

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

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## 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.

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.

## Methods

- Our Cancer Center's protocol acuity model aims to account for individual effort by measuring:
  - frequency of visits,
  - quantity of study-related procedures
  - data reporting
  - A static score is given for screening and enrollment
- Utilizing the staffing model protocol acuity and corresponding budgets, we looked at change over time as well as their relationship in industry studies.
  - Total complexity score was used from the staffing model, along with total per-patient budget and screening per-patient budget
- A total of 120 studies were analyzed.
- Outliers greater than three times the standard deviation above the means were removed (n=2).

## Figures

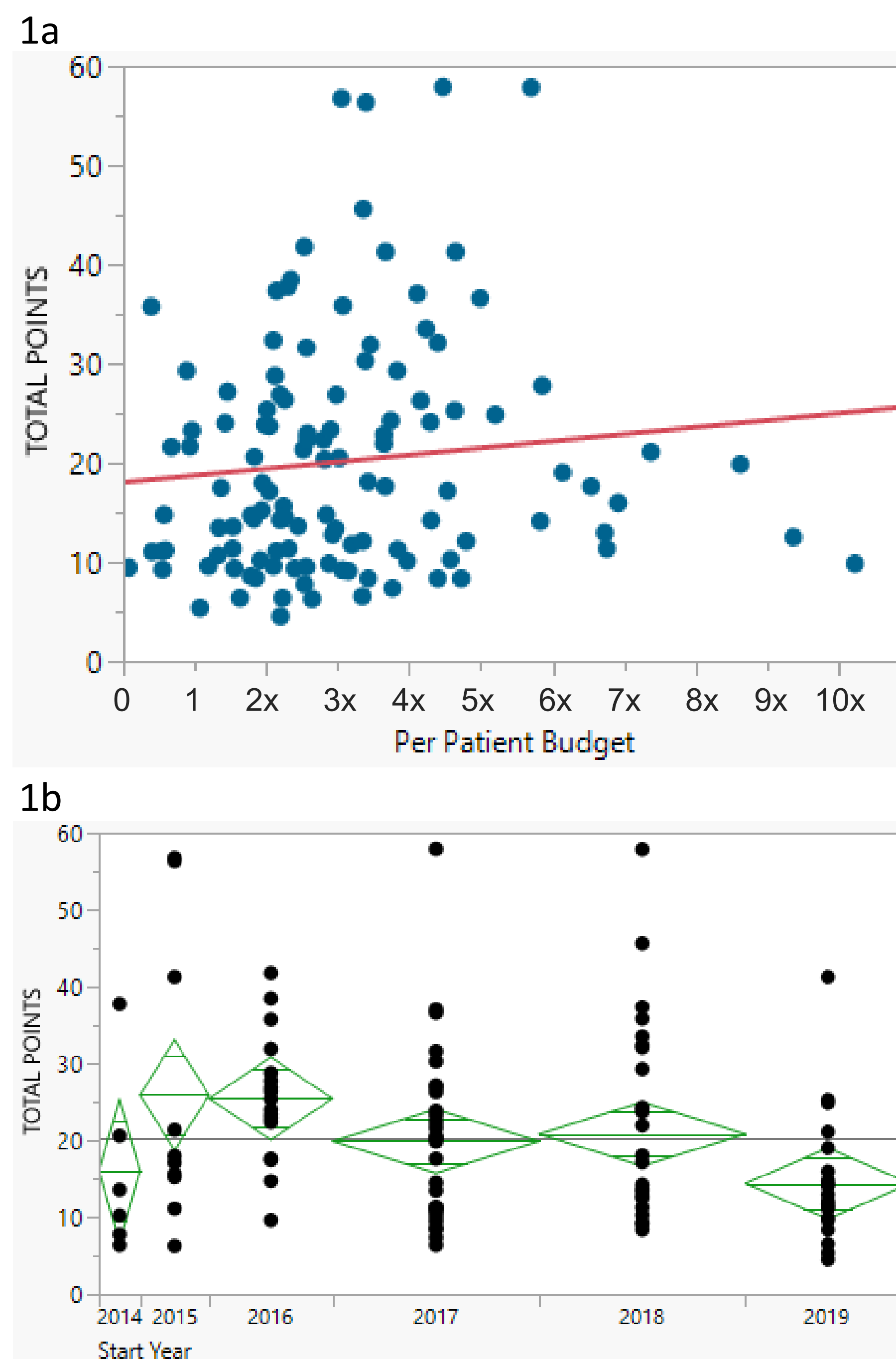


Figure 1a-b: Total complexity score versus per-patient budget and total complexity score by year.

## Results

- No significant correlation between per-patient study budget and study complexity score (Fig 1a)
- Mean per-patient budget increased each year, including the portion of the budget dedicated to screening of potential patients
- Total complexity score did not have a definitive trend over the years (Fig 1b).

## Discussion

- The discrepancy between increasing per-patient budget and stagnant complexity score could be a product of our acuity score not accounting for screening complexity.
- 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.

## Conclusion

- Legacy staffing models need to be reevaluated to keep up with changes in oncology clinical trial design.
- Proposed modifications to our current staffing model 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
- Future research will review the increase in budgets versus inflation, to ensure that the complexity is truly matched by budget allocation.