Category: Clinical Trial Operations – Completed Project

Staffing Model Reported Effort and Study Budgets: Are We In Sync?

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1. Background

Over the past several years, clinical trials in Oncology have increased in cost and complexity. The SCCC has developed a homegrown staffing model which measures the complexity of protocols to help determine the appropriate amount of staff to handle the workload. The staffing model is utilized across disease sites and studies in a consistent manner. Budgets are developed by individual teams. It is critical to ensure that the increase in workload is appropriately quantified and matched by budget.

2. Goals

We aimed to study the trends in trial complexity using the SCCC staffing model. Second, we investigated budgets and study complexity scores over the last six years to observe if there is a correlation between budget and complexity, in part to ensure that there is not a significant discrepancy.

3. Solutions and Methods

Our Cancer Center's protocol acuity model has been in use for six years, incorporating modifications over time, and aims to account for individual effort by measuring elements such as frequency of visits, quantity of study-related procedures, and data reporting . A static score is given for screening and enrollment of new subjects, which is retrospective, based on coordinator input. Utilizing the staffing model protocol acuity and corresponding budgets, we looked at change over time as well as their relationship. Specifically, we reviewed the numbers for industry studies, excluding investigator-initiated trials and cooperative group studies from the analysis. Total complexity score was used from the staffing model, and both total per-patient budget and screening per-patient budget were used in our analyses. A total of 120 studies were analyzed. Outliers greater than three times the standard deviation above the means were removed (n=2).

4. Outcomes

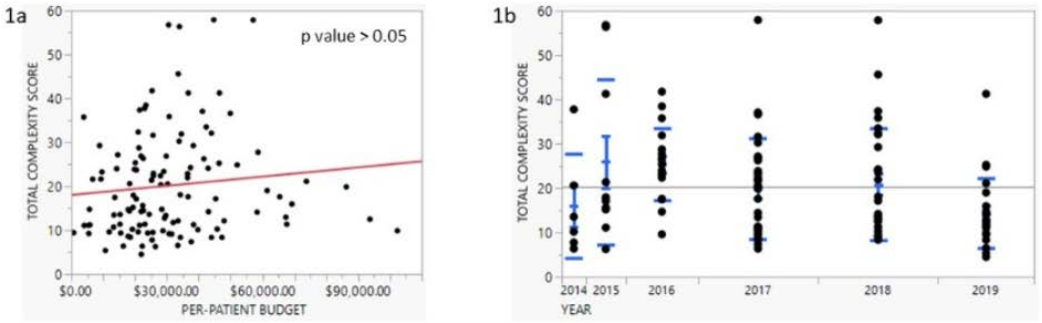

Figure 1a-b: Total complexity score versus per-patient budget and total complexity score by year.

There was no significant correlation between per-patient study budget and study complexity score (Fig 1a). While the mean per-patient budget increased each year, including the portion of the budget dedicated to screening of potential patients, the total complexity score did not have a definitive trend over the years (Fig 1b). We believe this difference is a product of our acuity score not accounting for screening complexity; if the primary increase in study complexity is screening-related, the current protocol acuity score would not account for this change, yet budgets increased. The lack of a significant relationship between the total per-patient budget and total complexity score may also be attributed to differences in how managers calculate their budgets and negotiate with sponsors.

5. Lessons Learned

Legacy staffing models need to be reevaluated to keep up with changes in oncology clinical trial design. Based on our analyses, we hypothesize that the complexity of clinical trials has increased due to intense screening activities, however, more evaluation is needed. We have proposed a modification to our current staffing model to account for the screening period of studies in order to ensure that study complexity is inclusive of staff efforts during that time. Instead of a static number, the screening score would vary based on procedures and staff time before enrollment. Future research will review the increase in budgets versus inflation, to ensure that the complexity is matched by budget allocation.