Category: Training, Career Development, and Staff Retention – Work in Progress

Optimizing Workload Management in Phase-I Oncology Clinical Research through Novel Oncology - Phase-I Acuity Scoring System

S. Fabrie, M. Dort, W. Paez, T. Kochukoshy, A. Olszanski

Fox Chase Cancer Center, Temple Health

1. Background

Phase-I oncology treatment trials are known to be challenging to manage. The Ontario Protocol Assessment Level (OPAL) is widely used to assess trial acuity but assigns a uniform score of eight (OPAL = 8) to all Phase-1 trials. This generalization fails to account for workload variability within Phase-1 programs, creating an unmet need for clinical research teams. Additionally, high workloads contribute to burnout among clinical research professionals, highlighting the need for a workload management tool tailored to the complexities of Phase-I oncology trials. Optimizing workload management through a dedicated Oncology – Phase-I Acuity Scoring System (O-PASS) can help mitigate these concerns and develop a more effective Phase-I program.

2. Goals

O-PASS was designed to more accurately estimate the workload of Phase-I oncology clinical research coordinators (CRCs) and clinical research nurses (CRNs). By improving workload distribution, O-PASS aims to reduce burnout and turnover, ultimately stabilizing staffing and strengthening the Phase-I program to expand patient access to clinical trials.

3. Solutions and Methods

O-PASS evaluates each Phase-I clinical trial using 20 study-specific criteria on a standardized scoresheet, assigning each criterion a score of 0 to 5 points [Fig. 1 – Step 1]. These scores are totaled to generate a raw acuity score (maximum = 100), which is then converted into a weighted score of 1, 2, or 3 points [Fig. 1 – Step 2].

Studies are then adjusted for several scenarios that impact individual CRC/CRN workloads [Fig. 1 – Step 3]. The final workload for each CRC/CRN is determined using a standardized equation, allowing for workload reallocation based on experience level [Fig. 1 – Step 4].

The total weighted workload across all studies should not exceed the combined maximum total workload capacity of the CRC/CRN team. If a discrepancy arises, management can use O-PASS to assess staffing needs and determine the experience level required for new hires.

4. Outcomes

Prior to implementation of O-PASS, an anonymous survey of the Fox Chase Cancer Center (FCCC) Phase-I team identified workload distribution as the top concern for 50 percent of respondents. Six months after implementation, a follow-up survey assessed quality of life and workload perception.

Results showed:

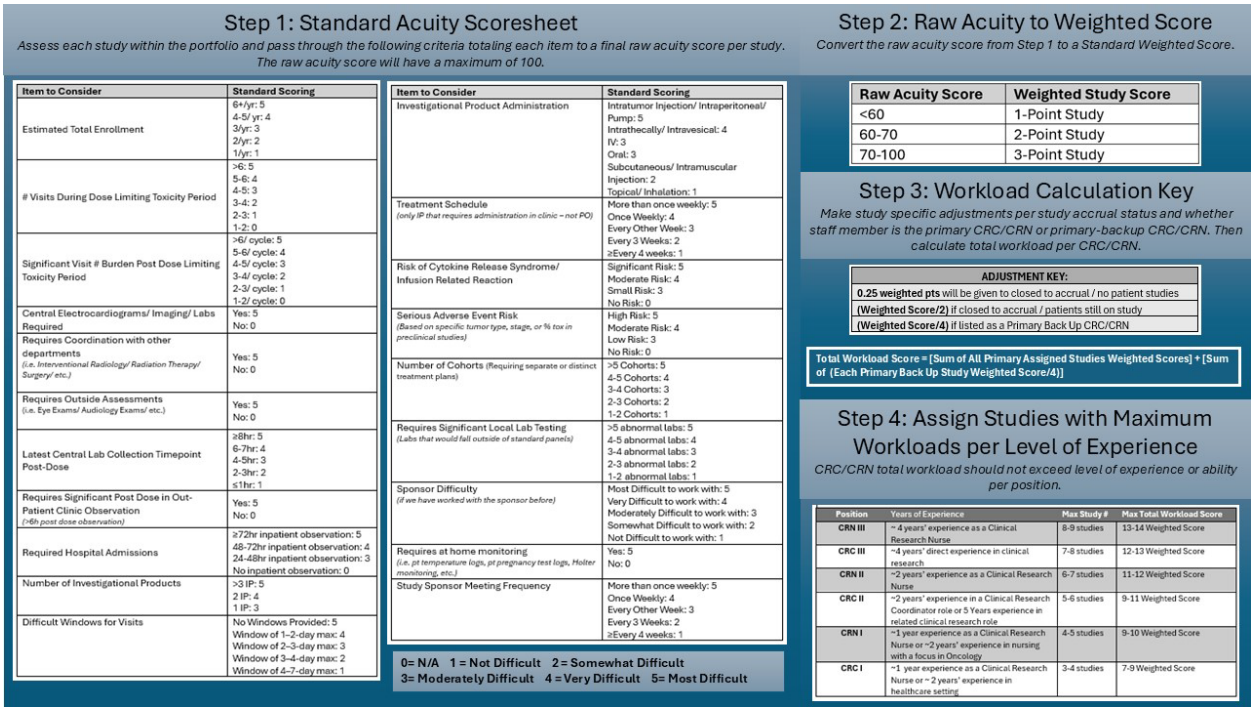
- 67 percent of CRC/CRNs reported improved work-life balance and reduced burnout
- 100 percent believed O-PASS could help reduce staff turnover

Category: Training, Career Development, and Staff Retention – Work in Progress

5. Learned and Future Directions

Preliminary data suggests O-PASS has enhanced the FCCC Phase-I clinical research program at FCCC. Limitations of this study include a small cohort size and single institution setting. Additionally, concurrent staffing changes may have influenced results. Ongoing follow-up questionnaires will further assess long-term effects, while management will analyze retention data to evaluate its impact on turnover. Further refinement of the tool will increase its effectiveness. In the future, O-PASS will serve as a model for workload assessment tools for data specialists and regulatory coordinators.

Figure



Step 1: Standard Acuity Scoresheet

Assess each study within the portfolio and pass through the following criteria totaling each item to a final raw acuity score per study. The raw acuity score will have a maximum of 100.

Item to Consider	Standard Scoring
Estimated Total Enrollment	6+/yr: 5 4-5/ yr: 4 3/yr: 3 2/yr: 2 1/yr: 1
# Visits During Dose Limiting Toxicity Period	>6: 5 5-6: 4 4-5: 3 3-4: 2 2-3: 1 1-2: 0
Significant Visit # Burden Post Dose Limiting Toxicity Period	>6/ cycle: 5 5-6/ cycle: 4 4-5/ cycle: 3 3-4/ cycle: 2 2-3/ cycle: 1 1-2/ cycle: 0
Central Electrocardiograms/ Imaging/ Labs Required	Yes: 5 No: 0
Requires Coordination with other departments *(i.e. Interventional Radiology/ Radiation Therapy/ Surgery/ etc.)*	Yes: 5 No: 0
Requires Outside Assessments (i.e. Eye Exams/ Audiology Exams/ etc.)	Yes: 5 No: 0
Latest Central Lab Collection Timepoint Post-Dose	≥8hr: 5 6-7hr: 4 4-5hr: 3 2-3hr: 2 ≤1hr: 1
Requires Significant Post Dose in Out-Patient Clinic Observation *(>6h post dose observation)*	Yes: 5 No: 0
Required Hospital Admissions	≥72hr inpatient observation: 5 48-72hr inpatient observation: 4 24-48hr inpatient observation: 3 No inpatient observation: 0
Number of Investigational Products	>3 IP: 5 2 IP: 4 1 IP: 3
Difficult Windows for Visits	No Windows Provided: 5 Window of 1–2-day max: 4 Window of 2–3-day max: 3 Window of 3–4-day max: 2 Window of 4–7-day max: 1

Item to Consider	Standard Scoring
Investigational Product Administration	Intratumor Injection/ Intraperitoneal/ Pump: 5 Intrathecally/ Intravesical: 4 IV: 3 Oral: 3 Subcutaneous/ Intramuscular Injection: 2 Topical/ Inhalation: 1
Treatment Schedule *(only IP that requires administration in clinic – not PO)*	More than once weekly: 5 Once Weekly: 4 Every Other Week: 3 Every 3 Weeks: 2 ≥Every 4 weeks: 1
Risk of Cytokine Release Syndrome/ Infusion Related Reaction	Significant Risk: 5 Moderate Risk: 4 Small Risk: 3 No Risk: 0
Serious Adverse Event Risk *(Based on specific tumor type, stage, or % tox in preclinical studies)*	High Risk: 5 Moderate Risk: 4 Low Risk: 3 No Risk: 0
Number of Cohorts (Requiring separate or distinct treatment plans)	>5 Cohorts: 5 4-5 Cohorts: 4 3-4 Cohorts: 3 2-3 Cohorts: 2 1-2 Cohorts: 1
Requires Significant Local Lab Testing *(Labs that would fall outside of standard panels)*	>5 abnormal labs: 5 4-5 abnormal labs: 4 3-4 abnormal labs: 3 2-3 abnormal labs: 2 1-2 abnormal labs: 1
Sponsor Difficulty *(if we have worked with the sponsor before)*	Most Difficult to work with: 5 Very Difficult to work with: 4 Moderately Difficult to work with: 3 Somewhat Difficult to work with: 2 Not Difficult to work with: 1
Requires at home monitoring *(i.e. pt temperature logs, pt pregnancy test logs, Holter monitoring, etc.)*	Yes: 5 No: 0
Study Sponsor Meeting Frequency	More than once weekly: 5 Once Weekly: 4 Every Other Week: 3 Every 3 Weeks: 2 ≥Every 4 weeks: 1

0= N/A 1 = Not Difficult 2 = Somewhat Difficult 3= Moderately Difficult 4 = Very Difficult 5= Most Difficult

Step 2: Raw Acuity to Weighted Score

Convert the raw acuity score from Step 1 to a Standard Weighted Score.

Raw Acuity Score	Weighted Study Score
<60	1-Point Study
60-70	2-Point Study
70-100	3-Point Study

Step 3: Workload Calculation Key

Make study specific adjustments per study accrual status and whether staff member is the primary CRC/CRN or primary-backup CRC/CRN. Then calculate total workload per CRC/CRN.

ADJUSTMENT KEY:
0.25 weighted pts will be given to closed to accrual / no patient studies
(Weighted Score/2) if closed to accrual / patients still on study
(Weighted Score/4) if listed as a Primary Back Up CRC/CRN

Total Workload Score = [Sum of All Primary Assigned Studies Weighted Scores] + [Sum of (Each Primary Back Up Study Weighted Score/4)]

Step 4: Assign Studies with Maximum Workloads per Level of Experience

CRC/CRN total workload should not exceed level of experience or ability per position.

Position	Years of Experience	Max Study #	Max Total Workload Score
CRN III	~ 4 years' experience as a Clinical Research Nurse	8-9 studies	13-14 Weighted Score
CRC III	~4 years' direct experience in clinical research	7-8 studies	12-13 Weighted Score
CRN II	~2 years' experience as a Clinical Research Nurse	6-7 studies	11-12 Weighted Score
CRC II	~2 years' experience in a Clinical Research Coordinator role or 5 Years experience in related clinical research role	5-6 studies	9-11 Weighted Score
CRN I	~1 year experience as a Clinical Research Nurse or ~2 years' experience in nursing with a focus in Oncology	4-5 studies	9-10 Weighted Score
CRC I	~1 year experience as a Clinical Research Nurse or ~ 2 years' experience in healthcare setting	3-4 studies	7-9 Weighted Score