Developing A Scoring Tool to Calculate Protocol Acuity for Clinical Research Nurse Workload

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Background

Nurse managers in our Clinical Trials Office experienced a discrepancy among nurses and their perceived workload. Management requested a tool to assist with human resource management that could apply empirical objective values to face to face patient interactions and allow for fair and equitable case assignments. A literature search did not yield a tool that addressed nursing duties specifically. This project began in early 2022 was implemented Spring of 2023.

Goals

- Improve existing staffing assignments
- Quantify staffing needs per protocol
- Develop objective scoring criteria
- Improve staff retention and employee satisfaction
- Define optimal FTE workload
- Project future staffing needs

Outcomes

- ☑Levelized existing workloads
- ☑Identified manageable baseline nurse workload score
- ☑Decreased Projected staffing needs for studies in pipeline
- ☑Adjusted assignments during staffing shortages

Future Directions

- Score studies in the pipeline
- Provide objectivity during feasibility evaluation
- Collaborate with other institutions to further develop this tool

Methods

Criteria were developed for each aspect of the nursing interactions that occur in each phase of the clinical trial such as Screening, Treatment, and Follow up. Values were assigned to each nursing task required and averaged for a score for each arm of the study. The plan was to incorporate the protocol acuity score into our Clinical Trials Management System and provide reports that assess current nurse workload. Once all studies were scored and available in our CTMS, managers were provided access and were able to assess current staff workloads and levelized as needed. Mangers then were able to discuss with individual staff nurses to compare actual work performed to the workload measurement tool, determining the tool's reliability and validity.

Nurse Workload Report Scoring Grid

Determie a score for each epoch by determining the score for each epoch item and taking the average for all items in that epoch.

Epochs	Epoch Items	0	1	2	3	4	5
Screening	Pages in Consent	N/A	from 1 to 6	from 7 to 15	from 16 to25	from 26 to 35	36+
	Eligibility Items	N/A	1	from 1 to 10	from 11 to25	from 26 to 35	36+
	Eligibility Testing	N/A	None	(Minimal)-Can be completed the day of consent. No tests require scheduling or a second visit.	(Moderate)-Requires a second visit but can be completed in one visit.	(Extensive)-Requires more than one additional day	(Maximum)-Requires more than one additional visit and an invasive procedure such as a biopsy
Treatment	Number of Visits	N/A	from 1 to 2	3-4 Visits OR >4 week intervals	5-8 Visits OR 3-4 week intervals	9+ Visits OR 1-2 week intervals	Multiple visits per week
	Visit Complexity	N/A	(Brief)-QOL or equivalent only	(Focused)-Con meds or AEs, +/- QOL	(Standard)-AEs and Con meds, +/- QOL	(Complex)-Standard plus one or more of the following: Pill Count, Diary, Photos, Measurements, EKG by CRN or Hospitalization (non-Heme)	(Intense)-Multiple visits per week or Hopitalization (Hematology)
	Modalities	N/A	N/A	N/A	1	>1	Transplant
Follow-up	Follow-up	N/A	<3 visits per year (5yr average)	>/=3 visits and < 5 visits per year (5yr average)	5+ visits per year (5yr average)	N/A	N/A

Definitions:
Screening--All activites from consent through enrollment.
Treatment-During protocol intervention
Follow-up-Post protocol intervention.
Consent--The IRB apprived document excluding the HIPAA section
Modality--Treatment Discipline such as, Medical, Surgical, Radiation

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