Spring 1-24-2023

Mapping the Opal Score for Clinical Trials to Coordinator Hours: A Single Site Study

Kesley Tyson
Medical University of South Carolina

MAPPING THE OPAL SCORE FOR CLINICAL TRIALS TO COORDINATOR HOURS: A SINGLE SITE STUDY

BY

Kesley D. Tyson

A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

Acknowledgments

With my sincerest gratitude, I thank my family and friends who have encouraged me throughout my matriculation in the Doctor of Health Administration (DHA) program at the Medical University of South Carolina (MUSC). Thank you to the Morehouse School of Medicine, Emory University, and Georgia State University faculty and staff for supporting my educational efforts with understanding while working full-time. I want to thank the Health Information Management Systems Society and the MUSC College of Health Professions for supporting me with scholarships to pursue my studies. I also want to thank my committee and MUSC's DHA faculty and staff for their help and guidance throughout this entire process. Lastly, I want to thank my peers in this cohort, who have truly made this a memorable experience.

This project was supported, in part, by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR002378 and UL1TR001450. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

This project was also supported, in part, by the National Institute of Minority Health and Health Disparities of the National Institutes of Health under Award Number U54MD007602. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Abstract of Dissertation Presented to the
Medical University of South Carolina
In Partial Fulfillment of the Requirements for the
Degree of Doctor of Health Administration

MAPPING THE OPAL SCORE FOR CLINICAL TRIALS TO COORDINATOR HOURS: A SINGLE SITE STUDY

by

Kesley D. Tyson

Chairperson: Daniel Brinton, PhD
Committee: Jillian Harvey, PhD
Leila Forney, DNP, CCRP

Abstract

Workload assessments help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. The Ontario Protocol Assessment Level (OPAL) is one of the most widely used protocol assessment tools. This study mapped an adapted OPAL score for clinical trials to actual coordinator hours from a single site to determine if the adapted OPAL score could predict coordinator hours. The purpose was to project a more accurate capacity estimate when considering new studies. The Morehouse School of Medicine (MSM) clinical trials management system was queried for actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022. Protocols were graded using an adapted OPAL tool. Linear regression analysis was performed to determine whether a linear association exists between the adapted OPAL score and coordinator effort. Seven studies were included in the analysis. The overall regression was statistically significant ($R^2 = 0.78$, $p = 0.008$), and the adapted OPAL score significantly predicted tracked coordinator hours ($\beta = 77.22$, $p = 0.008$).

Table of Contents

List of Figures

List of Tables

CHAPTER I INTRODUCTION

1.1 Background and Need

Approximately 90% of clinical trials fail; however, despite the high failure rate, the number of trials is steadily increasing (Sun et al., 2022). According to ClinicalTrials.gov, there has been over a 30% increase in the number of registered clinical trials since 2020 (NIH, 2023). As the number of trials has increased, so has their complexity. An increase in protocol amendments and the challenges with pivoting to remote studies during the COVID-19 pandemic has not only contributed to their complexity but also to high study costs, delays, and increased regulatory burdens (Miessler, 2022). In addition, sites that primarily serve underserved communities face unique challenges, such as recruiting in populations with limited access to the internet and internet-enabled devices (Brody et al., 2022).

The clinical research coordinator (CRC) plays an integral role in the success of clinical trials and manages and oversees various aspects of studies. They have a broad scope of responsibilities that range from recruiting subjects and conducting study visits to budget development and managing study finances (Buchanan et al., 2020; acrpnet.org, 2020; Speicher et al., 2012). This role requires specialized skills, training, and medical knowledge due to increased protocol complexity and regulatory oversight (Buchanan et al., 2020). Unfortunately, job satisfaction has declined due to increased responsibilities and workload, leading to burnout and high turnover. As a result, there is a national shortage of qualified professional coordinators (Buchanan et al., 2021; Richie et al., 2020).

To help retain staff, sites should assess workloads and capacity (Richie et al., 2020). This project will apply resource management and capacity planning principles to examine the workload in a research coordinator pool at an academic research center. The data from this

project will improve clinical research leaders' ability to make informed decisions to increase operational efficiency and ensure workloads are adequately resourced.

1.2 Problem Statement

Workload assessments help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. The Ontario Protocol Assessment Level (OPAL) is one of the most widely used protocol assessment tools. It provides a quantifiable score for clinical trial activities based on the complexity of the study protocol, is easy to use, and has limited variability across sites when applied uniformly. Although the tool is largely successful, there is limited sensitivity in differentiating between studies with the same complexity score as it relates to the protocol workload. Therefore, this project will use an adapted OPAL tool to account for these sensitivities.

The complexity score can also serve as a predictive measure of how much coordinator effort should be budgeted, so this study will link the adapted OPAL score to tracked coordinator effort to project a more accurate capacity estimate.

Lastly, the data derived from this study will set a precedent at the current site for workload management and study budget negotiations for coordinator effort.

1.3 Research Questions

This study will map the adapted OPAL score for clinical trials to actual coordinator hours from a single site. The aim is to determine if the adapted OPAL score can be a predictor of coordinator hours. The purpose is to project a more accurate estimate of capacity when considering new studies and to establish a precedent for workload management to help inform budget negotiations.

The primary research question is, "How does the tracked coordinator effort compare to

the OPAL score?" Sub-questions include: "How do study characteristics compare to the coordinator effort" and "How do study characteristics compare to the OPAL score?"

1.4 Population

Actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022, at Morehouse School of Medicine (MSM) will be included in the analysis. Research protocols will be graded using an adapted OPAL tool. All information will be obtained from the MSM clinical trials management system (CTMS).

2 CHAPTER II SCOPING LITERATURE REVIEW

This literature review aims to describe the role of the clinical research coordinator (CRC) and examine the use of the Ontario Protocol Assessment Level (OPAL). A search of relevant literature was conducted using PubMed and Google Scholar. This review includes articles that mention clinical research coordinator, protocol complexity, coordinator workload, and protocol workload. To evaluate OPAL, a search of Smuck et al.'s (2011) article, "Ontario protocol assessment level: Clinical trial complexity rating tool for workload planning in oncology clinical trials," on PubMed yielded 12 journal article citations. The peer-reviewed articles were then evaluated for relevance. Twenty-two articles are included in this review.

The Clinical Research Coordinator

Kassis et al. (2017), defined a clinical research coordinator (CRC) as "*A research professional who manages and oversees one or more aspects of human subject research studies under the immediate supervision and direction of the principal investigator and/or sub-investigators"* (pg 335). This position requires specialized skills, training, and medical knowledge. Core responsibilities often include recruiting subjects, conducting study visits, maintaining study documents, and acting as a liaison between clinical, regulatory, and administrative personnel. However, additional responsibilities such as regulatory submissions, budget development and negotiation, and managing study finances may be required (Buchanan et al., 2020; Lorduy et al., 2020; Speicher et al., 2012).

According to ClinicalTrials.gov, there was more than a 65% increase in clinical trials registered between 2015-2019 (NIH, 2023). However, the pool of clinical trial workforce professionals has steadily decreased since the nineties resulting in a national shortage of

qualified professional coordinators. The shortage is partly attributed to increased regulatory burdens, protocol complexity, and staff burnout (Buchanan et al., 2020; Getz et al., 2008; Lorduy et al., 2020; Richie et al., 2019). Increased responsibilities and workload have negatively affected job satisfaction, leading to coordinators remaining in the position for a shorter time. This high turnover rate is costly and adversely affects the timely management of clinical trials (Buchanan et al., 2020).

Organizations like the Association of Clinical Research Professionals and the Society of Clinical Research Associates attempt to grow the clinical trial workforce by validating staff qualifications, defining competencies, and establishing clear career paths. However, the COVID-19 pandemic further complicated trial management and disrupted operations, preventing many sites from continuing their existing trial activities (Shiely et al., 2021; Van Norman, 2021). As institutions resume regular operations, many are now facing staffing shortages (Gohar et al., 2020; Shiely et al., 2021). The CRC plays an integral role in the success of clinical trials; therefore, leaders must understand how to apply resource management and capacity planning principles to ensure workloads are adequately resourced.

Workload Assessments

Richie et al. (2020) state that research sites should assess workloads and develop an understanding of the capacity to enhance job satisfaction and reduce turnover. Workload assessments also help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. Multiple tools have been created to calculate the workload of a clinical trial and measure the clinical research coordinator's capacity to manage it.

These tools help assign studies to the coordinator (Deglise-Hawkinson et al., 2020; Good et al., 2013; Morin et al., 2020; Morin et al., 2019; Richie et al., 2019; Smuck et al., 2011).

The Ontario Protocol Assessment Level (OPAL) is one of the most widely used protocol assessment tools. It provides an objective, quantifiable score for clinical trial activities based on the complexity of the study protocol. The OPAL score represents the protocol workload for the administrative component of managing a project and has been validated in oncology and non-oncology studies (Baer et al., 2011; Fabbri et al., 2021; Lledo et al., 2020; Lorduy et al., 2020; Smuck et al., 2011; Sarmento and Silvino, 2017; Wu et al., 2022).

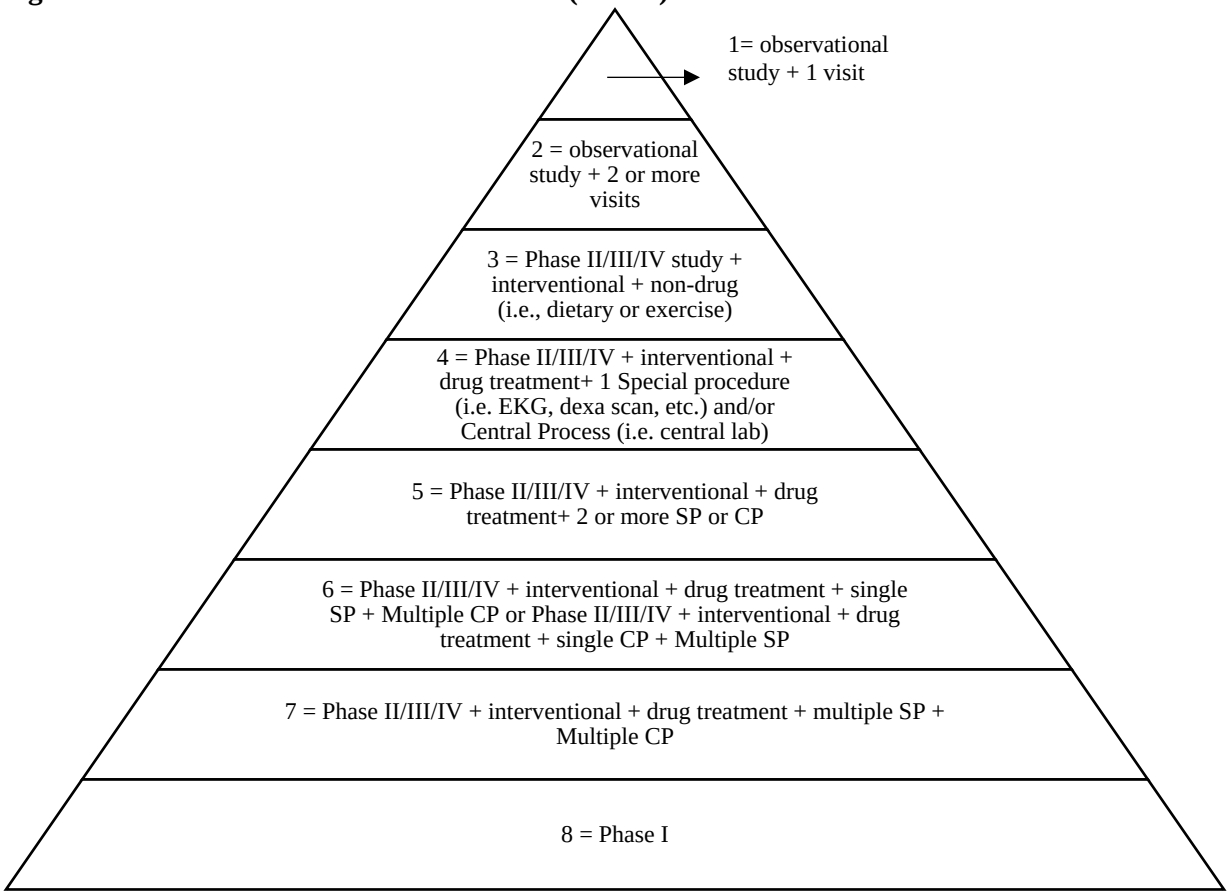
The OPAL tool is easy to use and has limited variability across sites when applied uniformly. Many sites have adapted the tool to account for other elements, such as the sponsor type, number of visits, and the coordinator's experience (Lorduy et al., 2020; Smuck et al., 2011). Lorduy et al. (2020) compared two similar adaptations of OPAL and demonstrated the tool's flexibility and implications for improved efficiency and productivity. The results showed OPAL's adaptability in oncology and non-oncology settings.

Sarmento and Silvino (2017) demonstrated the successful application of OPAL in another language. The team performed a validation study by using fifteen fictitious protocols. They measured the consistency of the observed items, including intra- and inter-observer variability compared to the average result. Their results demonstrated a significantly high degree of agreement between intra- and interobserver, confirming that the tools' score did not overestimate nor underestimate the committee's evaluations. This is significant since, according to clinicaltrials.gov, approximately 5% of clinical trials (~21,476) are registered in the U.S. and non-U.S. locations.

Calculating the OPAL Score

The OPAL score is calculated based on a pyramid scale from 1 through 8 of incremental procedures representing an increase in trial complexity [Figure 1]. Scoring ranges from non-treatment trials with low contact (OPAL score=1) and increases to the more complicated Phase I trials (OPAL score=8). The number of contacts, study type, study phase, number of special procedures, and the number of central processes are considered when reviewing the protocol. Examples of central processes and special procedures are outlined in Table 1.

Figure 1. Ontario Protocol Assessment Level (OPAL)



Note. Ontario Protocol Assessment Level (OPAL) pyramid scale adapted from Smuck, et al. (2011). Ontario protocol assessment level: Clinical trial complexity rating tool for workload planning in oncology clinical trials. *Journal of Oncology Practice*, *7*(2), 82.

The tool allows for calculating optional elements that may influence complexity, such as adding or decreasing weight in 0.5 increments to account for the number of study visits or the increased administrative work required when managing industry-sponsored trials. This allows sites to adapt the tool to account for unique protocol and institutional needs.

Table 1: Examples of Central Processes and Special Procedures

Central Process (CP)	Special Procedure (SP)
• Use of central lab • Central eligibility review • Central tissue review • Central ECG review	• Imaging (i.e., MRI) • EKG • Biopsy • Cognitive testing

In addition to measuring protocol workload by complexity, the tool measures case, total, and departmental workloads. The case workload represents the participant management component of the trial. The number of participants and their study status, such as on or off intervention, affect the case workload score.

Active case workload is defined as the number of subjects on study intervention. It is calculated by multiplying the number of participants on intervention by the OPAL score. For example, if a trial is considered to have an OPAL score of 4, and has 5 active participants on study intervention, then the active case workload score would be 20 (OPAL score 4 x 5 active subjects). If a participant has completed study treatment, but follow-up visits continue, they are now considered a follow-up case. A trial can have both, active and follow-up cases. The follow-up case workload is also calculated using OPAL. The OPAL score is divided in half because of the reduced workload. The score is then multiplied by the number of participants in the follow-up phase of the study. For example, if a study has an OPAL score of 4, and has 1 participant in follow-up, then the follow-up case score would be 2 (OPAL score 4 ÷ 2, then 2 x 1 follow-up

participant). The case workload score can now be calculated by adding the active and follow-up case scores.

OPAL score and case workload are added to create the total workload. This score represents an objective measurement of the research coordinator's workload. The total workload for each protocol is then summed to represent the department workload (Smuck et al., 2011).

Factors like protocol amendments, increased or decreased target enrollment goals, and changing study timelines can alter the complexity score throughout a study so it is suggested to assess workload at least quarterly (Morin, 2020; Smuck et al., 2011).

OPAL Score Limitations

Although the tool appears to be largely successful, there are some limitations. Fabbri et al. (2021) discussed how most of their studies had the same OPAL complexity scores yet had substantial variability in coordinator workload. Additionally, they found that most acuity scores were representative of nurse workloads instead of the research coordinator's workload. The team then developed a workload assessment tool that converted workload into actual time spent on the activity. Coordinators recorded their activities in a diary over two months. Fabbri et al. (2021) then developed the Istituto Scientifico Romagnolo perlo Studio e la Cura dei Tumor Workload Assessment Tool (IWAT) based on the recorded task times. The tool was tested across three sites where coordinators measured their workload for 30 months to evaluate the accuracy and the reproducibility of the IWAT. Results demonstrated a high reproducibility rate of 82% to 100% (Fabri et al., 2021). Limitations of this study include the lack of generalizability. The study was conducted in Italy, where the coordinator role is not formally recognized, and their duties differ between sites. The differences in the roles across sites may make it difficult to predict the tool's

performance in different contexts. The different regulatory regulations also limit generalizability because the United States has to operate under the Food and Drug Administration. Lastly, numerous tasks performed were omitted in the development of the tool.

The Effect of Complexity Scores on Coordinator Effort and Productivity

Effort-tracking metrics help provide the optimal data needed for study budget negotiations and workload management (James et al., 2011). Ritchie et al. (2020) created a protocol complexity tool and attempted to see if the complexity score could serve as a predictive measure of how much coordinator effort should be budgeted. The team retrospectively reviewed contracts for the budgeted coordinator effort and compared them to the calculated complexity score. The team then created rule sets for the complexity scores. They categorized them into three ranges, low (25-45 points), moderate (46-65 points), and high (66-85 points), and determined the average percent effort per subject was 11%, 28%, and 40% respectively. The data derived from the study allowed the study team to develop more accurate study budgets and created a precedent for the site, which assisted in budget negotiations with sponsors. Limitations of their review are that the effort did not consider the number of visits, and there were no protocols above 85 points included in the retrospective review. The estimates also assume budgeted efforts were accurate and were not under or overestimated.

Morin (2020) highlighted how traditional workload tools assumed maximum enrollment and trial participation and did not consider other factors that may affect performance. The team presented an approach to determine the effect of protocol complexity on productivity over time without manual effort tracking. They defined productivity as “the ratio of paid work per CRC compared to uncompensated work” (pg 980). They discussed how measuring the CRC activity

over time will provide a pattern demonstrating where study assignments would result in maximum productivity. Limitations to the approach are that a coordinator can be busy but still be considered poorly productive due to spending too much time on uncompensated work. Therefore, performance issues like low budgets and high site expenses are not considered when evaluating coordinator and study productivity.

Conclusion

The OPAL tool has proven to be easily applied and is effective for measuring coordinator workload. The tool is flexible and has been demonstrated to be useful in other languages. However, the tool has limited sensitivity in differentiating workloads between studies with the same score. Administration of just the OPAL does not consider organizational structure, budget restraints, and patient demographics, which can influence coordinator effort and productivity. Given these limitations, enhancements like linking the research coordinator's tracked effort over time with an adapted OPAL score may provide a more accurate assessment of workload. Ritchie et al. (2020) demonstrated the usefulness of linking the two, workload and effort, but assumed estimated effort from past contracts was not over or underestimated instead of using actual effort. In addition, measuring coordinator activity over time can provide a pattern demonstrating where study assignments result in maximum productivity (Morin, 2020). The historical data can then be used to establish a precedent for the site and assist in budget negotiations with sponsors. Tracking actual effort may help capture hidden costs associated with internal processes due to real-time dynamic tracking allowing clinical research leaders to make better-informed decisions to assess capacity and improve operational efficiency. To date, there have been no known attempts to link the OPAL score to the coordinator's effort. Therefore, this study will map an

adapted OPAL score for clinical trials to actual coordinator hours from a single site to determine if the adapted OPAL score can be a predictor of coordinator hours.

3 CHAPTER III METHODOLOGY

3.1 Research Design

This case study will use resource management and capacity planning principles to assess the workload in a research coordinator pool at an academic research center. The project will map an adapted OPAL score for clinical trials to actual coordinator hours to project a more accurate estimate of capacity when considering new studies, and to establish a precedent for workload management.

3.2 Sample Selection

Information will be obtained from the Morehouse School of Medicine (MSM) clinical trials management system (CTMS). Actively enrolling interventional studies at MSM with corresponding coordinator effort tracking from June 1, 2022 to December 1, 2022 will be included in the analysis.

3.3 Instrumentation

Ontario Protocol Assessment Level

Research protocols in the Morehouse School of Medicine (MSM) Clinical Research Center will be graded using an adapted Ontario Protocol Assessment Level (OPAL) tool. The OPAL is one of the most widely used protocol assessment tools. It provides an objective, quantifiable score for clinical trial activities based on the complexity of the study protocol. The OPAL score represents the protocol workload for the administrative component of managing a project and has been validated in oncology and non-oncology studies (Lorduy et al., 2020; Smuck et al., 2011; Fabbri et al., 2021; Lledo et al., 2020; Wu et al., 2022; Baer et al., 2011; Sarmento and Silvino, 2017).

Time and Task Tracking Application

The research coordinators at this institution use a time and task tracking application to track the total time spent conducting study activities. The application is accessible through TEAMS, is mobile optimized, and links to the MSM CTMS in real time. Study activities are tracked in broad categories: Recruitment, Communication, Scheduling, Subject Visits, Regulatory/Compliance, Sponsor Visits, Sponsor Training, and Data Entry/Query Resolution. Studies are billed hourly based on the hours tracked in the application.

3.4 Data Set Description

An existing Microsoft Excel database will be exported from the Morehouse School of Medicine (MSM) Clinical Trials Management System (CTMS) to obtain study characteristics, such as:

- Coordinator hours tracked from 6/1/22-12/1/22
- Sponsor Type
- Intervention Type

3.5 Data Collection/Procedure

The MSM CTMS will be queried for actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022 to December 1, 2022. A committee comprised of personnel from the MSM Clinical Trials Office will then review and grade each study protocol using an adapted OPAL tool. Committee members include the Director of the Clinical Trials Office and Research Operations, the Assistant Director of Clinical Trials, the Clinical Research Navigator, the Clinical Project Director of the Vaccine Trials Unit, and the Vaccine Trials Unit Project Director.

Adapted OPAL Calculation

Research protocols were graded using an adapted OPAL tool. The base score for the adapted tool is derived from the standard OPAL pyramid scale of 1-8 [Figure 1]. Examples of central processes and special procedures are outlined in Table 1. Weighted elements were then added to the base score to calculate the adapted score. A summary of these weighted elements is outlined in Table 2.

Table 2: Summary of the Adapted OPAL Weighted Elements

Positively Weighted Elements (+0.5)		Negatively Weighted Elements
• On-site monitoring (every 3 months or more) or 100% source documents submission • Industry sponsor/CRO • Multiple surveys or questionnaires (> 3 time points) Duration of follow-up visits > 2 years • Management and oversight of one subsite • Management and oversight of >1 subsite • Management of study visits requires travel between campuses • Study requires fresh tissue biopsy	• Requires sample processing (clotting, centrifuging, aliquoting, packaging, shipping) • Requires PK or PD labs • Length of treatment >18 months (or until disease progression) • Inpatient days • Study requires specialized personnel (i.e., blinded coordinator, needs more than 1 coordinator) • Enrollment period ≤ 2 months • Investigator-initiated or pilot study	• (-0.25) Length of treatment 0-3 months • (-0.5) for visits less frequent than every 4 weeks • (-0.5) for no data entry

3.6 Independent and Dependent Variables

VARIABLE	DEFINITION
Coordinator Effort/Tracked Coordinator Hours:	The number of hours spent conducting study activities
Adapted OPAL Score:	Represents the protocol workload for the administrative component of managing a project
Study or Protocol Characteristics:	Describes study details like sponsor type (i.e., Industry or Federal) and intervention type (i.e., drug, device, or behavioral)

3.7 Data Analysis

Research Question 1 - Descriptive statistics will compare the coordinator's effort to the adapted OPAL score for each study protocol. We will also use linear regression analysis to determine if a linear association between OPAL score and coordinator effort exists.

Research Question 2 - Descriptive statistics will compare study characteristics to the tracked coordinator effort hours for each study protocol.

Research Question 3 - Descriptive statistics will compare study characteristics to the calculated adapted OPAL score for each study protocol.

3.8 Protection of Human Subjects

The Medical University of South Carolina's Institutional Review Board self-certification tool determined this study to be a quality improvement project and was therefore not subject to IRB review or approval.

4 CHAPTER IV JOURNAL MANUSCRIPT

4.1 Journal Manuscript

Abstract

Introduction

According to clinicaltrials.gov, there has been more than a 30% increase in the number of registered clinical trials since 2020. As the number of trials has increased, so has their complexity. However, there is a national shortage of qualified clinical research coordinators due to increased responsibilities and workload. Therefore, leaders must understand how to apply resource management and capacity planning principles to ensure workloads are adequately resourced to help retain staff. Workload assessments help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. The Ontario Protocol Assessment Level (OPAL) is one of the most widely used protocol assessment tools. It provides a quantifiable score for clinical trial activities based on the complexity of the study protocol, is easy to use, and has limited variability across sites when applied uniformly. Although the tool is largely successful, there is limited sensitivity in differentiating between studies with the same complexity score as it relates to the protocol workload. Therefore, this project will use an adapted OPAL tool to account for these sensitivities. To date, there have been no known attempts to link the OPAL score to the coordinator's effort. Therefore, this study will map an adapted OPAL score for clinical trials to actual coordinator hours from a single site to determine if the adapted OPAL score can be a predictor of coordinator hours.

Methods

The Morehouse School of Medicine (MSM) clinical trials management system was queried for actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022. Protocols were graded using an adapted OPAL tool. Descriptive statistics were used to compare the protocol characteristics to the adapted OPAL score and tracked coordinator hours. Linear regression analysis was also performed to determine whether a linear association exists between the adapted OPAL score and tracked coordinator hours, and to quantify this association.

Results

The overall regression was statistically significant ($R^2 = 0.78$, $p = 0.008$). It was found that the adapted OPAL score significantly predicted tracked coordinator hours ($p = 0.008$).

Conclusion

The adapted OPAL score can be used as a predictive measure of coordinator effort, empowering clinical research leaders to make informed decisions to increase operational efficiency and ensure workloads are adequately resourced.

Keywords: clinical trials; protocol complexity; OPAL score; coordinator effort; operational efficiency; HBCU; historically black college and university

Introduction

Approximately 90% of clinical trials fail; however, despite the high failure rate, the number of trials is steadily increasing (Sun et al., 2022). According to the National Institutes of Health's website ClinicalTrials.gov, there has been over a 30% increase in registered clinical trials since 2020 (NIH, 2023). As the number of trials has increased, so has their complexity. An increase in protocol amendments and the challenges with pivoting to remote studies during the COVID-19 pandemic has not only contributed to their complexity but also to high study costs, delays, and increased regulatory burdens. In addition, sites that primarily serve underserved communities face unique challenges, such as recruiting in populations with limited access to the internet and internet-enabled devices (Brody et al., 2022).

The clinical research coordinator (CRC) plays an integral role in the success of clinical trials and manages and oversees various aspects of studies. They have a broad scope of responsibilities that range from recruiting subjects and conducting study visits to budget development and managing study finances (Buchanan et al., 2020; Lorduy et al., 2020; Speicher et al., 2012). This role requires specialized skills, training, and medical knowledge due to increased protocol complexity and regulatory oversight (Buchanan et al., 2020). Unfortunately, job satisfaction has declined due to increased responsibilities and workload, leading to burnout and high turnover. As a result, there is a national shortage of qualified professional coordinators (Buchanan et al., 2021; Richie et al., 2020).

To help retain staff, sites should assess workloads and capacity (Richie et al., 2020). This project will apply resource management and capacity planning principles to examine the workload in a research coordinator pool at an academic research center. The data from this project will improve clinical research leaders' ability to make informed decisions to increase

operational efficiency and ensure workloads are adequately resourced.

The Clinical Research Coordinator

Kassis et al. (2017) defined a clinical research coordinator (CRC) as "*A research professional who manages and oversees one or more aspects of human subject research studies under the immediate supervision and direction of the principal investigator and/or sub-investigators"* (pg 335). Core responsibilities often include recruiting subjects, conducting study visits, maintaining study documents, and acting as a liaison between clinical, regulatory, and administrative personnel. However, additional responsibilities such as regulatory submissions, budget development and negotiation, and managing study finances may be required (Buchanan et al., 2020; Lorduy et al., 2020; Speicher et al., 2012).

According to ClinicalTrials.gov, there was more than a 65% increase in the number of clinical trials registered between 2015-2019 (NIH, 2023). However, the pool of clinical trial workforce professionals has steadily decreased since the nineties resulting in a national shortage of qualified professional coordinators. The shortage is partly attributed to increased regulatory burdens, protocol complexity, and staff burnout (Lorduy et al., 2020; Getz et al., 2008; Buchanan et al., 2020; Richie et al., 2019). Increased responsibilities and workload have negatively affected job satisfaction, leading to coordinators remaining in the position for a shorter time. This high turnover rate is costly and adversely affects the timely management of clinical trials (Buchanan et al., 2020).

Organizations like the Association of Clinical Research Professionals and the Society of Clinical Research Associates attempt to grow the clinical trial workforce by validating staff qualifications, defining competencies, and establishing clear career paths. However, despite these efforts, the professional workforce continues to dimmish. Furthermore, the COVID-19 pandemic

complicated trial management and disrupted operations, preventing many sites from continuing their existing trial activities (Shiely et al., 2021; Van Norman, 2021). As institutions resume regular operations, many are now facing staffing shortages (Shiely et al., 2021; Gohar et al., 2020). The CRC plays an integral role in the success of clinical trials; therefore, leaders must develop tools to assist with managing workloads to help combat burnout.

Workload Assessments

Richie et al. (2020) state that research sites should assess workloads and develop an understanding of the capacity to enhance job satisfaction and reduce turnover. Workload assessments also help provide validation to increase staff, evaluate and ensure equal distribution of work, and assist with budget justifications. Multiple tools have been created to calculate the workload of a clinical trial and measure the clinical research coordinator's capacity to manage it. These tools help assign studies to the coordinator (Richie et al., 2019; Smuck et al., 2011; Deglise-Hawkinson et al., 2020; Good et al., 2013; Morin et al., 2020; Morin et al., 2019).

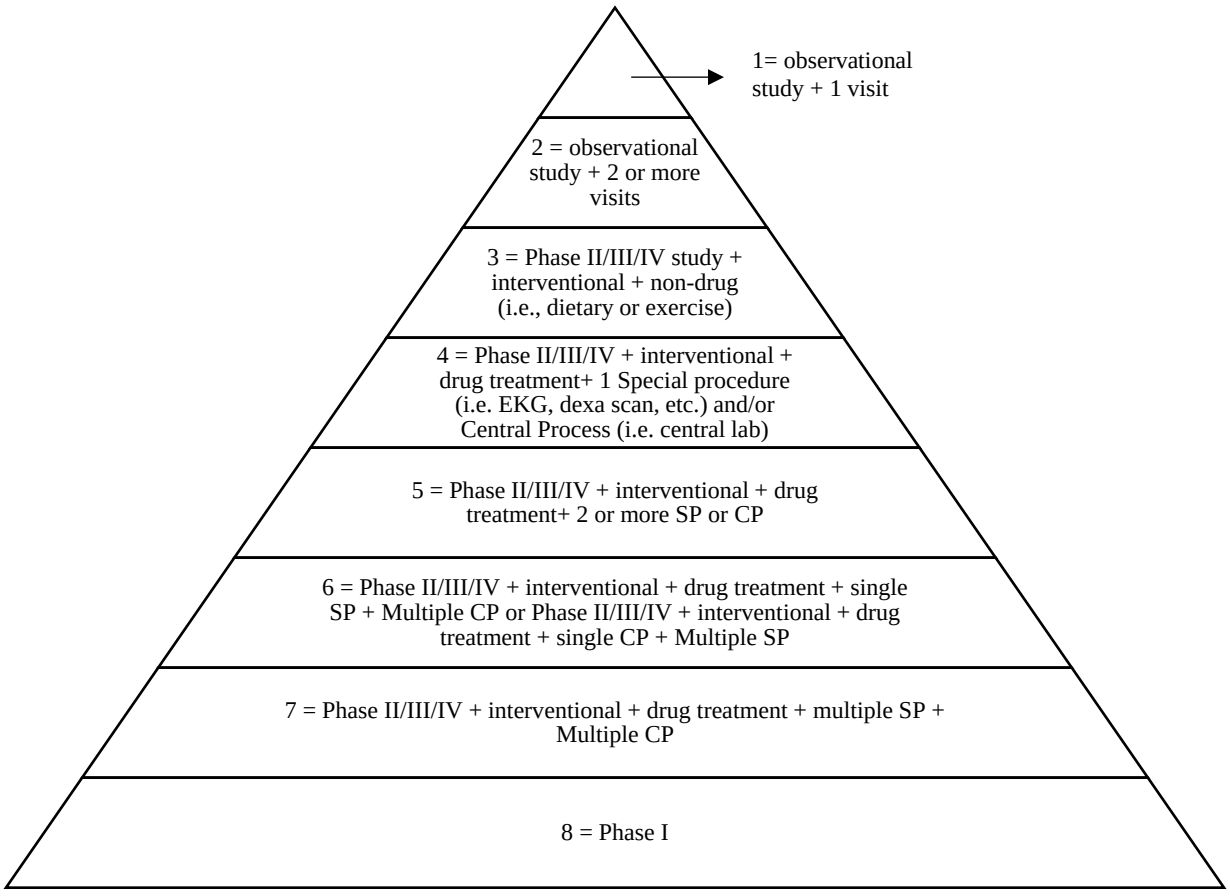
The Ontario Protocol Assessment Level (OPAL) is one of the most widely used protocol assessment tools. It provides an objective, quantifiable score for clinical trial activities based on the complexity of the study protocol. The OPAL score represents the protocol workload for the administrative component of managing a project and has been validated in oncology and non-oncology studies (Lorduy et al., 2020; Smuck et al., 2011; Fabbri et al., 2021; Lledo et al., 2020; Wu et al., 2022; Baer et al., 2011; Sarmento and Silvino, 2017).

The OPAL tool is easy to use and has limited variability across sites when applied uniformly. Many sites have adapted the tool to account for other elements, such as the sponsor type, the number of visits, and the coordinator's experience (Lorduy et al., 2020; Smuck et al., 2011).

Calculating the OPAL Score

The OPAL score is calculated based on a pyramid scale from 1 through 8 of incremental procedures representing an increase in trial complexity [Figure 1]. Scoring ranges from non-treatment trials with low contact (OPAL score=1) and increases to the more complicated Phase I trials (OPAL score=8). The number of contacts, study type, study phase, number of special procedures, and the number of central processes are considered when reviewing the protocol. Examples of central processes and special procedures are outlined in Table 1.

Figure 1. Ontario Protocol Assessment Level (OPAL)



Note. Ontario Protocol Assessment Level (OPAL) pyramid scale adapted from Smuck, et al. (2011). Ontario protocol assessment level: Clinical trial complexity rating tool for workload planning in oncology clinical trials. *Journal of Oncology Practice, 7*(2), 82.

The tool allows for calculating optional elements that may influence complexity, such as adding or decreasing weight in 0.5 increments to account for the number of study visits or the increased administrative work required when managing industry-sponsored trials. This allows sites to adapt the tool to account for unique protocol and institutional needs.

Table 1: Examples of Central Processes and Special Procedures

Central Process (CP)	Special Procedure (SP)
• Use of central lab	• Imaging (i.e., MRI)
• Central eligibility review	• EKG
• Central tissue review	• Biopsy
• Central ECG review	• Cognitive testing

In addition to measuring protocol workload by complexity, the tool measures case, total, and departmental workloads. The case workload represents the participant management component of the trial. The number of participants and their study status, such as on or off intervention, affect the case workload score.

Active case workload is defined as the number of subjects on study intervention. It is calculated by multiplying the number of participants on intervention by the OPAL score. For example, if a trial is considered to have an OPAL score of 4, and has 5 active participants on study intervention, then the active case workload score would be 20 (OPAL score 4 x 5 active subjects). If a participant has completed study treatment, but follow-up visits continue, they are now considered a follow-up case. A trial can have both, active and follow-up cases. The follow-up case workload is also calculated using OPAL. The OPAL score is divided in half because of the reduced workload. The score is then multiplied by the number of participants in the follow-up phase of the study. For example, if a study has an OPAL score of 4, and has 1 participant in follow-up, then the follow-up case score would be 2 (OPAL score 4 ÷ 2, then 2 x 1 follow-up

participant). The case workload score can now be calculated by adding the active and follow-up case scores.

OPAL score and case workload are added to create the total workload. This score represents an objective measurement of the research coordinator's workload. The total workload for each protocol is then summed to represent the department workload (Smuck et al., 2011).

Factors like protocol amendments, increased or decreased target enrollment goals, and changing study timelines can alter the complexity score throughout a study so it is suggested to assess workload at least quarterly (Morin, 2020; Smuck et al., 2011).

The Effect of Complexity Scores on Coordinator Effort and Productivity

The OPAL tool has proven to be easily applied and is effective for measuring coordinator workload. The tool is flexible and has been demonstrated to be useful in other languages. However, the tool has limited sensitivity in differentiating workloads between studies with the same score. Administration of just the OPAL does not consider organizational structure, budget restraints, and patient demographics, which can influence coordinator effort and productivity. Given these limitations, enhancements like linking the research coordinator's tracked effort over time with an adapted OPAL score may provide a more accurate assessment of workload. Ritchie et al. (2020) demonstrated the usefulness of linking the two, workload and effort, but assumed estimated effort from past contracts was not over or underestimated instead of using actual effort. In addition, measuring coordinator activity over time can provide a pattern demonstrating where study assignments result in maximum productivity (Morin, 2020). The historical data can then be used to establish a precedent for the site and assist in budget negotiations with sponsors. Tracking actual effort may help capture hidden costs associated with internal processes due to

real-time dynamic tracking allowing clinical research leaders to make better-informed decisions to assess capacity and improve operational efficiency. To date, there have been no known attempts to link the OPAL score to the coordinator's effort. Therefore, this study will map an adapted OPAL score for clinical trials to actual coordinator hours from a single site to determine if the adapted OPAL score can be a predictor of coordinator hours.

Research Design and Methods

The Morehouse School of Medicine (MSM) clinical trials management system (CTMS) was queried for actively enrolling interventional studies with corresponding coordinator effort tracking from June 1, 2022, to December 1, 2022. Studies that had less than six months of coordinator hours logged against it were excluded. A total of seven studies were included in the data set. A committee comprised of personnel from the MSM Clinical Trials Office then reviewed and graded each study protocol using an adapted OPAL tool. Descriptive statistics were used to compare the protocol characteristics to the adapted OPAL score and tracked coordinator hours by using student's t-test to compare averages. A univariate analysis was performed using non-parametric tests for the differences in the continuous variables. Linear regression analysis was also performed to determine whether a linear association exists between the adapted OPAL score and tracked coordinator hours, and to quantify this association. This study is a quality improvement project and was not subject to IRB review or approval.

Time and Task Tracking Application

The research coordinators at MSM use a time and task tracking application to track the total time spent conducting study activities. The application is accessible through TEAMS, is mobile optimized, and links to the MSM CTMS in real-time. Study activities are tracked in broad categories: Recruitment, Communication, Scheduling, Subject Visits,

Regulatory/Compliance, Sponsor Visits, Sponsor Training, and Data Entry/Query Resolution.

Adapted OPAL Tool Calculation

Research protocols were graded using an adapted OPAL tool. The base score for the adapted tool is derived from the standard OPAL pyramid scale of 1-8 [Figure 1]. Examples of central processes and special procedures are outlined in Table 1. Weighted elements were then added to the base score to calculate the adapted score. A summary of these weighted elements is outlined in Table 2.

Table 2: Summary of the Adapted OPAL Weighted Elements

Positively Weighted Elements (+0.5)		Negatively Weighted Elements
• On-site monitoring (every 3 months or more) or 100% source documents submission • Industry sponsor/CRO • Multiple surveys or questionnaires (> 3 time points) Duration of follow-up visits > 2 years • Management and oversight of one subsite • Management and oversight of >1 subsite • Management of study visits requires travel between campuses • Study requires fresh tissue biopsy	• Requires sample processing (clotting, centrifuging, aliquoting, packaging, shipping) • Requires PK or PD labs • Length of treatment >18 months (or until disease progression) • Inpatient days • Study requires specialized personnel (i.e., blinded coordinator, needs more than 1 coordinator) • Enrollment period ≤ 2 months • Investigator-initiated or pilot study	• (-0.25) Length of treatment 0-3 months • (-0.5) for visits less frequent than every 4 weeks • (-0.5) for no data entry

Results

A total of seven protocols were included in the dataset. Of these, five (71%) protocols were federally funded compared to two (29%) that were industry-sponsored, and four (57%) studies were behavioral interventions compared to three (43%) drug studies. The range of the adapted OPAL scores was 4.75-9.0.

There were significant differences between sponsor and intervention types when compared to the adapted OPAL score. Industry-sponsored studies yielded a higher workload estimate than federally-sponsored studies (7.25 ± 1.77 vs. 6.45 ± 1.65; $p < 0.0001$). In addition, behavioral interventions (i.e., exercise and diet) were estimated at a higher workload assessment than drug studies (6.88 ± 1.56 vs. 6.42 ± 1.91, $p < 0.0001$). These findings are summarized below in Table 3.

Table 3: Protocol Characteristics compared to the Adapted OPAL Score

Protocol Characteristics	Adapted OPAL Score	p-value
Sponsor Type:		
Industry (N=2)	7.25 ± 1.77	< 0.0001
Federal (N=5)	6.45 ± 1.65	
Intervention Type:		
Drug (N=3)	6.42 ± 1.91	< 0.0001
Behavioral (N=4)	6.88 ± 1.56	

Although industry-sponsored studies and drug studies had more coordinator hours tracked against them, there was no significant relationship between the number of hours tracked and the study sponsor type. Industry-sponsored studies had an average of 181 ± 152.7 coordinator hours compared to federally sponsored studies with 98 ± 142.6 hours tracked and a p-value of 0.0599. Drug intervention studies had an average of 128.7 ± 141 hours tracked

compared to behavioral interventions with 116.5 ± 157.6 hours tracked (p = 0.0595). These findings are summarized below in Table 4.

Table 4: Protocol Characteristics compared to the Tracked Coordinator Hours

Protocol Characteristics	Tracked Hours	p-value
Sponsor Type:		
Industry (N=2)	181 ± 152.74	0.0599
Federal (N=5)	98 ± 142.62	
Intervention Type:		
Drug (N=3)	128.67 ± 140.99	0.0595
Behavioral (N=4)	116.5 ± 157.61	

A simple linear regression was fit to examine the relationship between the adapted OPAL and coordinator hours. The fitted regression model was:

$$\text{Coordinator Hours} = 77.22*(\text{Adapted OPAL Score}) - 394.03$$

The overall regression was statistically significant ($R^2 = 0.78$, $p = 0.008$). It was found that the adapted OPAL score significantly predicted tracked coordinator hours ($\beta = 77.22$, $p = 0.008$), meaning for every 1 unit increase in the adapted OPAL score, we expect a 77.2 minute increase in CRC hours (Figure 2). Table 5 displays an estimated amount of coordinator hours for the adapted OPAL score ranges using the fitted regression model.

Figure 2. Regression Model of Charted Coordinator Hours to the OPAL Score

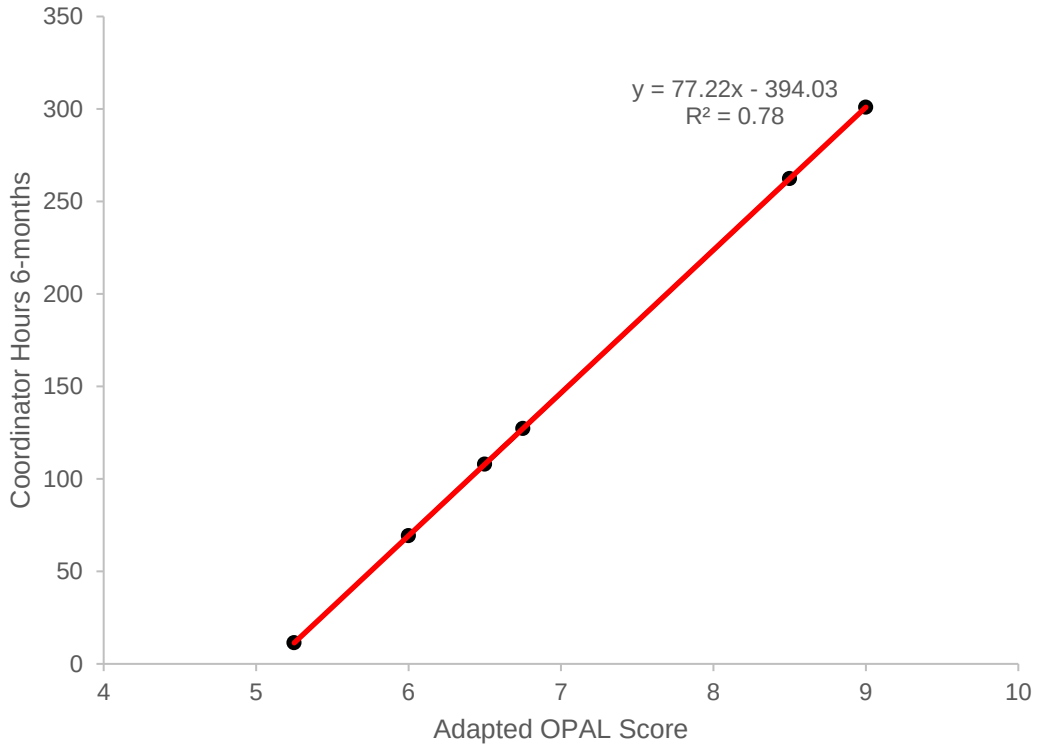


Table 5: Estimated Coordinator Hours for the Adapted OPAL Score

Adapted OPAL Score	Estimated Hours (6-months)	Estimated Hours per Month
5.5	30.7	5.1
6.0	69.3	11.5
6.5	107.9	18.0
7.0	146.5	24.4
7.5	185.1	30.9
8.0	223.7	37.3
8.5	262.3	43.7
9.0	301.0	50.2
9.5	339.6	56.6

Leaders must first have an understanding of the existing operational capacity of each coordinator before reviewing new studies. The maximum CRC capacity can be determined by multiplying the number of full-time hours per day (7.5 hours) by the number of working days per month (Table 6). The average working hours per month (163 hours) can now be used as a guide for assessing current capacity.

Table 6: Maximum Working Hours per Month

Month	Working days/mo	Maximum working hours per month
January	21	158
February	20	150
March	23	173
April	21	158
May	22	165
June	22	165
July	21	158
August	23	173
September	22	165
October	21	158
November	22	165
December	22	165

According to James et al. (2011), 25%-30% of effort should be allocated to non-study activities, such as general office meetings, sick time, and vacation; the remaining effort is then assigned to study management activities for a full-time equivalent (FTE). Table 7 displays coordinator hours logged over a 6-month period from June 1, 2022-December 1, 2022. An additional 25% effort was added to account for non-study activities (163*0.25 = 41 hours). This calculation represents an estimate of the current operational capacity of each coordinator. At this point, leaders can determine if there needs to be any project reallocations.

Table 7: An Estimate of Current Operational Capacity

Member	Total Study Hours logged (6-months)	Hours Logged per Month	Monthly Hours Plus 25%	Current % Monthly Capacity
Coordinator 1	651	109	150	92%
Coordinator 2	967	161	202	124%
Coordinator 3	305	51	92	56%
Coordinator 4	439	73	114	70%
Coordinator 5	222	37	78	48%
Coordinator 6	145	24	65	40%
Coordinator 7	14	2	43	27%

Discussion

The adapted OPAL tool can be used to assess the workload of potential new projects once an estimate of the current operational capacity is known. The regression model can be applied to calculate the estimated coordinator hours required to conduct the study over the next 6-months. For example, a new study with an OPAL score of 8.5 would be calculated as follows:

Coordinator hours = 77.22*(Adapted OPAL Score) - 394.03

Coordinator hours = 77.22*(8.5) - 394.03

Coordinator hours = 262.34

You can then divide this by 6 to determine the estimated hours per month (262.34/6 = 43.72). This information can now be used to determine if a coordinator has enough capacity to be assigned to this project or if a new FTE is required. Other study metrics, like enrollment periods, length of treatment, and the number of visits, are captured in the complexity score. This process is to supplement operational processes for determining capacity. Other metrics like enrollment end dates and recruitment goals of ongoing studies should still be reviewed.

Leaders can quantitatively conduct a coverage analysis to ensure that coordinator effort covers unique infrastructure needs at the study site. This workload assessment method helps

capture effort that may otherwise be “hidden” when only viewing study tasks and participant recruitment milestones. Examples of hidden effort include time spent on query resolution in complicated or poorly developed electronic data capture systems, activating and loading payments for subject stipends, and scheduling and phone contacts with participants. This is especially useful for sites that primarily serve underrepresented populations where coordinators may spend additional time on activities like informed consent when a literacy evaluation or an interpreter is required. Smaller institutions with less centralized processes where the coordinator has more responsibilities would also benefit from this method of capturing a more accurate workload. Additionally, underestimating this effort during the budget development process can result in a deficit fund balance, causing sites to exceed budgeted infrastructure costs which are usually based on FTEs. Therefore, it is important to establish a precedent so sites can ensure they are covering operational costs during budget negotiations with the sponsor.

The methods of this study can be applied consistently across multiple sites. Sites can adapt the OPAL tool to their needs and link coordinator effort from any time management application. Study limitations include that the study only evaluated OPAL scores to all study activities logged against it, regardless of the coordinator. Multiple coordinators can be assigned to studies, so it is worth evaluating individual coordinator effort and adapted OPAL scores in future studies. The results show the best-fit line because of linear regression, so some values on the lower adapted OPAL scores may not make sense. Therefore, the adapted OPAL score beginning at 5.5 can serve as a starting point for leaders in determining coordinator hours required. Lastly, there was no significant relationship demonstrated between the number of tracked hours compared to the sponsor type and intervention. This may be due to having a small sample size, and a difference may be seen with more studies.

Conclusion

The results demonstrate that protocol complexity scores can be used as a predictive measure of coordinator effort. This information is useful when determining the capacity to accept new projects. Having a standardized process for assigning studies allows leaders to objectively distribute projects without overburdening “good” coordinators. Thus, improving coordinator satisfaction and reducing burnout. The coordinator may also be more productive due to not being over-allocated.

Future studies include using the knowledge gained from this study, along with other clinical trial metrics, to develop machine learning models to assist in workload assessment, coordinator assignments, and to forecast study productivity.

References

Baer, A. R., Zon, R., Devine, S., & Lyss, A. P. (2011). The clinical research team. *Journal of Oncology Practice, 7*(3), 188-192. doi:10.1200/JOP.2011.000276

Brody, A. A., Convery, K. A., Kline, D. M., Fink, R. M., & Fischer, S. M. (2022). Transitioning to remote recruitment and intervention: A tale of two palliative care research studies enrolling underserved populations during COVID-19. *Journal of Pain and Symptom Management, 63*(1), 151-159. doi:10.1016/j.jpainsymman.2021.06.017

Buchanan, D. A., Goldstein, J., Pfalzer, A. C., Lin, Y., Kang, H., & Claassen, D. O. (2020). Empowering the clinical research coordinator in academic medical centers. *Mayo Clinic Proceedings: Innovations, Quality & Outcomes, 5*(2), 265-273. doi:10.1016/j.mayocpiqo.2020.09.014

Deglise-Hawkinson, J., Kaufman, D. L., Roessler, B., & Van Oyen, M. P. (2020). Access planning and resource coordination for clinical research operations. *IISE Transactions, 52*(8), 832-849. doi:10.1080/24725854.2019.1675202

Fabbri, F., Gentili, G., Serra, P., Vertogen, B., Andreis, D., Dall'Agata, M., . . . Nanni, O. (2021). How many cancer clinical trials can a clinical research coordinator manage? the clinical research coordinator workload assessment tool. *JCO Oncology Practice, 17*(1), e68-e76. doi:10.1200/JOP.19.00386

Getz, K. A., Wenger, J., Campo, R. A., Seguine, E. S., & Kaitin, K. I. (2008). Assessing the impact of protocol design changes on clinical trial performance. *American Journal of Therapeutics, 15*(5), 450-457. doi:10.1097/MJT.0b013e31816b9027

Gohar, B., Larivière, M., & Nowrouzi-Kia, B. (2020). Sickness absence in healthcare workers during the COVID-19 pandemic. *Occupational Medicine, 70*(5), 338-342. doi:10.1093/occmed/kqaa093

Good, M. J., Lubejko, B., Humphries, K., & Medders, A. (2013). Measuring clinical trial-associated workload in a community clinical oncology program. *Journal of Oncology Practice, 9*(4), 211-215. doi:10.1200/JOP.2012.000797

James, P., Bebee, P., Beekman, L., Browning, D., Innes, M., Kain, J., . . . Waldinger, M. (2011a). Effort tracking metrics provide data for optimal budgeting and workload management in therapeutic cancer clinical trials. *Journal of the National Comprehensive Cancer Network: JNCCN, 9*(12), 1343-1352. doi:10.6004/jnccn.2011.0116

Kassis, S., Winkler, S., Gianforti, M. J., & Needler, N. A. (2018). Research coordinator networks and support models among academic health centers in the CTSA consortium. *Journal of Clinical and Translational Science, 1*(6), 334-339. doi:10.1017/cts.2017.309

Lledo, L., Johnson, C., Chew, A., Gilmore, J., Dengel, K., & Anderson, J. (2020). A measure to determine acceptable workload for increasing operational efficiencies for the conduct of clinical trials. *Doctor of Nursing Practice (DNP) Manuscripts,* Retrieved from https://dsc.duq.edu/dnp/1

Lorduy, K., Brown, V., & Rose, S. (2020). Adapting productivity models to improve efficiency and progress in clinical research practice. *Clinical Researcher, 34*(4) Retrieved from https://acrpnet.org/2020/04/14/adapting-productivity-models-to-improve-efficiency-and-progress-in-clinical-research-practice/

Miessler, J. (2022, January 17,). No end in sight for trial complexity, CSDD report reveals. Retrieved from https://cms.centerwatch.com/articles/25921-no-end-in-sight-for-trial-complexity-csdd-report-reveals

Morin, D. J. (2019). Use of proxy variables to determine the impact of protocol complexity on clinical research site productivity. *Therapeutic Innovation & Regulatory Science, 53*(1), 52-58. doi:10.1177/2168479018769290

Morin, D. J. (2020). Harmonizing protocol complexity with resource management and capacity planning at clinical research sites. *Therapeutic Innovation & Regulatory Science, 54*(5), 978-987. doi:10.1007/s43441-020-00120-8

Richie, A., Gamble, D., Tavlarides, A., & Griffin, C. (2019). Trial complexity and coordinator capacity: The development of a complexity tool. Clinical Researcher. *33*(5)

Richie, A., Gamble, D., Tavlarides, A., Strok, K. & Griffin, C. (2020). Establishing the link between trial complexity and coordinator capacity. Clinical Researcher, 34(2) Retrieved from https://acrpnet.org/2020/02/11/establishing-the-link-between-trial-complexity-and-coordinator-capacity/

Sarmento, R., & Silvino, Z. (2017). Measuring workload of clinical trials: Transcultural adaptation and validation to portuguese lanquage of ontario protocol assessment level (OPAL). *Journal of Clinical Research & Bioethics, 08* doi:10.4172/2155-9627.1000308

Shiely, F., Foley, J., Stone, A., Cobbe, E., Browne, S., Murphy, E., . . . Eustace, J. A. (2021). Managing clinical trials during COVID-19: Experience from a clinical research facility. *Trials, 22*(1), 62. doi:10.1186/s13063-020-05004-8

Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., . . . Friel, K. (2011). Ontario protocol assessment level: Clinical trial complexity rating tool for workload planning in oncology clinical trials. *Journal of Oncology Practice, 7*(2), 80-84. doi:10.1200/JOP.2010.000051

Speicher, L. A., Fromell, G., Avery, S., Brassil, D., Carlson, L., Stevens, E., & Toms, M. (2012). The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: Recommendations from the clinical and translational science award research coordinator taskforce*. *Clinical and Translational Science, 5*(6), 470-475. doi:10.1111/j.1752-8062.2012.00423.x

Sun, D., Gao, W., Hu, H., & Zhou, S. (2022). Why 90% of clinical drug development fails and how to improve it? *Acta Pharmaceutica Sinica. B, 12*(7), 3049-3062. doi:10.1016/j.apsb.2022.02.002

National Institutes of Health (2023). Trends, charts, and maps. (2023). Retrieved from https://clinicaltrials.gov/ct2/resources/trends

Van Norman, G. A. (2021). Decentralized clinical trials. *JACC: Basic to Translational Science, 6*(4), 384-387. doi:10.1016/j.jacbts.2021.01.011

Wu, K., Wu, E., DAndrea, M., Chitale, N., Lim, M., Dabrowski, M., . . . Zou, J. (2022). Machine learning prediction of clinical trial operational efficiency. *The AAPS Journal, 24*(3), 57. doi:10.1208/s12248-022-00703-3