(7-235.5)	107	18	(1-119)	24	8.75	(1-66)	37	48.5	(1.5-99)	11	27	(3-41.5)
	# Patient Encounters		15	(2-165.5)		9	(1-56.5)		4.25	(1-29)		16.5	(1.5-40)		9.5	(1-14.5)
Cancer Control	Acuity Score	33	4	(1-68)	73	4	(1-54)	14	2.75	(1-20)	9	4	(1-6)	8	3.75	(1-13)
	# Patient Encounters		3	(1-67)		2	(1-27)		2	(1-17.5)		2	(1-3)		1.75	(1-12.5)
Correlative Science	Acuity Score	10	4.5	(1-23)	11	2	(1-6)	5	1.5	(1-6)	1	50	-	2	1	(1-1)
	# Patient Encounters		3	(1-23)		2	(1-3.5)		1.5	(1-3)		25			1	(1-1)
Observational/ Registry	Acuity Score	25	3.5	(1-18)	42	2.25	(1-19.5)	10	3.5	(1-22.5)	18	2.5	(1-14)	7	2	(1-5)
	# Patient Encounters		3.5	(1-10)		2	(1-10)		2	(1-7.5)		2.25	(1-6.5)		1.5	(1-5)

Monthly Staff Acuity Scores & Number of Patient Encounters by Staff Title

		CCOP/MBCCOP ≤ 7 FTE (13)			CCOP/MBCCOP > 7 FTE (10)			Community Hospital / NCCCP (8)			Private Practice / Research Network (12)			Hospital-Based Private Practice (7)		
		N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range	N	Median	Range
Research Nurse	Acuity Score	22	42	(10.5-265.5)	45	19.5	(1-115)	18	12.75	(2-70)	28	53	(11.5-107.5)	9	30	(3-42.5)
	# Patient Encounters		16	(3.5-81)		9	(1-41.5)		5	(1-34)		18	(5-43)		11.5	(1-20)
Research Coordinator	Acuity Score	1	44	-	34	33.5	(2-110)	3	20.5	(11-23.5)	1	21	-	4	16.75	(1-27)
	# Patient Encounters		44			15.5	(2-41)		10.5	(9-15.5)		10.5			9.25	(1-13)
Clinical Research Associate	Acuity Score	6	38.75	(8-93)	34	15.5	(1-119)	5	15	(3.5-25.5)	7	50	(5.5-79)	1	3	-
	# Patient Encounters		26.75	(7-187.5)		7.5	(1-38.5)		8.5	(2.5-15)		25	(5.5-29.5)			

Next Workload Metric?

- Data collection
- Screening
- Regulatory
- Quality Assurance
- Academic sites



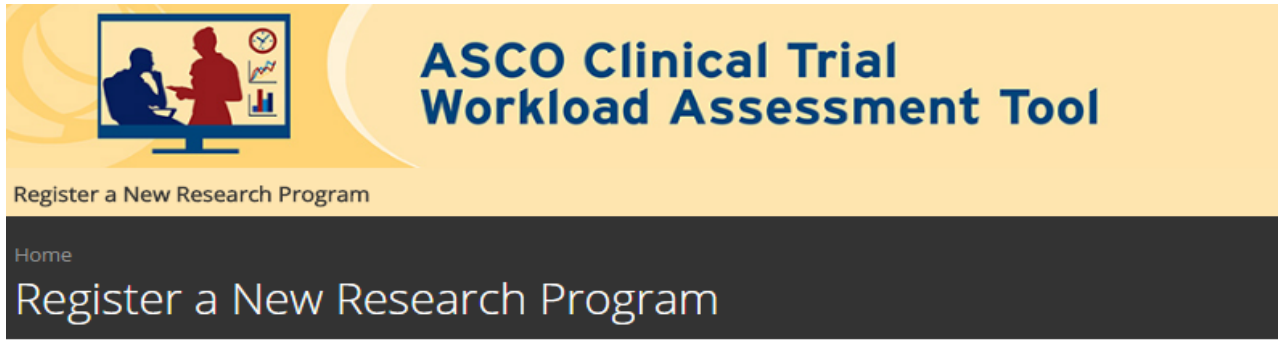
www.workload.asco.org

Features

- ✓ Reports and graphs
- ✓ Assess staff workload:
  - ✓ Per protocol
  - ✓ Per individual staff person
  - ✓ Compare
- ✓ Assists with monitoring and managing research staff
  - ✓ Monitor performance
  - ✓ Compare productivity

Getting Started

Register Your Research Program



My Workbench Dashboard Content Structure Appearance People Modules Configuration Reports Help Shortcuts

Create Report

Month

Month *Year *

Dec 2014

Month and Year for this report.

Show row weights

Workload Data

Site	Research Staff	FTE	Study	Patient Status	#Patients	
Test HOA	TestDW	1	Test Study 5-ASCOTEST-NCT55555555 (61556)	On Study Treatment	15	Remove
- None -	- None -			- None -		Remove

Add another item

Add Screening Information (optional)

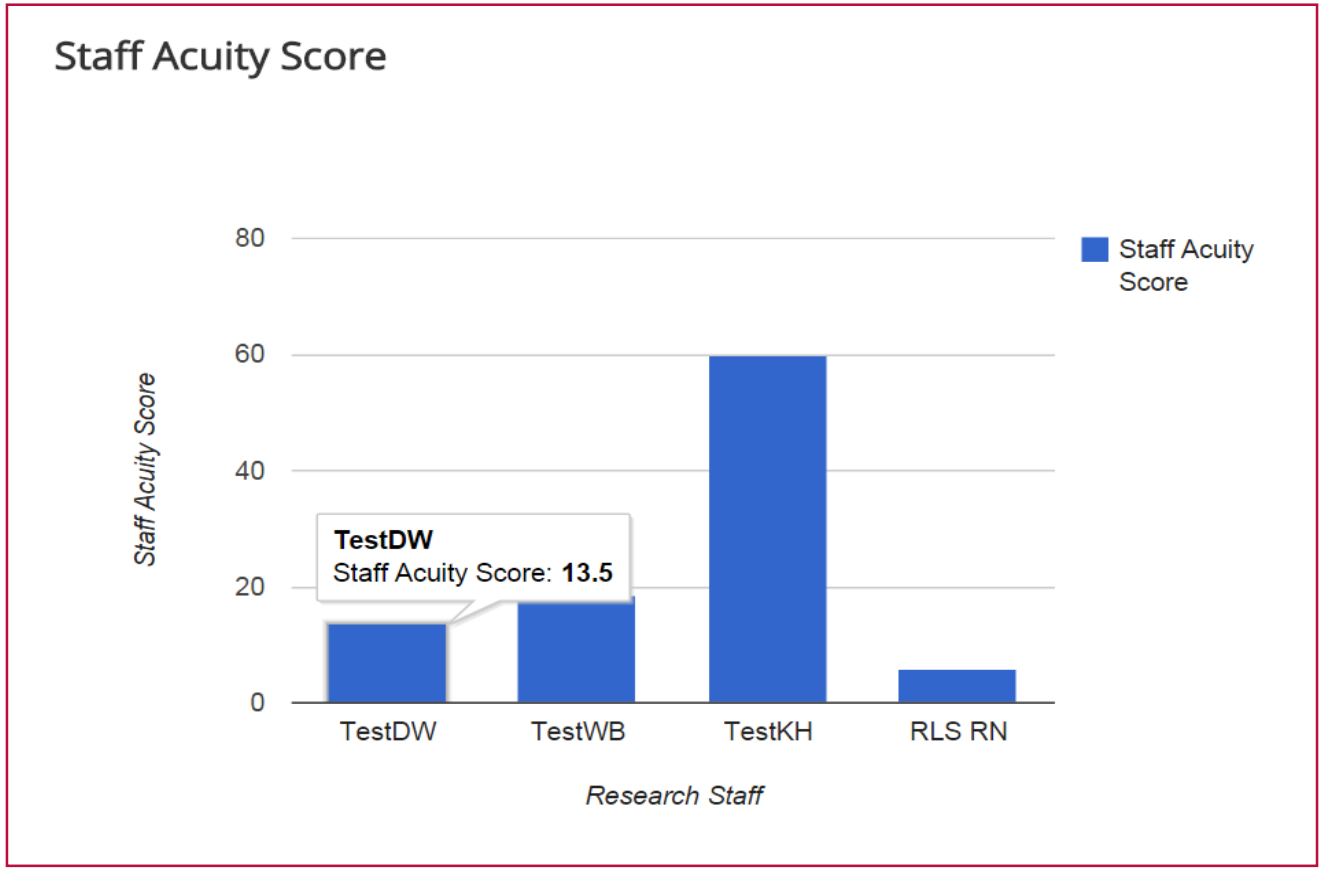
Number of patients who were pre-screened

i.e., to determine potential eligibility; consent not yet signed; at least one hour of time devoted.

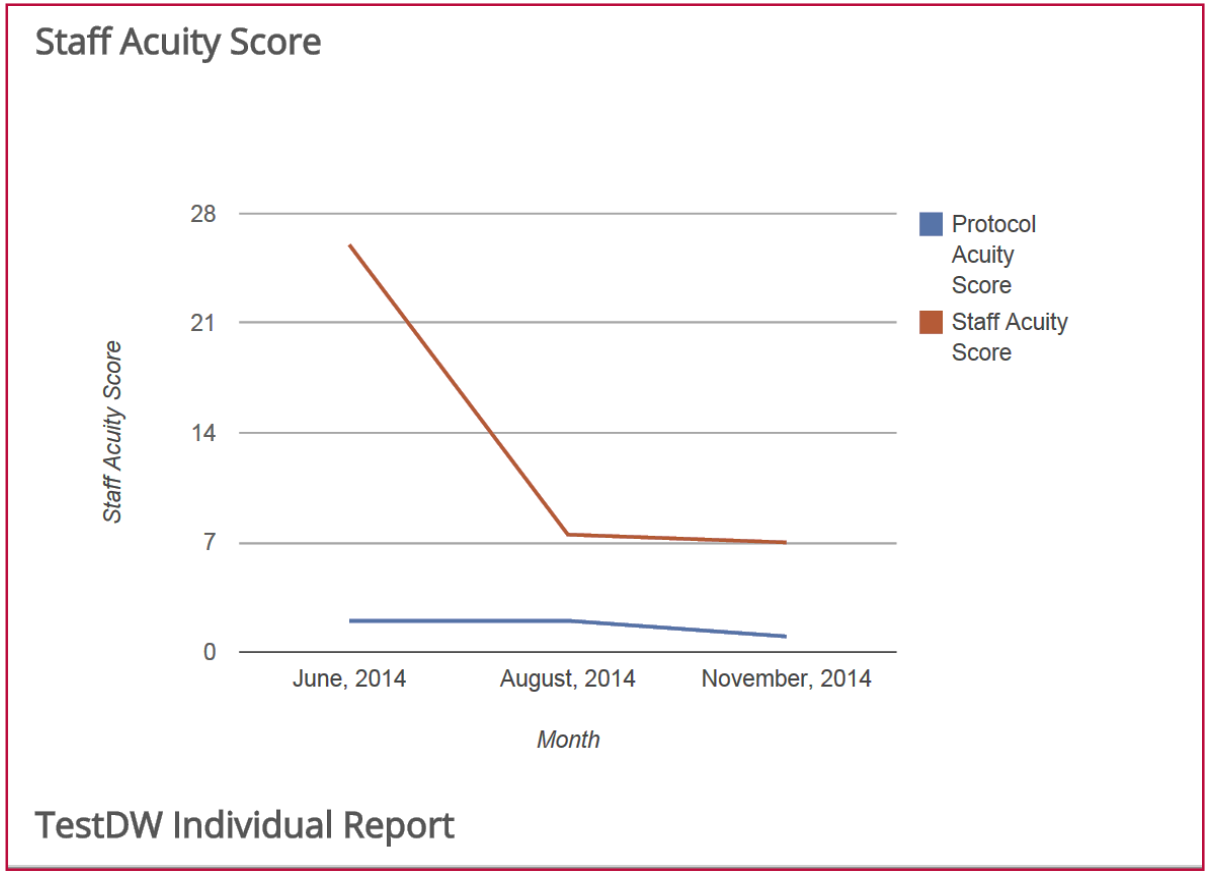
Number of patients who were screened

i.e., eligibility was confirmed and consent provided and signed.

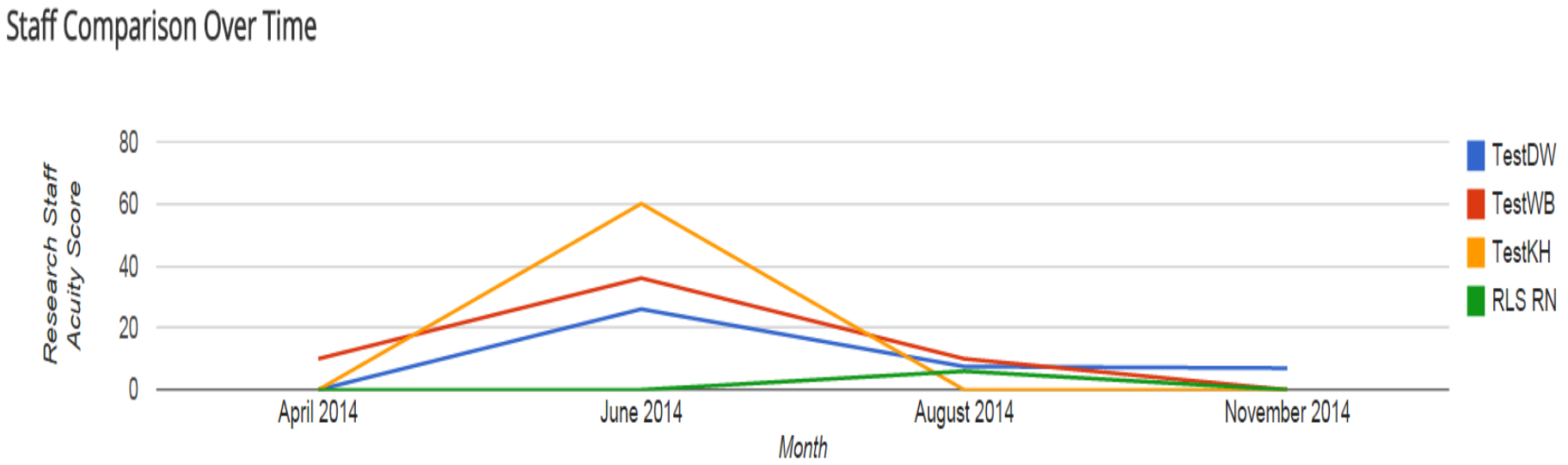
Available Graphs –
Overall Average Acuity Scores for Research Team



Available Graphs –
Acuity Score per Individual Staff Over Time



Available Graphs – Acuity Scores Over Time



Questions - Discussion