4-1-2024

Exploring Barriers to Ophthalmic Clinical Research Care Delivery

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This is to certify that the doctoral dissertation by

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has been found to be complete and satisfactory in all respects,
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Walden University
2024

Abstract

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Health Services

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Abstract

Clinical research plays a crucial role in advancing healthcare through the development of new treatments and enhanced clinical practices. Despite the field's increasing complexity and administrative demands, there is a significant research gap regarding the experiences of ophthalmic clinical research professionals (CRPs) involved in clinical research care delivery. The purpose of this descriptive-interpretive qualitative study was to explore the barriers to ophthalmic clinical research care delivery as experienced by ophthalmic CRPs. The Donabedian quality-of-care framework served as the conceptual framework, providing a structured approach to understanding the various dimensions of clinical care delivery. Participants for this study were recruited from the ophthalmology department of an academic medical center. A survey instrument was distributed through email, allowing participants to share their perspectives and experiences on clinical research care delivery. The collected data underwent rigorous analysis, including meaning unit delineation and thematic categorization, with a focus on identifying meaning units related to structure, process, and outcomes of clinical research care delivery. Barriers unique to ophthalmic clinical research care delivery identified by CRPs in this study included lack of time, enrollment, cost, and limited resources in workforce development guided by increased protocol complexity. The findings from this study could promote positive social change by informing practice and policy changes in clinical research care to mitigate burnout and improve workload balance for CRPs, and to augment the capacity of CRPs to deliver high-quality clinical research care.

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Dedication

This dissertation is dedicated to the many amazing people who have inspired me throughout my life. To my grandmother, who told me I would accomplish “great things.” To my parents for their unyielding and unconditional support. To my high school English teacher who believed in me at a time few else did. To my other half, my patient and unshakeable wife, for putting up with my late nights and crazy days. To my boys, for whom everything I do is done. And above all, to God, from whom all gifts are given, and to whom all given is returned.

Acknowledgments

My eternal gratitude goes to my unbeatable committee members, Dr. Diana Naser and Dr. Kristin Wiginton. Without your time, guidance, insight, expertise, and limitless support, this dissertation would not have been possible.

A special thank you to the many advisors I have had the pleasure of working with in my academic and professional career, especially Dr. Naomi DeShore-Osborne, Dr. Jeananne Elkins, Dr. Grant Comer, and Dr. Julie Rosenthal.

Thank you to the staff and faculty at my research site for their expertise and participation, your contributions have been invaluable.

Lastly, I would like to thank all my friends and family for their love and their gentle reminders that I am, in fact, allowed to go outside.

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Chapter 1: Introduction to the Study

Introduction

Clinical research is an integral component of the healthcare delivery system that requires the coordination of care by many healthcare professionals, including physicians, nurses, allied health professionals, and administrative staff. The purpose of clinical research is the proliferation of knowledge regarding new treatments, new interventions, and their efficacy in a medical or health-related context with evidence indicating sustained commitment to research enhances performance and patient outcomes (Downing et al., 2017; Portier, 2020; U.S. National Library of Medicine [NLM], 2019). Despite its importance, clinical research care delivery remains a neglected area of study, with limited research focusing on the experiences of the staff responsible for facilitating clinical research. The social implications of this research are significant because clinical research care delivery is an essential aspect of the healthcare system. By exploring the experiences of the personnel involved in delivering clinical research care, the findings of this study have the potential to offer valuable insights into measures that can be implemented to improve the well-being of clinical research professionals (CRPs). This study was needed to understand the barriers faced by CRPs and to help develop effective policies and practices to enhance care delivery, as the demand for clinical research studies continues to increase. The literature on clinical research care delivery from an ophthalmic perspective is limited, despite the growing importance of clinical research in this field. Understanding the experiences of CRPs and the underlying factors that contribute to these challenges is crucial for developing policies and practices that effectively support

clinical research care delivery and the individuals responsible for providing care. This chapter will present an overview of the research problem, background, purpose, research questions, the conceptual framework, and the nature of the study. Assumptions, scope, and delimitations, as well as limitations relating to the research design, will also be presented.

Background

Clinical research is a vital aspect of healthcare delivery that informs novel ways of understanding healthcare through the study of various aspects of clinical care delivery. However, the increasing complexity of clinical research poses many challenges. The intricate protocols, narrow selection criteria, high data demands, extended safety and outcome monitoring strain staff and site capabilities leading to increased risk, regulatory monitoring, and administrative burden on clinical research centers (Lee et al., 2021; Malik & Lu, 2019; National Cancer Policy Forum, 2016).

Despite the importance of clinical research, studies have yet to be produced that explore the experiences of the wide-ranging staff who ensure clinical research is conducted safely, ethically, and to the high-quality standards necessary for success. Much of the focus in the literature is on the scientific aspects of clinical research rather than on the experiences of CRPs who participate in clinical research. The lack of research in this area hampers understanding of the challenges faced by CRPs and the impact of these challenges on clinical research care delivery. This gap is particularly evident in the field of ophthalmic clinical research, which is witnessing significant growth and increasing

complexity compared to other areas of care (Mansour et al., 2020; Rowe-Rendleman, 2019; Sacchi et al., 2020; Turner et al., 2020).

Successful clinical research care delivery depends on study recruitment, participant retention, consistent staffing, and manageable cost. However, the growing complexity of clinical research protocols has been linked to a reduction in study enrollment with particular attention to minority enrollment and increased institutional burden due to failures to meet enrollment targets (Brøgger-Mikkelsen et al., 2022; Carcel & Reeves, 2021; Duma et al., 2018; Vaswani et al., 2020). Similarly, the cost of conducting clinical research is rising, with most of the financial burden related to administrative costs and staff salaries (Buchanan et al., 2020; Chen et al., 2021; Moore et al., 2020). Staff burnout is a growing concern, with CRPs reporting moderate levels of burnout and citing workload imbalance as a chief concern (Mascaro et al., 2021).

Ophthalmology is a growing area of clinical research and exists within a healthcare sector predicted to affect nearly 10 million Americans by 2050 (Centers for Disease Control and Prevention, 2020; Moore et al., 2020). Clinical research studies have demonstrated improvements in ophthalmic clinical care. There is a knowledge gap regarding the experiences of CRPs, who are responsible for ensuring the safe, ethical, and high-quality conduct of clinical research, as limited research has been conducted in this area. Operational evaluations, such as technology assessment, training, capacity planning, and research delivery models, should involve subject-matter experts to provide grounded knowledge and insight (Jones et al., 2020). Therefore, further research was recommended

to qualitatively evaluate workload and complexity with input from the experts who play a fundamental role in its delivery (Jones et al., 2020).

Problem Statement

Over the past few decades, the field of clinical research has experienced substantial growth accompanied by an increase in the complexity and administrative demands of individual studies (Brennan et al., 2019; Brøgger-Mikkelsen et al., 2022; Getz & Campo, 2017; Lee et al., 2021). However, this growth has also resulted in significant burdens for clinical research volunteers and an increasing prevalence of burnout among clinical research staff (Duma et al., 2018; Moerdler et al., 2020). Numerous challenges remain in the development and management of clinical research, particularly concerning enrollment, cost, workload, and complexity assessment (Brennan et al., 2019; Brøgger-Mikkelsen et al., 2022; Duma et al., 2018; Jones et al., 2020; Milani et al., 2017; Morin, 2019; Rennane et al., 2021).

However, the impact of the increasing complexity of clinical research studies on the rising levels of staff burnout, workload imbalance, or disruptions to clinical research care delivery remain unknown, with no known research exploring these topics from an ophthalmic perspective. This gap in the literature underscores the need to explore the experiences of CRPs and the barriers they encounter in delivering clinical research care. Therefore, this study aimed to address a significant knowledge gap by exploring the experiences of clinical research staff and the factors contributing to the barriers to ophthalmic clinical research care delivery. By bridging this knowledge gap, it may be possible to enhance the quality of care in ophthalmic clinical research and contribute to

the well-being of both patients and CRPs involved in this critical aspect of healthcare delivery.

Purpose

The purpose of this descriptive-interpretive qualitative study was to explore the barriers to ophthalmic clinical research care delivery as experienced by ophthalmic CRPs. I conducted a web-based, asynchronous, anonymized, open-ended survey study with ophthalmic CRPs to explore their experiences in delivering clinical research care in ophthalmology as viewed within Donabedian's (1988) quality-of-care framework.

Research Questions

The research question (RQ) that guided this study is the following:

RQ. What barriers to ophthalmic clinical research care delivery are experienced by ophthalmic CRPs?

This open-ended research question was further broken into sub-questions (SQ), using Donabedian's (1988) quality-of-care framework as an organizing tool for interpretation:

SQ1: What barriers to clinical research care delivery, if any, are structurally oriented?

SQ2: What barriers to clinical research care delivery, if any, are process-oriented?

SQ3: What barriers to clinical research care delivery, if any, are outcome oriented?

Conceptual Framework

This study aimed to comprehensively assess the quality of clinical research care through the experiences of ophthalmic CRPs. Donabedian's (1988) quality-of-care

framework, introduced by Avedis Donabedian, offers a well-established framework for evaluating healthcare quality through three interconnected dimensions: structure, process, and outcomes. Donabedian's quality-of-care framework is widely used in all modalities of healthcare research to effectively evaluate healthcare quality through the three dimensions of care, offering unique perspectives and identifying areas for improvement (Binder et al., 2021; Donabedian, 1988; Ramírez-Morera et al., 2022; Udod et al., 2022.; White et al., 2022).

Structure refers to the physical and organizational resources necessary to provide care, such as equipment and staffing, and are external to individuals. Process of care refers to the activities during care delivery, such as diagnosis, treatment, and follow-up. In clinical research, this would include the daily tasks associated with a human participant volunteer's protocol-determined research visit. Outcomes of care refer to the results of care delivery, such as patient health status and satisfaction with care (Donabedian, 1988). In clinical research, outcomes can also be interpreted to include concepts such as enrollment or financial benchmarks. Applying Donabedian's (1988) quality-of-care framework to this study may lead to valuable insight into the quality of clinical research care delivery in ophthalmology, contributing to the identification of potential areas for improvement and the development of targeted interventions.

Nature of the Study

This study used a descriptive-interpretive qualitative approach through a web-based application to collect data through asynchronous, anonymized, open-ended survey questions. Conducting this research in a virtual environment ensures the confidentiality

and anonymity of participants' responses. Responses generated from the web-based survey will be used to explore barriers to clinical research care delivery through the experiences of ophthalmic CRPs and further explore quality of clinical research care delivery through its structure, process, and outcomes.

A descriptive-interpretive qualitative approach is well-suited for research aiming to describe participants' experiences through their own words, with minimal researcher interpretation (Elliot & Timulak, 2021; Sandelowski, 2000). The asynchronous, open-ended survey allowed participants to provide detailed and nuanced accounts of their experiences at their convenience (Hawkins, 2018). By ensuring anonymity, participants can feel confident about the confidentiality of their answers and empowered to speak candidly about their experiences without fear of negative consequences (Hawkins, 2018). Anonymity was expected to yield a more honest and accurate portrayal of the barriers to clinical research care.

The survey questions asked participants to provide detailed perspectives, challenges, and barriers related to clinical research care delivery. The participants for this research study were CRPs from a single academic medical center. The responses from the web-based survey were directly imported into the qualitative data analysis software NVivo 14. The data were reviewed for completeness and saturation, and then delineated into meaning units. The data was categorized into structure, process, or outcome-related experiences, according to Donabedian's quality-of-care framework. Finally, data were interpreted within the context of the research question (Rubin & Rubin, 2012).

Definitions

Burnout: a state of emotional, mental, and physical exhaustion caused by excessive and prolonged stress (World Health Organization, 2019).

Clinical research professional (CRP): individuals who conduct research studies in a clinical setting, such as a hospital or medical center, manage clinical research studies and ensure they are conducted according to established protocols and guidelines (Society of Clinical Research Associates, n.d.). In this study, CRP encompasses a range of roles, including principal investigators, co- or sub-investigators, clinical research coordinators, clinical research administrative staff, and clinical research support staff (such as technicians and photographers). It is important to note that non-professional research staff, such as volunteers or students, are excluded from this definition.

Healthcare professional (HCP): individuals who provide healthcare services to patients. This includes physicians, nurses, pharmacists, and other allied health professionals (World Health Organization, 2013).

Human subject volunteers: A living person who voluntarily provides an investigator data about themselves or their condition through intervention or interaction (Protection of Human Subjects, 2023b)

Protocol: a detailed plan outlining the procedures and methods for a clinical research study (U.S. Food and Drug Administration, 2018b).

Assumptions

The primary assumptions that underlined this study was that the complexity of protocols and the management of workloads in clinical research may contribute to an

increased risk of burnout and a decreased ability to deliver clinical research care effectively. Additionally, several other assumptions were made:

- By exploring the experiences of CRPs in the field of ophthalmology, it is possible to identify specific topics related to barriers, project complexity, CRP capacity, CRP priorities, and efficient care delivery.
- This research has the potential to uncover problems unique to ophthalmology, adding unique perspectives on clinical research that have yet to be explored in the existing literature.
- Participants will be asked to provide honest responses based on their recollections of their own lived experiences.
- The data generated by this study will be valuable not only to CRPs within the field of ophthalmology but also to those outside of it, contributing to the broader clinical research community.
- By using a web-based, asynchronous, open-ended, and anonymized survey instrument, participants can openly express their experiences with minimal risk of bias.

These assumptions were crucial to establishing the foundational principles for the research and acknowledge potential bias and limitations. These assumptions provided a rationale for conducting the study and emphasized the potential benefits for the clinical research community.

Scope and Delimitations

The scope of this study was limited to the perceptions of CRPs in the field of ophthalmology at a single academic medical center. The population under investigation included investigators, clinical research coordinators, regulatory specialists, research area specialists, project managers, and clinical support staff. Excluded from this population were research professionals from non-ophthalmic disciplines, non-research ophthalmic professionals, and ophthalmic professionals from other centers to focus the study on staff who are most engaged in clinical research care delivery. The population for this study was chosen due to their underrepresentation in existing literature and was an accessible group with unique experiences and perspectives in delivering clinical research care in an ophthalmic setting.

Although the study was conducted within a single academic medical center, it was expected that the results would have broader applicability to CRPs in ophthalmic clinical research. The research question and survey questions were specifically designed to gain insights into clinical research care delivery from a direct perspective. Using Donabedian's (1988) quality-of-care framework, the descriptive-interpretive qualitative approach provided a structured pathway that limited broad interpretation. Thus, the data collected are expected to be transferrable to other ophthalmic clinical research care delivery teams.

Various frameworks could be used to analyze ophthalmic clinical research care delivery in the context of an academic medical center. Other frameworks considered, but not used, include:

- The health belief model is a framework that examines the relationships between the beliefs and behaviors of patients receiving care and the quality of care provided (Skinner et al., 2015)
- The chronic care model is a framework that emphasizes the importance of coordination and collaboration in healthcare delivery across the spectrum, specifically in the management of chronic health conditions (Wagner et al., 1996)
- The Institute of Medicine quality framework introduces six aims, or focus areas, for quality improvement, including safety, effectiveness, patient-centeredness, efficiency, timeliness, and equity (Institute of Medicine & Committee on Quality of Health Care in America, 2001).

While each of these frameworks, among others, are well researched and vital for healthcare research, Donabedian's (1988) quality-of-care framework allowed for a comprehensive view of healthcare systems. It has been used in a wide variety of specialties and healthcare settings and recognized as a valuable framework for evaluating the quality of care (Binder et al., 2021; Donabedian, 1988; Ramírez-Morera et al., 2022; Udod et al., 2022; White et al., 2022).

Limitations

One potential limitation of this study was the possibility of a small sample size and potential homogeneity of experiences resulting from the inclusion of participants from a single academic medical center. As such, the generalizability of the findings may be constrained, impacting the credibility of the results. However, qualitative research

designs are well-suited to delve deeply into individual experiences, providing rich and detailed insights. By using Donabedian's (1988) quality-of-care framework as the guiding theoretical framework, the data collected can be ensured to be reliable and valid. Additionally, maintaining participant anonymity throughout the study may have encouraged honest responses.

Transferability was another potential limitation of this study, primarily due to the narrow focus on a specific population. To address this, meticulous documentation of the study approach was conducted to facilitate the potential transferability of findings to other settings. Another critical limitation of this study to be acknowledged is my role within the clinical research program, which introduced the potential for bias. To mitigate this, the administration of open-ended survey questions was conducted anonymously, electronically, and asynchronously. This approach minimized my ability to infer respondents' identities and influence their responses. Despite these limitations, this study produced valuable insights into ophthalmic clinical research care delivery. Furthermore, results of this study may contribute to informing further research endeavors and guiding practical applications in this field.

Significance

This study has the potential to make significant advancements in the field of clinical research, specifically within ophthalmology. As clinical research studies become increasingly complex, implications for staff burnout, workload distribution, and the ability to provide clinical research care need to be clarified (Lee et al., 2021). This knowledge is essential for CRPs across various disciplines, as it can inform practice and

policy. However, there is limited research in this domain, specifically related to ophthalmology. By exploring the experiences of CRPs in this context, this study sought to uncover previously unidentified barriers to care delivery to better understand the challenges faced by CRPs. The insights gleaned from this study may inform changes in practice and policy, mitigating burnout, improving workload balance, and augmenting the capacity to deliver high-quality clinical research care.

This study contributes to a broader understanding of clinical research care delivery, particularly within academic medical centers. By employing Donabedian's (1988) quality-of-care framework, the study provides valuable insights into the quality of clinical research care and informs areas for improvement. The findings of this study have significant implications for positive social change, as the findings have the potential to enhance patient outcomes in the face of escalating clinical research study complexity (Brennan et al., 2019).

By identifying barriers to care delivery and addressing the well-being of CRPs, this study also has a positive impact on the broader healthcare system. Enhancing the quality of life for CRPs will aid in retaining experienced professionals and ensuring patients receive high-quality care. The study contributes to social change by highlighting the importance of clinical research and advocating for the support and recognition of the professionals who conduct this vital work. Lastly, this study adds to the existing body of knowledge and can serve as a catalyst for social change by improving clinical research care delivery and, consequently, influencing future clinical outcomes.

Summary

Clinical research plays a vital role in the development of the healthcare delivery system, as it contributes to the expansion of knowledge, the discovery of new information, treatments, or interventions, and the application of these findings to healthcare practice (Portier, 2020; NLM, 2019). However, the increasing complexity of clinical research studies has led to poorly understood outcomes and posed challenges to clinical research care delivery (Lee et al., 2021). Within the field of ophthalmology, clinical research is highly complex and holds particular significance, given its potential impact on the lives of approximately 10 million Americans by 2050 (Centers for Disease Control and Prevention, 2020; Moore et al., 2020; Turner et al., 2020). Nevertheless, further research was needed to explore the barriers and experiences of CRPs in ophthalmic clinical research care delivery.

This study aimed to bridge a knowledge gap by using Donabedian's (1988) quality-of-care framework to explore the experiences of CRPs and the barriers they face in clinical research care delivery. Donabedian's quality-of-care framework offered a comprehensive framework for evaluating healthcare quality encompassing three interconnected components: structure, process, and outcomes. Chapter 2 of this study will provide a literature review covering the background, importance, relevant research, and ongoing needs of clinical research care delivery in healthcare. Additionally, the conceptual framework that guided this study will be discussed in detail.

Chapter 2: Literature Review

Introduction

Clinical research is a vital aspect of healthcare delivery that informs novel treatments for and enhances the understanding of clinical care. Despite the importance of clinical research, studies have yet to be conducted to explore the experiences of the wide-ranging staff who ensure clinical research is conducted safely, ethically, and to the high-quality standards necessary for success. Clinical research studies, especially clinical trials, are becoming increasingly complex, leading to increased risk, regulatory monitoring, and administrative burden on clinical research centers (Lee et al., 2021). It needs to be clear how the increasing complexity of clinical research studies contributes to rising levels of staff burnout, workload imbalance, or disruptions to clinical research care delivery. Only some studies explore these topics, and none do so within the context of an ophthalmology-focused clinical research care delivery system. The purpose of this study was to explore the barriers to ophthalmic clinical research care delivery as experienced by ophthalmic CRPs. Chapter 2 provides the conceptual framework for this study and describes the relevant literature related to the topic, methodology, and definitions of the research problem.

Literature Search Strategy

A literature review was performed using the Walden University and the University of Michigan online libraries. Specific keywords and phrases were designed to filter and identify recent peer-reviewed articles and topics related to barriers to ophthalmic clinical research care delivery. Only articles published from January 1, 2017,

to December 31, 2022 were reviewed in-depth. Key search terms included: clinical research coordinator, competency, clinical trials as topic, clinical research coordinator, workload, enrollment, burnout, cost, resource management, quality, ophthalmology, oncology, clinic management, and care delivery. These search terms were often combined to include multiple search terms to narrow results.

Most searches included the MESH tag "Clinical Trials as Topic" to keep results consistent with a literature review on clinical research administration as compared to. articles reviewing specific clinical research protocols. Of the many combinations, the searches that returned the most useful articles included the following: clinical research coordinator AND work-load or work load or workload or demands or pressure (19 returned articles, of which four were included); clinical trials AND quality AND oncology AND burnout (five reviewed, two included); and an EBSCOhost search for clinical trial complexity, limited to United States (21 reviewed, two included). In cases where there were less than 200 results and concern about losing relevant articles through a narrowing strategy, all titles were reviewed for relevancy, further reviewed through abstract summary as appropriate, and included if they met the inclusion criteria. Articles met inclusion criteria if they reported relevant data on challenges within clinical research as a topic. Because much of the research on clinical trial management has been focused on oncology, the literature review includes those topics as they relate to clinical research broadly. Articles used were found primarily in EBSCO, CINAHL, and PubMed databases. In total, 549 articles were topically reviewed (including overlapping search results), with 36 meeting the overall inclusion criteria.

When relevant, articles cited within reviewed articles were explored for further understanding or inclusion. Many of these articles were excluded from the overall literature review for falling outside the strict 5-year period but played an essential role in formulating this topic. Topically relevant articles were included in the broader history of barriers to ophthalmic clinical research care delivery or other disciplines.

Conceptual Framework

This study used Donabedian's (1988) quality-of-care framework to assess the quality of clinical research care in ophthalmology. Donabedian's quality-of-care framework was valuable in identifying areas for improvement in care delivery due to the systematic way it organizes the varied aspects of healthcare. Donabedian argued that measuring and assessing healthcare quality is an essential but challenging task. He proposed a framework for evaluating healthcare quality that consists of three components: structure, process, and outcomes. The structure of healthcare refers to the physical and organizational resources necessary to provide care, such as equipment and staffing. The process of care refers to the activities that take place during care delivery, such as diagnosis, treatment, and follow-up. The outcomes of care refer to the results of care delivery, such as patient health status and satisfaction with care (Donabedian, 1988).

Donabedian (1988) noted that measuring healthcare quality is essential because it can help identify areas for improvement and guide quality improvement efforts. He also acknowledged that assessing healthcare quality is complex, as it involves evaluating multiple dimensions of care and accounting for factors beyond the control of healthcare providers, such as patient preferences and social determinants of health. Despite these

challenges, Donabedian argued that measuring and assessing healthcare quality is necessary for improving patient outcomes and ensuring that healthcare resources are used effectively. This framework for evaluating healthcare quality can be used to develop quality measures, guide quality improvement efforts, inform health policy decisions, and compare the quality of care provided by different healthcare providers and organizations. The Donabedian quality-of-care framework is widely recognized and frequently used in healthcare research.

Using the Donabedian quality-of-care framework, White et al. (2022) evaluated the relationship between burnout and healthcare quality across three dimensions: structure, process, and outcomes, finding burnout was a common problem among healthcare professionals and has been shown to have negative impacts on both the well-being of healthcare providers and the quality of care they provide. They found that burnout among nurses was associated with lower quality of care across all three dimensions, including decreased availability of necessary resources (structure), decreased adherence to evidence-based practices (process), and poorer patient outcomes (outcomes) (White et al., 2022).

Udod et al. (2022) conducted a study using the Donabedian quality-of-care framework to examine the quality of transitional care for cardiac patients and family caregivers. The study aimed to identify areas for improvement in the delivery of transitional care, focusing on the structure, process, and outcomes of care. The Donabedian (1988) quality-of-care framework was a valuable tool for evaluating transitional care, as it allowed the identification of areas for improvement in each of the

three dimensions. The structure of care, including the availability of resources and staff training, was crucial for ensuring the quality of care. In terms of process, effective communication and collaboration between healthcare providers and patients/caregivers were essential. Outcome measures such as patient satisfaction and readmission rates are necessary to assess the effectiveness of transitional care (Udod et al., 2022).

Shroyer et al. (2019) discussed the application of the Donabedian quality-of-care framework in improving the quality of clinical care in the context of health services information, arguing that the Donabedian quality-of-care framework provides a comprehensive approach to evaluating the quality of clinical care that includes not only the technical aspects of care but also the structure and process of care. The importance of using data to monitor and improve the quality of care is highly emphasized, and the Donabedian quality-of-care framework can guide the selection of appropriate measures for evaluating various aspects of care (Shroyer et al., 2019).

Ramírez-Morera et al. (2022) conducted a systematic review to evaluate the effects of evidence-based clinical practice guidelines (CPGs) on healthcare quality improvements for breast cancer. The study used the Donabedian (1988) quality-of-care framework to assess the quality of healthcare delivered. The researchers analyzed 26 articles that met the inclusion criteria and identified a positive correlation between implementing evidence-based CPGs and healthcare quality improvements. The study found that evidence-based CPGs can improve healthcare quality by promoting patient-centered care, increasing adherence to treatment protocols, and reducing clinical errors. The researchers noted that using the Donabedian quality-of-care framework facilitated

the evaluation of healthcare quality improvements and helped identify areas that require improvement. The study concluded that the implementation of evidence-based CPGs can lead to significant healthcare quality improvements and that the Donabedian quality-of-care framework can serve as a valuable tool in evaluating the effectiveness of healthcare interventions (Ramierz-Morera et al., 2022)

Guta (2022) applied the Donabedian quality-of-care framework to assess the quality of neonatal resuscitation, its outcome, and associated factors among resuscitated newborns at public hospitals in Western Ethiopia. The study aimed to assess the quality of neonatal resuscitation using the structure, process, and outcome components of the Donabedian quality-of-care framework. Guta used a cross-sectional study design and collected data through chart review, direct observation, and interviews with healthcare providers. The study found that the quality of neonatal resuscitation was suboptimal in most public hospitals, and the outcome was also poor. Guta recommended improving neonatal resuscitation quality by providing essential equipment and supplies, regular training of healthcare providers, and developing clinical guidelines based on the Donabedian quality-of-care framework. The study highlights the importance of using the Donabedian quality-of-care framework to assess and improve the quality of care in neonatal resuscitation, especially in resource-limited settings (Guta, 2022).

Using a case report methodology, Binder et al. (2021) explored using the Donabedian quality-of-care framework in the context of the COVID-19 response at a hospital in suburban Westchester County, New York. The study aimed to describe the use of the Donabedian quality-of-care framework to evaluate the quality of care provided

during the COVID-19 pandemic and identify areas for improvement in the hospital's COVID-19 response. Binder et al. found that the Donabedian quality-of-care framework helped evaluate the hospital's COVID-19 response. The structure component included the hospital's preparedness for the pandemic, such as its availability of personal protective equipment and testing capabilities. The process component included the hospital's response to the pandemic, its triage and treatment protocols, and its communication strategies. The outcome component included the hospital's COVID-19 patient outcomes, such as mortality rates and length of stay.

The Donabedian (1988) quality-of-care framework is a widely recognized framework for evaluating the quality of healthcare delivery. It helps identify areas for improvement in care delivery and allows for evaluating healthcare quality across the dimensions of structure, process, and outcomes. The Donabedian quality-of-care framework is applicable across many disciplines and can serve as a valuable tool in exploring clinical research care delivery.

This study aimed to explore the barriers to clinical research care delivery among ophthalmic CRPs. The Donabedian (1988) quality-of-care framework provided a structure for interpreting the findings of the study. The study's central research question, "What barriers to clinical research care are experienced by ophthalmic CRPs?" was broken down into sub-questions that used the Donabedian quality-of-care framework as an organizing tool for interpretation.

The first sub-question focused on identifying the structure-oriented barriers to clinical research care that CRPs in ophthalmology experience. The Donabedian (1988)

quality-of-care framework considers these barriers related to the organization of care, such as the availability of resources, staffing levels, and the physical environment. The second sub-question explored process-oriented barriers related to the processes involved in delivering care, such as the procedures used, the quality of communication between staff, and the coordination of care, all of which are important to a clinical research visit. The third sub-question investigated outcome-oriented barriers related to the results of the care, such as patient satisfaction, clinical effectiveness, and safety. From a clinical research perspective, outcomes may also be associated with protocol enrollment goals and financial benchmarks. The Donabedian quality-of-care framework was used to organize and interpret the data gathered from survey responses from ophthalmic CRPs and provided a more comprehensive understanding of the challenges experienced by ophthalmic CRPs.

Literature Review

Clinical research encompasses a wide range of observational and investigational studies designed to determine whether a new treatment or intervention is safe and effective in a medical or health-related context (Portier, 2020). Clinical research is conducted through the involvement of volunteer human subjects who participate in a highly organized research study to learn something new about a particular intervention or observation, often, but not exclusively, in the form of an investigational drug, device, procedure, or behavioral intervention (NLM, 2019). Clinical research is conducted under a principal investigator's (PI's) direction. It can involve many CRPs, such as research nurses, doctors, allied health professionals, and administrative staff, all coordinating

clinical research delivery. Clinical research studies are primarily conducted in a clinical setting, such as hospitals, academic medical centers, or community physician offices (NLM, 2019), and are highly regulated by both the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services to protect human volunteers and thus require a great deal of administrative and regulatory support (Feehan & Garcia-Diaz, 2020; Protection of Human Subjects, 2023a; Protection of Human Subjects, 2023b).

Clinical research can be divided into two broad categories: observational and investigational. An observational study aims to understand the natural history of a disease or the behaviors of individuals with a particular diagnosis. However, it does not intervene or seek to change the outcomes of a particular health concern (Lamberti et al., 2018). Interventional studies take on many forms and are broadly characterized as clinical trials. The National Institute of Health defines a clinical trial as:

> A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (National Institutes of Health, 2017).

These clinical trials are essential in developing novel drugs, treatments, and devices. The FDA regulates the development of new treatments and moves through five steps from discovery to the public (U.S. Food and Drug Administration [FDA], 2018a). The first step is discovery and development, where laboratory research produces novel molecular compounds that have some effect on a specific disease. Step 2 is to assess this

new compound in non-human subjects (sample tissue or animal testing) to determine whether the compound is safe to use in live subjects. Step 3 is clinical research, where treatments are put through several phases of testing in human subjects to determine whether the treatment is safe and efficacious in each disease state. Steps 4 and 5 involve the initial review and approval (Step 4) of the new treatment by the FDA and continued safety monitoring (Step 5) after the treatment has been widely available (FDA, 2018a).

Step 3, clinical research, is similarly broken into steps or "phases." In Phase 1, clinical research uses data collected from preclinical research and applies it to a small number of healthy volunteers and is focused on determining overall safety and dosing tolerance. Approximately 70% of studies move to Phase 2, where the treatment is evaluated on a larger group of human participants (generally no more than 100) with the disease for which the treatment was designed to study side effects and efficacy further. If successful, the study will move into Phase 3, which can involve hundreds to thousands of eligible volunteers and are designed to determine overall efficacy and longer-term side effect monitoring (FDA, 2018b)

Over the last several decades, clinical research has been an essential fixture in developing new treatments. Working in tandem with standard clinical care, successful clinical trials have led to impressive improvements across health systems. For example, the overall 5-year survival rate for children with cancer, that is, the percentage of children with cancer surviving five years from diagnosis, has increased from 58% in the 1970s to 85%, due to advancements made in clinical trials (American Cancer Society [ACS], 2023; Portier, 2020).

Challenges in Clinical Research Care Delivery

Despite the clear need for clinical research, there remain significant problems that clinical research programs face in the execution of their studies. The literature identified several themes: enrollment, cost, quality, workload management, and the resources to assess signs of burnout and clinical research protocol complexity to align these programs into actionable solutions.

Enrollment

While each challenge is unique, it can be understood that clinical trials are only successful with the recruitment of human volunteers. Enrollment in clinical trials faces many issues which have been studied and discussed throughout the literature. Within the issues commonly cited as barriers to enrollment is a sub-discussion of low enrollment of minority populations. Due to the increasing complexity of clinical research protocols, recruitment periods for clinical research studies, and the number of registered sites per trial, have been steadily increasing since 2008; however, the total number of participants per study is decreasing (Brøgger-Mikkelsen et al., 2022).

Feuer et al. (2022), in a cross-sectional analysis of non-cancer respondents using the Health Information National Trends Survey, noted that in 47% of respondents that reported they had been invited to participate in a clinical trial, most participants reported that participating in clinical trials was highly influenced by a desire to "get better" (80.5%) and "helping other people" (61.4%). At the same time, 82.5% of respondents indicated that they knew very little, if anything, about clinical trials, while others cited significant time and financial barriers to participating in clinical trials (Feuer et al., 2022).

Dickens et al. (2020) performed quality improvement surveys among PIs and CRPs in pediatric oncology sites, aiming to improve PI engagement and increase enrollment among the National Cancer Institute Community Oncology Research Program (NCORP) and Children's Oncology Group (COG) sites. Of particular interest to this literature review were the second survey results. A telephone interview among 23 NCORP COG PIs identified that the most cited barriers to clinical trial enrollment were limited research assistance and limited protected time to manage recruitment efforts effectively. Dickens et al. concluded that more research is needed to identify education, time, and resource barriers.

In their review of oncology clinical trials, Nipp et al. (2019) found that a patient's diagnosis is highly associated with an increased financial burden, thus limiting the representation of lower-income participants due to the lack of resources to participate in a clinical trial. Patients and providers reported a sense of worry when discussing the unknown risks of a novel treatment, which can limit confidence in the efficacy of clinical trials. Nipp et al. concluded that using Patient Navigators (PNs), CRPs who can educate patients and find ways to navigate the barriers patients face when considering joining or continuing a clinical trial, can help alleviate some of that worry.

Vuong et al. (2020) described similar low enrollment rates of minority populations (African Americans, Asian Americans, Pacific Islanders, American Indians, and Latino/Hispanic Americans) despite ethnic disparities in cancer incidence and mortality. In a 2013 review, despite the cancer prevalence in Latino/Hispanic Americans of 7%, clinical trial participation in that population was only 2.6%. In these minority

populations, the barriers to enrollment are historically tied to a lack of access or awareness, distrust in the medical establishment, and other sociocultural issues, from language barriers to exclusionary co-morbidities. Increases in PNs, cultural and linguistic adaptation, and community partnerships are all significant factors in increasing minority enrollment in clinical trials (Vuong et al., 2020).

Though there has been awareness of minority enrollment challenges and attempts at increasing enrollment rates in women and minorities, Duma et al. (2018) found that participation in these groups in oncology clinical trials has steadily decreased from 2003-2016. In a review of all studies listing race and ethnicity data on ClinicalTrials.gov and cancer rates from the Surveillance, Epidemiology, and End Results database – a collection of cancer registries across several institutions in the United States, there were multiple issues regarding minority, age, and gender enrollment data. Though the prevalence of cancer was about even in men and women, enrollment of women in clinical trials was 41%. Similarly, minority populations accounted for nearly 21% of cancer diagnoses but only 14% of clinical trial participants (Duma et al., 2018).

While much of the literature revolves around oncology, these topics are not limited to oncology clinical research. Concerning clinical trials in Stroke care, Carcel and Reeves (2021) reported similar disparities in gender enrollment. Only 40% of the trial participants in the review were women. Women reported barriers limiting their participation in clinical trials as being less concerned about the severity of disease, more concerned about being able to maintain family responsibilities and being more risk-averse than men (Carcel & Reeves, 2021).

Lastly, Vaswani et al. (2020) explored the topic of participation in clinical trials for Parkinson's Disease. Only 1/3 of studied clinical trials met their enrollment goals, and the most cited barriers to enrollment were financial (37%), time commitment related (15%), or concerning the amount of testing or protocol requirements (47%). This review also affirmed previously stated low participation rates (<6%) in nonwhite participants (Vaswani et al., 2020).

Cost and Quality

It is estimated that pharmaceutical research and development for new drugs and drug candidates can cost between US$133 million to US$6 billion (Rennane et al., 2022). The costs of conducting a clinical trial and the reliability of the data a clinical trial produces are essential to investigative sites and industry drug developers. Moore et al. (2020) studied the estimated costs of pivotal clinical trials in the United States and the costs to achieve FDA approval and found a considerable variation from $20-$102 million per trial. Across research disciplines, the per-study participant cost of conducting clinical trials (for drugs that would go on to achieve FDA approval) was approximately US$41,000. Further, costs per trial or trial participant were significantly increased for studies with a significant target enrollment goal or a high frequency of study visits required to achieve meaningful results (Moore et al., 2020).

Of the many costs of conducting clinical trials, the salary cost of CRPs stands out among the sites. Little research on the direct impact of CRP cost on the conduct of clinical trials exists in the literature. There is no requirement to release this data in the United States publicly; however, one study reviewed the fees associated with conducting

clinical trials in China and discovered that non-medical labor costs were increased or added and were projected to continue to rise (Chen et al., 2021; Moore et al., 2020). The highest costs for conducting a clinical trial are generally found in staff salary and administrative tasks (Buchanan et al., 2020).

Mitchell et al. (2020) conducted a cross-sectional analysis of increasing post-approval costs of cancer treatments to determine whether there is an association with improved clinical value. The researchers discussed that there was no positive relationship between drug prices and clinical trial outcomes. Through an evaluation of 1,386 treatments, the clinical value of cancer treatments did not seem to determine the treatment cost (Mitchell et al., 2020). These limited studies on the cost of clinical trial administration point to a need to understand further the workload and capacity of CRPs.

Workload, Burnout, Complexity, and Assessment

As a fixture in the broader medical community, CRPs face many challenges that all healthcare professionals face. Of great concern in recent years is employee burnout. Burnout is characterized by symptoms of emotional exhaustion, depersonalization, and a sense of low accomplishment (Moerdler et al., 2020). Burnout leads to decreased job satisfaction and, if unchecked, can lead to substance abuse, suicide, or patient safety concerns (Moerdler et al., 2020).

There are limited studies exploring burnout among CRPs. In what is the most relevant and recent study on this topic, Mascaro et al. (2021) conducted a mixed-methods exploration of the prevalence and predictors of burnout among clinical research coordinators in a single oncology clinical research center. From a quantitative

perspective, clinical research coordinators reported moderate levels of burnout, with sleep dysfunction, stress, and incivility experienced from patients; however, CRPs overwhelmingly cited workload imbalance as a primary concern in the qualitative focus groups (Mascaro et al., 2021).

Clinical research studies, especially clinical trials, are becoming much more complex, which contributes to feelings of increased or unmanageable workload. Getz and Campo (2017) reviewed 9,737 clinical trial protocols between 2001 and 2015 and found that the number of distinct procedures, the total number of procedures performed, and the number of planned research visits per protocol have increased drastically across all phases of clinical trials. This increase in protocol complexity can have further implications for on-site management and administration, with an increased regulatory review, amendments, and staffing. Similarly, Malik and Lu (2019) evaluated 102 phase I protocols from their institution and found significant increases in procedures required per protocol from 1996 to 2016. Understanding workload informs staffing decisions and could affect patient outcomes (Brennan et al., 2019).

A challenge then emerged from the literature on how to properly rate a clinical trial's complexity to appropriately assign and balance study management within a clinical research site. Milani et al. (2017), in their approach to creating a clinical trial assessment tool for research nursing staff, found that resources are lacking that appropriately quantify workload. Morin (2019) posited that standard ways of measuring protocol complexity and workload management fail to acknowledge output, productivity, or efficiency and are thus impractical to use broadly. Workload in clinical research is ever

shifting; traditional methods to quantify workload management are too burdensome to conduct efficiently (Morin, 2019).

Jones et al. (2020) conducted an eDelphi, three-round, multi-center, online survey among thirteen National Health Service (NHS) oncology hospital sites in Scotland and England with the intent to identify CRP priorities, understand local challenges, and define study complexity and workloads for the development of a trial rating and complexity assessment tool (TRACAT). Through seven open-ended questions, Jones et al. (2020) identified 75 consensus statements that were considered factors contributing to complexity and clinical trial management and 14 "Trial Rating Indicators" (TRIs) weighted by priority and informed the development of TRACAT. Among the 75 consensus statements, the statements with the highest level of consensus (96%) indicated that CRPs view protocol burden significantly affecting the ability to operate (Jones et al., 2020).

Clinical Research in Ophthalmology

Few studies explore clinical research care delivery in an exclusively ophthalmic-focused care setting. Moore et al. (2020) described the costs of conducting clinical trials and found that costs in ophthalmology range from US$34-$44 million per study or up to US$30,000 per study participant. This section will provide a brief overview of ophthalmic care delivery in the United States, the relationship between clinical research and clinical care, an overview of the literature in ophthalmology specifically, and the overall justification for this research.

Prevalence and Burden of Eye Disease in the United States

In 2015, 4.2 million Americans were blind or had an uncorrectable vision impairment, with estimated growth approaching 10 million by 2050 (Centers for Disease Control and Prevention [CDC], 2020). Among correctable vision impairments (i.e., vision impairments that can be reversed with eyeglasses, contact lenses, or surgery), the number of people with a vision impairment increased to 12.4 million in 2015, with an estimated 25.36 million people predicted to have a vision impairment by 2050 (CDC, 2020). Rein et al. (2022) estimated the total economic burden of vision loss to be US$134.2 billion, with the most significant burdens associated with vision loss being nursing home care (US$41.8 billion), other medical costs such as eyeglasses and home healthcare services (US$30.9 billion) and a reduction in labor force participation (US$16.2 billion).

Ophthalmic Care Delivery

Vision care is accomplished by many eye care professionals, from ophthalmologists, optometrists, ophthalmic technicians, nurses, photographers, and opticians (Churchill & Gudgel, 2022). Ophthalmologists, and their typical care team of ophthalmic technicians and photographers, make up the bulk of primary ophthalmic vision care and vision care research. An ophthalmologist is a medical doctor who specializes in eye care and is thus capable of diagnosing, treating, and operating on all vision-related diseases (Churchill & Gudgel, 2022).

A routine eye examination can uncover more than vision-related disease. An ophthalmologist can view and photograph the many vessels and nerves within the eye

allowing for the diagnosis of systemic diseases, such as diabetes, brain tumors, aneurysms, high blood pressure, high cholesterol, stroke, thyroid disease, and more, often before bodily symptoms appear (Mukamal, 2020). The American Academy of Ophthalmology recommends that all adults receive a complete eye exam by age forty, as many vision-threatening diseases can be caught early (Turbert, 2022). Adults with family or personal risk factors, such as diabetes, high blood pressure, or a family history of eye disease, are encouraged to get a complete eye exam soon and more frequently. The guidance is similar for individuals 65 and older, as age-related, vision-threatening eye disease is more common (Turbert, 2022).

Clinical Research Relationship to Clinical Care

Ophthalmic research and clinical care are intricately linked. Patient Reported Outcome Measures (PROMs) are surveys commonly used in the clinical setting to determine the impact of vision disorders on quality of life. PROMs are, therefore, helpful in the development and clinical trial design and are often used as endpoint measures in clinical research protocols (Rowe-Rendlemann, 2019). Clinical trial outcomes have also helped inform clinical care in populations that are more challenging to study. Sacchi et al. (2020) reviewed clinical trials conducted for glaucoma medical therapies in children. In the author's synthesis of the studied trials, they were able to recommend safer and more efficient clinical care (Sacchi et al., 2020). Similarly, Mansour et al. (2020) reviewed the literature regarding managing diabetic retinopathy. They concluded that "substantiation of safety, efficacy, and cost-effectiveness by a body of sound clinical trials" is "central to the widespread adoption of any therapeutic regimen" (Mansour et al., 2020).

Rationale for a Descriptive-Interpretive Qualitative Approach

Despite a demonstrated need to understand barriers to clinical research care delivery, few studies have explored this topic across the clinical research field, and none in ophthalmology. Ophthalmic clinical trials are less common than other fields of medicine, making up less than 3% of interventional trials between 2007 and 2018, yet tended to show higher levels of complexity than other fields (Turner et al., 2020). This apparent gap in the literature supports the need to explore the topic in such a way as to identify barriers to clinical research care delivery from those who live the experience.

A descriptive-interpretive qualitative research approach is a research methodology applicable to a broad range of research questions commonly used to provide a summarized understanding of an experience (Elliot & Timaluk, 2021; Sandelowski, 2000; Willis et al., 2016). In a descriptive-interpretive qualitative study, researchers typically select a small sample of participants with experience with the phenomenon being studied and collect data through in-depth interviews, focus groups, surveys, or observation. The collected data is then analyzed using thematic or content analysis techniques to identify key themes and patterns (Elliot & Timaluk, 2021; Sandelowski, 2008; Willis et al., 2016).

The findings of a descriptive-interpretive qualitative study are presented in an individual's own words, often using direct quotes from participants to illustrate key themes and insights (Danford, 2023). The resulting conclusions provide a rich and nuanced understanding of the phenomenon being studied and may contribute to developing new theories or hypotheses for future research. Chen and Lin (2021) used a

descriptive-interpretive qualitative approach through focus-group interviews in a Taiwanese study on barriers to advance care planning for patients with kidney disease. Chen and Lin found significant barriers associated with a lack of knowledge or communication skills and conflicting perspectives, uncovering a need to increase or reprioritize aspects of nursing care training and information dissemination. The descriptive-interpretive qualitative approach was vital to increase awareness of the realities faced in advanced care nursing (Chen & Lin, 2021). Jones et al. (2020) used a similar approach in the context of NHS oncology research professionals. Though their exact methodology is not compatible with the purpose of this study, Jones et al. provide an introduction to the exploration of this topic through their use of qualitative web-based survey questions, concluding that "[h]igh levels of consensus relating to operational challenges in research are relevant to wider global settings and the concepts should be tested in other therapeutic areas" (Jones et al., 2020, p. 13).

Conclusion

The literature confirmed a need to better understand the barriers to ophthalmic clinical research care delivery. The increasing complexity of clinical research studies and rising levels of staff burnout, workload imbalance, and disruptions to clinical research care delivery have been partially explored in this literature review. Nevertheless, more research needed to be done. Using Donabedian's (1988) quality-of-care framework to evaluate the quality of care, this study explored the barriers to clinical research care delivery through the experiences of CRPs in three components of Donabedian's quality-

of-care framework: structure, process, and outcomes. Chapter 3 will explore this methodological approach and considerations for completing this study.

Chapter 3: Research Method

Introduction

The purpose of this study was to explore the barriers to clinical research care delivery experienced by ophthalmic CRPs. I conducted a web-based, asynchronous, anonymized, open-ended survey study with ophthalmic CRPs to understand their experience delivering clinical research care in an ophthalmic setting, exploring topics including burnout, workload, and protocol complexity, through the lens of Donabedian's (1988) quality-of-care framework. This chapter will describe the research design and rationale, the role of the researcher, and the study methodology. Additional topics of importance that will be addressed include issues of trustworthiness and ethical procedures/considerations.

Research Design and Rationale

The RQ that guided this study was the following:

RQ: What barriers to ophthalmic clinical research care delivery are experienced by ophthalmic CRPs?

This open-ended research question is further broken into SQs, using Donabedian's (1988) quality-of-care framework as an organizing tool for interpretation:

SQ1: What barriers to clinical research care delivery, if any, are structurally oriented?

SQ2: What barriers to clinical research care delivery, if any, are process-oriented?

SQ3: What barriers to clinical research care delivery, if any, are outcome oriented?

The central concept of this study was to explore the barriers experienced by ophthalmic CRPs and the impact those challenges have on the delivery of clinical research care. Of primary importance was the real-world experience of CRPs. Therefore, this study was conducted within a tradition that allows for subjective experience through a broader epistemological context.

A descriptive-interpretive design bridges the gap between complete objectivity and overreliance on theory, allowing the researcher to gain a practical understanding of an experience through a social context (Thorne, 2016). Descriptive interpretation is a way for researchers to produce high-quality research where the method is less important than articulating the disciplinary motivation to the reader (Thorne, 2016). This study intended to speak for itself through the voices of the participants. A descriptive-interpretive qualitative approach strongly focuses on participant response with little interpretative interaction from the researcher (Sandelowski, 2000). This design was chosen to gain practical understanding of CRPs direct experience from their varied perspectives, which is crucial to developing an in-depth understanding of barriers to clinical research care delivery.

Role of the Researcher

The study was conducted with CRPs from an ophthalmology department within an academic research center, where I am the administrative director of ophthalmic clinical research. Although I am the direct supervisor of a small percentage of eligible participants, I recognized that there existed a positional power differential. For this reason, the study was conducted with complete anonymity. This study intended to

understand firsthand experiences within clinical research care delivery, and as such, neither the questions nor the expected answers were expected to be sensitive. However, because respondents will have the opportunity to discuss their work conditions, there may have been potential for fear of retaliation, and participants may have withheld some of their experiences. Nevertheless, the study was meant to be informative and create a space where voices could be heard to improve the quality of clinical research care delivery and lead to an organizational use for quality improvement. Thus, the overall risk for bias and my positional influence was low, and steps were taken to reduce any existing positional influence.

Despite the minimal risk of bias my dual role as researcher and director could not be ignored. It was imperative that I removed myself as much as possible from activities that could influence the outcomes of the study in addition to consciously considering my own bias and motivation. However, the questions were not designed to illicit high sensitivity responses and could be asked from the perspective of quality assurance or quality improvement. The study was conducted through a web-based, asynchronous, anonymized, open-ended survey, where individuals responded on their own time and could feel confident that their answers were completely confidential. Outside of the email invitations to participate, the study was not discussed in the workplace with any potential respondents. As participant responses were electronic, there was virtually no risk of transcription error. Because the survey instrument was asynchronous, participants could take their time with their answers, allowing for richness and nuance without fear of misinterpretation.

Methodology

Participant Selection Logic

The study population for this research were individuals working in ophthalmology with experience in clinical research. I used convenience sampling and participants were recruited from the ophthalmology department of a single academic medical center. This site was chosen as it employs nearly 80 CRPs with varied roles and responsibilities. To be eligible, one must have worked in clinical research for at least six months. All ophthalmic CRPs in the department were emailed an invitation link that led directly to the REDCap survey instrument and, after reading the informed consent landing page, answered brief demographic questions regarding their years of experience, role, gender (optional), and age range to determine eligibility. There was no attempt to link this data to an individual. Participants were sequentially assigned a study ID.

The REDCap survey space remained active for four weeks when saturation was obtained with a total of 18 respondents, meeting the anticipated goal of 15-20 respondents.

Instrumentation

The instrumentation for this study consisted of six open-ended survey questions administered via a web-based, asynchronous, anonymized, open-ended survey instrument. The questions that participants were asked are as follows:

1. Barriers and burdens: Please describe the phenomena you encounter in your role within ophthalmology clinical research which you perceive as barriers or burdens to effective study implementation and delivery. Please feel free to list

as many issues or concepts as you wish. These could relate to local, departmental, institutional, regional, or national factors, as well as resource and study design elements.

2. Complexity: Please provide your analysis of complexity in delivering ophthalmology clinical trials. This could include the complexity of the clinical research protocol or the complex nature of the disease, or the interactions involved in managing the treatment and care pathway for an ophthalmology patient participating in a research study. Please feel free to suggest as many themes as you wish.
3. Capacity factors: Please describe factors affecting your capacity to support and deliver ophthalmology clinical research. These can be elements relative to your specific role, department, institution, or global factors. Please list as many considerations as you wish.
4. Top priorities: Please suggest your top three strategic priorities for the future delivery of ophthalmology clinical research in your department, institution, or as it relates to clinical research delivery in general.
5. Effective practice: Please provide your views on existing elements of ophthalmology clinical research practice that contribute to or demonstrate efficient study delivery and practice.
6. Additional considerations: Please add any additional elements you feel should be considered in relation to reviewing the operational delivery, challenges, and complexity of ophthalmology clinical research.

These survey questions were adapted from Jones et al. (2020), who conducted a multimodal, mixed-methods study evaluating follow-up and complexity in cancer clinical trials. The study was designed to explore, through an anonymized, multi-round, eDelphi panel, the experiences and challenges of CRPs implementing and delivering cancer clinical trials in hospital settings - a topic of key importance to this study and a rare exploration of the topic in the literature. Jones et al. (2020) designed the set of survey questions to generate various responses over a wide range of clinical research challenges CRPs in oncology research may face. The questions generated 201 statements, with 75 reaching consensus in further rounds. It was similarly expected that CRPs in ophthalmology provide diverse sentiments and experience in clinical research.

The focus of Jones et al. (2020) was CRPs in cancer clinical trials among centers associated with The National Health Service in the United Kingdom. This required adapting the survey questions to align with a United States-based research team that does not operate within a nationalized medicine framework. The overall design of the survey instrument for this study kept the central themes and intention of the source material. Permission to adapt the research questions is granted through open access and under the Creative Commons Attribution Non-Commercial (CC BY-NC 4.0) license (Jones et al., 2020).

The questions adapted from Jones et al. (2020) aligned in targeted ways to answer the research questions. Broadly, each question explores various aspects of clinical research care delivery that may relate to barriers to care. Additionally, each question created opportunities to discuss experiences that can be viewed through Donabedian's

(1988) quality-of-care framework, exploring CRP experiences through clinical research care delivery structure, process, and outcomes.

Procedures for Recruitment, Participation, and Data Collection

Data were collected from participant responses to the open-ended qualitative REDCap survey. Participants were not required to provide identifying information within the electronic interview form to ensure anonymity and confidentiality. I collected all data and reviewed data collected at the end of weeks two and four to complete a preliminary review of participant response and determine evidence of saturation. Reminder emails were sent at the end of weeks two and four, and the study was closed after week five after saturation was determined.

Data Analysis Plan

The six questions were part of a web-based, open-ended survey study designed to explore the barriers to clinical research care delivery experienced by ophthalmic CRPs. These questions related directly to the main research question: "What barriers to ophthalmic clinical research care delivery are experienced by ophthalmic CRPs?"

It was assumed possible for each question to elicit a response applicable to each of the three sub-questions that aim to stratify the responses across structure, process, and outcome-related orientations. The following represents possible connections that were assumed prior to data analysis:

- Question 1 sought to elicit responses related to the barriers or burdens encountered by the participants in their role within ophthalmology clinical

research. These responses were intended to provide insights into structurally oriented (SQ1) or process-oriented (SQ2) barriers.

- Question 2 focused on the complexity of delivering ophthalmology clinical trials, including the complexity of clinical research protocols, the complex nature of the disease, or the interactions involved in managing the treatment and care pathway for ophthalmology patients participating in a research study. These responses were intended to provide insights into outcome-oriented barriers (SQ3).
- Question 3 sought to describe factors affecting the capacity of the participants to support and deliver ophthalmology clinical research. These responses were intended to provide insights into barriers that were structurally oriented (SQ1) or process oriented (SQ2).
- Question 4 asked participants to suggest their top three strategic priorities for the future delivery of ophthalmology clinical research. These responses were intended to provide insights into potential solutions to the barriers identified in the study.
- Question 5 sought to identify existing elements of ophthalmology clinical research practice that contribute to or demonstrate efficient study delivery and practice. These responses were intended to provide insights into aspects of clinical research care delivery that alleviate barriers.
- Finally, Question 6 asked participants to provide any additional elements that they feel should be considered in relation to reviewing the operational

delivery, challenges, and complexity of ophthalmology clinical research. These responses were intended to provide insights into barriers that are structurally oriented (SQ1), process-oriented (SQ2), or outcomes-oriented (SQ3) and potential solutions to these barriers.

In keeping with the overall goals of the research questions, data was collected and analyzed through theoretical coding based on an approach to qualitative data analysis for descriptive-interpretive qualitative research (Elliot & Timaluk, 2021). Data were carefully reviewed, delineated into meaning units, and then thematically sorted into the three categories of structure, process, and outcome as guided by Donabedian's quality-of-care framework. All data was copied directly into NVivo 14 software to preserve and ensure transcriptive integrity. NVivo 14 further provided access to methodical analysis and storage of analyzed data.

Issues of Trustworthiness

Validity refers to the essential quality of research to be considered accurate, trustworthy, and valid. Ravitch and Carl (2016) described four main components, or criteria, of validity: credibility, transferability, dependability, and confirmability.

In qualitative research, credibility is primarily concerned with ensuring that the findings of a study reflect the truth of the participant's responses (Ravitch & Carl, 2016). The credibility of a study is secured through thoughtful research design and the tools that will be discussed throughout this section, such as triangulation, thick description, and reflexivity (Ravitch & Carl, 2016).

Transferability attempts to explain how a study can be generalized to a broader context while preserving the research's contextual basis from the participants' perspective (Ravitch & Carl, 2016). Experiences from multiple CRPs in distinct roles were obtained, and all relevant positive and negative responses are analyzed and discussed. Through this approach, responses were not expected to be homogenous. Additionally, this study employs the concept of "thick description." Thick description is loosely defined as providing context for answers so that the reader may better understand the experiences presented and thus care about and understand the interpretations (Ravitch & Carl, 2016).

Dependability is achieved through research design by ensuring that the study is consistent and well-reasoned (Ravitch & Carl, 2016). A study may also employ strategies such as triangulation, which ensure that multiple sources of data are being presented and exploring varied perspectives (Ravitch & Carl, 2016). With the intent to draw in as many voices and CRPs as possible, this study satisfied this check.

Lastly, confirmability relates to the attempt at neutrality on the researcher's part to withdraw personal bias from the interpretation of the data (Ravitch & Carl, 2016). A chief tool in this regard is the concept of reflexivity. Reflexivity is the process by which a researcher self-analyzes, fully acknowledging bias where it may exist and being transparent about assumptions, motivations, or other aspects of personal identity that may factor into the research, and a purposeful attempt to mediate those issues (Ravitch & Carl, 2016). I missed the opportunity to witness nonverbal cues because I was not physically present during data collection. I relied on my familiarity with the topic and experiences to interpret participant responses. This required an in-depth evaluation of my own biases

and assumptions. Thus, the questions were based on an already established web-based survey instrument used in clinical research to avoid introducing personal bias into the questions themselves. The study responses were anonymized so that I had no way to know who has participated outside of my general knowledge of who will get an invitation to respond. My position as a fixture in clinical research operations could not be ignored, and continuous reflexivity was essential through data collection and analysis (Ravitch & Carl, 2016). I conducted this study while in a position of authority and thus aware that no matter how careful I was to provide a space for participants to share their experiences freely, there was still an opportunity for biased responses.

Similarly, my experience and position undoubtedly affected my assumptions and personal bias. My passion for this work and for exploring opportunities for improving the quality of clinical research care delivery is the reason for this study in the first place. For these precise reasons, I performed data collection and analysis as an observer only, limiting my ability to directly affect the data.

Ethical Procedures

This study used humans as research subjects, and therefore all ethical procedures and considerations were made in collaboration and agreement with Walden University's Institutional Review Board (IRB) and the IRB of the partner institution. The study was conducted under my role at the partner institution for non-research purposes, with research being a secondary purpose. The partner institution acted as the IRB of record for the data collection portion of this study and approved with an acknowledgement of exemption under exemption category 2. This approval was provided to Walden

University's IRB and the study (#10-09-23-1036503) was approved. A data use agreement was then put in place between the partner institution and Walden University for this study to perform the secondary data analysis described herein. All approvals were in place before any research activity began. All human subject-derived data were collected after an acknowledgement of informed consent and collected anonymously, ensuring the confidentiality and privacy of participants.

This study was conducted in my work environment where I directly supervise a small percentage of those invited to participate. Others within the department may also view me as an authority figure. Therefore, my direct involvement was minimal through the employment of a web-based, asynchronous, anonymized, open-ended survey study design. All potential participants were invited to the study via an email containing a link to the REDCap web-based study. The invitation link was necessary to maintain data integrity and ensure that only invited candidates may participate; however, no identifying information or signatures were requested, and all responses were anonymous. With sensitivity to my position, questions were structured to ensure that identities could not be ascertained, nor were the responses expected to be sensitive in nature.

Summary

In summary, this descriptive interpretive qualitative study aimed to explore the barriers to clinical research care delivery experienced by ophthalmic CRPs through a web-based, asynchronous, anonymized, and open-ended survey. This chapter outlined the research design and rationale, my role as a researcher, the chosen methodology,

trustworthiness issues, and ethical procedures. In Chapter 4, I will present the results of the data analysis.

Chapter 4: Results

Introduction

The purpose of this study was to explore the barriers to clinical research care delivery as experienced by ophthalmic CRPs. The primary RQ was:

RQ: What barriers to ophthalmic clinical research care delivery are experienced by ophthalmic CRPs?

This open-ended research question was further broken into SQs, using Donabedian's (1988) quality-of-care framework as an organizing tool for interpretation:

SQ1: What barriers to clinical research care delivery, if any, are structurally oriented?

SQ2: What barriers to clinical research care delivery, if any, are process-oriented?

SQ3: What barriers to clinical research care delivery, if any, are outcome oriented?

This chapter describes the research setting, participant demographics and data collection procedures, followed by a description of the data analysis process and emergent themes. Lastly, this chapter will review evidence of trustworthiness and the results of the data analysis as guided by the research question and Donabedian's (1988) quality-of-care framework.

Setting

The study was conducted using a web-based, asynchronous, anonymized, open-ended questionnaire distributed via email to CRPs within the ophthalmology department of an academic medical center. The data were collected as part of my role as

administrative director of clinical research in ophthalmology and shared with Walden University to undergo secondary data analysis. My dual role as researcher and director, and the disclosure of the data sharing arrangement may have influenced participation. Further, the data was collected between the dates of October 30, 2023, and December 1, 2023. It is possible that pre- and post- holiday time constraints may have negatively impacted participation.

Demographics

The target sample (n=12) was met with 18 CRPs completing the open-ended questionnaire. Of the 76 CRPs who received an invitation to participate, 43 CRPs completed the consent landing page, and 18 CRPs completed both the demographics and open-ended survey, constituting a 55.8% drop out rate. Only complete surveys were included in the final analysis. Partially completed responses consisting of one or more answered open-ended survey questions were considered complete. Summary demographics for completed surveys are shown in Table 1.

Table 1

Participant Demographics

Characteristic	*n*	%
Gender		
Male	5	27.8
Female	13	72.2
Age		
18-25	2	11.1
26-35	1	5.6
36-45	4	22.2
46-55	5	27.8
56+	6	33.3
Years in clinical research		
6 Months to 1 Year	1	5.6
1-2 Years	2	11.1
2-5 Years	3	16.7
5+ Years	12	66.7
Role		
Clinical research clinical support	1	5.6
Clinical research coordinator	7	38.9
Investigator (PI or Co/Sub-I)	6	33.3
Research administrative staff	3	16.7
Research assistant	1	5.6
Total participants	18	

Data Collection

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Michigan (Harris et al., 2009; Harris et al., 2019). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common

statistical packages; and 4) procedures for data integration and interoperability with external sources.

An invitation email with a link to the survey instrument was emailed to 76 ophthalmic CRPs as determined by internal clinical research listservs on October 30, 2023. A reminder email was sent on November 23, 2023, and a final reminder email was sent on November 27, 2023. The survey instrument was closed on December 8, 2023. All data were recorded directly into the REDCap database by the participant via the web-based, asynchronous, anonymized, open-ended survey instrument. The data were then reviewed for completeness, and entries meeting inclusion criteria were transferred directly to NVivo 14 for analysis.

Data Analysis

Descriptive-interpretive qualitative analysis was conducted. Elliot and Timaluk (2021) describe four data analysis modes comprised of 11 steps, all of which were reviewed for relevancy to the research questions and type of data and incorporated into this analysis. The main steps involved in this approach to qualitative analyses were as follows:

1. Pre-analysis: develop conceptual domains as an organizational tool for the data, collect data, prepare data through transcription, relevance, and delineation of meaning units (the smallest units conveying the essential meaning when out of their context)
2. Understanding and translating: summarize meaning units into briefer language and explicating implicit meaning.

3. Categorizing: construct categories using similarities in meaning units to accurately describe the data and create hierarchical structures, integrity checking the data through auditing, and exploring divergence from researcher expectations.
4. Integrating the findings: Depicting structure and providing a summary narrative of the data.

Donabedian's (1988) quality-of-care framework guided the development of the pre-analysis conceptual domain. Data were collected through a web-based, asynchronous, anonymized, open-ended questionnaire hosted by REDCap. The data was reviewed for completeness and eligibility and exported to NVivo 14 for further organization. Each provided statement was reviewed for relevance, summarized, and delineated into meaning units. Elliot and Timaluk (2021) described meaning units as the smallest units used in descriptive-interpretative qualitative research that can communicate the message and its relevance to the research topic. The meaning units were further reviewed for inclusion into one of the three categories (structure, process, outcomes) as defined by Donabedian's quality-of-care framework and its application to this study. A summary narrative and integration of the findings are described in the Results section.

Meaning Units and Categorization

Overall, the six open-ended survey questions generated 118 statements further categorized into 10 emergent meaning units. The meaning units were then categorized as defined by Donabedian's quality-of-care framework: structure, process, and outcomes.

A word frequency query was generated using NVivo 14 for each meaning unit to produce a word cloud of up to 50 of the most common terms to help direct the consolidation into meaning units. A word cloud presents qualitative data in a visual way, allowing the reader to visualize the frequency of words used through increasing and decreasing prominence within an image (Bletzer, 2015). The word clouds can be found in Appendix B.

The meaning units generated by the questions and categorized through Donabedian's (1988) quality-of-care framework are shown in Table 2. The responses are first summarized with major findings per question and then analyzed in further detail using Donabedian's quality-of-care framework.

Question 1: Barriers and Burdens

Question 1 had a 100% response rate and, overall, generated the most statements producing statements from each of 10 emergent meaning units. With the diversity of participants, the diversity of responses is not surprising. The most frequent concepts found in Question 1 included, "clinical," "sponsor," "staff," "coordinator," and "support," with additional concepts such as "experience," "time," "cost," and "burden" frequently appearing in the statements. The most referenced barriers tended to be structurally oriented (50% of statements), with 5/18 participant presenting challenges associated with the high cost of starting research and the limited financial resources or support for investigator-initiated studies. Additionally, 4/18 respondents referenced challenges related to staff turnover and staffing shortages leading to increased individual workloads and halting the progress of existing studies. One respondent, however, spoke positively

regarding departmental structure stating that "the environment for clinical research…is quite good in terms of [physical] infrastructure, financial support and research personnel."

Question 2: Complexity

Question 2 had a 72.2% response rate (13/18) with most respondents (9/13, 69.2%) referencing the specialized expertise required of CRPs in ophthalmic clinical research. Not surprisingly, the most common concept from Question 2 was "complexity" with similar concepts such as "testing," "determining," "needs," and "care," standing out. Individuals described an increase in diagnostic and specialized testing in ophthalmic clinical research, which CRPs must provide in addition to traditional data collection modalities, often requiring several individuals with different roles or skillsets to accomplish. One respondent stated, "You need highly trained technicians to perform the testing and it seems like it is increasingly harder to find techs of this caliber." Additional respondents discussed the complexity of ophthalmology as a specialty, describing efficiency loss when specific ophthalmological terms are not fully understood, either by CRPs or human subject volunteers. Two respondents shared that there is an increased complexity when working with volunteers with low vision, requiring advanced informed consent procedures and additional technical and professional skill.

Question 3: Capacity Factors

Question 3 likewise had a 72.2% (13/18) response rate and primarily produced process-oriented statements (13/21, 61.9%). The most common concepts in Question 3 were heavily favored toward "support," "clinical," "time," "recruitment," and "conduct."

The most common statements focused on competing priorities (either clinical or research related) and the lack of time. Two respondents referenced this phenomenon leading to burnout and reduced enrollment numbers for studies stating, “Lack of support leads to burnout faster so I am not as productive. Many complex tasks from PIs eat up a lot of my time so I am not always as successful in recruitment at those times,” and “The ability to support and deliver clinical research depends on study team member availability and the space…to do the necessary testing.” Comments regarding adequate staff and training were primarily focused on support staff, or lack thereof, to assist with tasks such as participant contact and data entry with one respondent commenting that they are asked to complete tasks “above” their role.

Question 4: Top Priorities

Question 4 had a 77.8% response rate (14/18) with varied responses. The most common concept for Question 4 featured “support,” “department,” “increase,” and “participants.” Responses were almost evenly distributed on the previously described meaning units regarding staffing prioritizing staffing support and increasing departmental financial support. Most respondents (5/18), however, prioritized communication and organizational structure. One respondent stating, “Having a strong team relationship is key for any department priority along with communication and transparency about what is going on.” Another respondent stated that, “More exchange among coordinators/researchers to build a community that can provide experience and feedback.” Additional respondents urged a prioritization of business strategies to increase

the total number of studies and expanding research recruitment to satellite and community clinics, where possible.

Question 5: Effective Practice

Question 5 asked respondents to provide their views on existing effective practices in ophthalmic clinical research that contribute to efficient study delivery. The most common concept included the terms "good," "team," "help," and "dedicated." The response rate for question 5 was 77.8% (14/18) with 57% commenting on the high-quality staff within the organization, reinforcing prior statements on the importance of adequate staffing.

> In our department we have staff that truly care. That may sound I, but caring about our patients, our coworkers, and taking ownership of our studies does set us apart from other centers and helps to ensure great retention of both participants and staff.

Three additional respondents had similar comments regarding the regulatory infrastructure (i.e. IRB) and the dedicated personnel responsible for regulatory oversight.

Question 6: Additional Considerations

Question 6 was a catch-all, allowing respondents to add any additional thoughts that may not have been covered by the previous questions. Only 27.8% of respondents (5/18) contributed additional thoughts. The most common concept was the term "need," with near even additional concepts including "testing," "direction," "faculty," and "people." Two respondents reinforced the need for practices that contribute to hiring quality CRPs and standardize training practices. One respondent commented on the need

to prioritize data quality and introducing quality assurance for studies that have protocols or other manuals. They stated, “Lately we have had several manuals where the testing instructions don't make sense. This has the potential to ruin a study when reviewed if the complex testing was not done properly.”

Table 2

Meaning Units and Categorization by Question

Meaning units and categories	Q1	Q2	Q3	Q4	Q5	Q6	Total statements
Respondents	18	13	13	14	14	5	
Structure							
Adequate staff and training	4		4	4	8	2	22
Prohibitive cost and limited resources	5		1	4		1	11
Organizational/departmental infrastructure	4			5	3	1	13
Complex regulatory environment	2				3		5
Process							
Communication and cooperation	4	1	2	5	3	1	16
Specialized expertise and complexity	2	9	4	2	1	2	20
Time constraints and competing priorities	3		7	1			11
Outcomes							
Recruitment and retention	2	3	3	3	1	1	13
External sponsor factors	2			3			5
Financial efficacy	2						2
Total statements	30	13	21	27	19	8	118

Evidence of Trustworthiness

In Chapter 3, issues of trustworthiness and research validity were discussed and addressed to ensure that the quality of this study can be considered accurate, trustworthy, and valid. Ravitch and Carl (2006) describe four components of validity: credibility, transferability, dependability, and confirmability.

Credibility is primarily concerned with ensuring that the findings of a study reflect the truth of the participants' responses (Ravitch & Carl, 2016). In this study, there is virtually no ability to limit the participant's responses. This study also employed additional strategies including triangulation, thick description, and reflexivity, that support credibility (Ravitch & Carl, 2016).

Transferability attempts to explain how a study can be generalized to a broader context while preserving the research's contextual basis from the participants' perspective (Ravitch & Carl, 2016). This study gathered the experiences from a diverse group of CRPs with all relevant responses presented, analyzed, and included for discussion. Where necessary, the use of "thick description" is applied to provide extra context for responses so that the reader may better understand the experiences presented and thus care about and understand the interpretations (Ravitch & Carl, 2016).

Dependability is achieved through strategies such as triangulation which ensure that multiple sources of data are being presented, exploring varied perspectives (Ravitch & Carl, 2016). This study sought the voices of many CRPs in varied roles, ensuring that multiple views were incorporated.

Lastly, confirmability relates to the attempt at neutrality on the researcher's part to withdraw personal bias from the interpretation of the data (Ravitch & Carl, 2016). This is accomplished in this study through reflexivity. Reflexivity is the process by which a researcher self-analyzes, fully acknowledging bias where it may exist and being transparent about assumptions, motivations, or other aspects of personal identity that may factor into the research, and a purposeful attempt to mediate those issues (Ravitch & Carl,

2016). For this reason, my involvement in this study was purely as a silent observer. My only interaction with participants was en masse e-mail providing a link to the RedCAP survey space. The survey questions were based on an established web-based survey instrument used previously in clinical research to avoid introducing personal bias into the questions themselves. The responses were anonymized, and no attempts could be made to ascertain the identities of the respondents.

Structure

Structure refers to the physical and organizational resources necessary to provide care, such as equipment and staffing, and are external to individuals (Donabedian, 1998). In this study this was defined also as resources outside the direct control of CRPs, such as institutional and departmental infrastructure, human resources activities (such as promotions, titles, or staffing), and other resources that would prevent clinical research care delivery from beginning. The four themes that emerged from the data were 1) Adequate staff and training, 2) Prohibitive cost and limited resources, 3) Organizational/departmental infrastructure, and 4) Complex regulatory environment

Process

Process refers to the activities during care delivery, such as diagnosis, treatment, and follow-up (Donabedian, 1998). In this study, process was defined as encompassing the tasks performed by CRPs in the provision of clinical research care, including the skills and knowledge required for the tasks associated with a human participant volunteer's protocol-determined research visit, interactions with other CRPs during clinical research care organization, and limiting factors within the CRPs workflow. The

themes that emerged as process-oriented were 1) Communication and cooperation, 2) Specialized expertise and complexity, 3) Time constraints and competing priorities.

Outcomes

In Donabedian's (1988) quality-of-care framework, outcomes are generally defined as the results of care delivery such as health status outcomes or satisfaction. While there are important end points in clinical research that are related to health outcomes and satisfaction, this study focused more on the operational provision of clinical research care. Therefore, outcomes in this context refer to the results of clinical research care delivery that impact a clinical research program's efficiency and effectiveness. The themes that emerged under this definition were 1) Recruitment and retention, 2) External sponsor factors, and 3) Financial efficacy.

Results

Donabedian's Quality-of-Care Framework

The research question for this study was what barriers to ophthalmic clinical research care delivery are experienced by ophthalmic CRPs? To answer this question, Donabedian's (1988) quality-of-care framework was used as a categorical framework, splitting the research question into three sub-questions addressing structure, process, and outcomes as they related to clinical research care delivery.

SQ1: What barriers to clinical research care delivery, if any, are structurally-oriented?

The structural barriers to clinical research care delivery encompass a wide range of challenges. Several meaning units stood out and resulted in 51 structurally-oriented categorized statements constituting 43.2% of all survey responses. The most significant

barriers include the necessity of a fully implemented workforce, organizational and departmental infrastructure, and limited resources for underfunded research programs.

The most structurally oriented statements (22/51, 43.1%) stressed the importance of access to high quality staffing support across the survey. One respondent elaborated that turnover has led to "increased workloads, delays [in] site activation…[which] impacts recruitment of subjects into new studies." Others also made note of workload imbalance, with one respondent suggesting that, "[We should] have a program in place to ensure that there are qualified staff to move up and replace others as they leave… these trainees could be utilized in many different ways that could benefit and overburdened staff." Maintaining study staff stood out as a top priority.

The impact of organizational structure on clinical research care delivery was also cited as a significant burden (13/51, 25.5%). The partner institution has a centralized administrative structure thus all research related start up tasks (such as budgeting, contracting, regulatory review, investigational drug review, invoices) are each governed by central departments that service the entire institution. Often, these tasks happen concurrently but any delay or stoppage in one section may result in a delay or stoppage in another department's review. Participants stated these multi-department reviews add to increasing study costs which limit the ability to take on new studies and contribute significantly to delayed startup times which limit the ability to participate in research studies. A respondent pointed to the unique needs of ophthalmology, stating, "Our department has increased needs that the larger institution needs to understand and give extra support and latitude for which will also improve patient care…"

Discussed less than anticipated but still comprising of 21.6% of structurally oriented statements, is the prohibitive cost or lack of resources to participate in clinical research. One respondent shared, "A huge barrier that I see…is the excessive cost of doing business here. Prices keep going up, and I see little if any benefit on our side." Most statements (6/11) regarding cost directly referenced a desire for institutional support to participate in research, with the remaining simply non-specifically stating that funding is a significant issue.

The complexity of the regulatory environment that governs clinical research delivery was referenced in 9.8% (5/51) of statements; however, most of those comments (3/5) suggested that these burdens are mitigated by the effectiveness of the administrative and regulatory support teams, stating that, "[Our dedicated IRB support/personnel] has definitely contributed to efficient study delivery and practice. Their guidance and expertise [are] instrumental in making sure any study runs smoothly and safely for patients and study teams." Another states, "The regulatory vigor we have is very important."

SQ2: What barriers to clinical research care delivery, if any, are process-oriented?

Process-oriented themes were categorized from 47 statements containing 39.8% of all survey responses. Three primary meaning units emerged from the data. Process-oriented barriers to clinical research care delivery were primarily focused on the specialized expertise required of ophthalmic CRPs, clear communication and cooperation between study team members, and managing competing priorities and time constraints that accompany multiple projects and clinical responsibilities.

Of the 47 process-oriented statements, 20 (42.6%) referred to the complex nature of ophthalmic clinical research and the specialized expertise required of ophthalmic CRPs to successfully delivery ophthalmic clinical research care. Ophthalmology utilizes a variety of non-provider staff who perform preliminary exams and diagnostic testing, maintain equipment, administer medications, and work alongside providers as medical professionals. In clinical research, these tasks are performed by non-provider CRPs who are also generally tasked with the additional responsibilities required for the safe and effective delivery of clinical research care. The specialized expertise required of ophthalmic CRPs is a unique perspective in the clinical research field. The complexity of ophthalmic clinical research extends from protocol design to scheduling activities, involving coordination of various testing, training, and certification requirements. One respondent expressed their concern with the difficulty of informed consent.

> The hardest part is determining that the patient fully understands what they are agreeing to. They may say that they understand but we have to make a determination on whether we think they understand. I never want to enroll ap participant that does not understand what they are agreeing to.

Another participant adds, in response to their analysis to the complexity of delivering ophthalmic clinical research, "Complex logistics [such as] end-point testing, intervention monitoring, scheduling of multiple [CRPs] with different skill sets." One CRP expressed some frustration with increasing protocol needs, stating, "The clinical trials continue to become more complex with each protocol. New equipment or testing is available and

sometimes sponsors want the data even though they don't know what to do with it." Another response reinforces the challenges associated with multiple tests.

> The complexity of ophthalmic clinical research many times begins with the protocol and schedule of activities. What testing needs to be done, and who needs to be assigned to those tasks, and what kind of training or certification is needed. This all adds up and ultimately leads to a high level of complexity when planning a study visit. If there are multiple study team members needed for various testing, then there needs to be an overlap in availability for the study visit to occur. Additional levels of complexity also occur when the testing/activity occurs offsite, such as the maze, radiology, surgery, etc. Managing all of these puzzle pieces can greatly vary in how long it takes to schedule a patient study visit, prep for that visit, and execute the study visit.

Another CRP references the complexity of the patient population.

> I believe that working with a population that has a large number of low-vision patients adds a layer of complexity that is unique to ophthalmology. For instance, the process of consenting can vary greatly depending on a patient's vision/whether or not they are able to read the consent form. This factor adds complexity to nearly all aspects of the clinical research process.

These responses provide some evidence that ophthalmic clinical research delivery faces additional challenges that are not common among the general CRP population.

Additional statements underscored the challenge of feeling disconnected among research staff, impeding resource location, knowledge transfer, and task efficiency. It

could be argued that these challenges are more structurally oriented than process-oriented; however, the respondents spoke less about a structural need and more about a sense of community and access to the community in the day-to-day provision of clinical research care.

> I believe that the lack of information/knowledge sharing across study groups (specifically by coordinators) at the departmental level is a barrier to effective study implementation because it unintentionally prevents study teams from being able to easily ask one another questions, troubleshoot logistical concerns, or share suggestions that would make clinical research efforts more effective and cohesive.

Another respondent echoes this sentiment.

> With providers primarily focused on clinical care, research is of interest to them, but is not necessarily a strength nor readily accessible to them as it may be in other clinical areas. They often lack experience in fully considering all aspects of a research study and rely heavily on support staff and hopes that their good intentions will override any blind spots. They are also rather isolated from working with other disciplines, and when they do work with other disciplines, it's typically bench scientists and engineers, where study activities that involve human interaction are atypical. Therefore, they have no other human subjects researcher colleagues to help mentor and advise them in designing or executing their studies.

These two respondents do not seem to be speaking to an institutional barrier prohibiting communication, but rather a personal or physical separation from other study teams. A

third respondent states, “Feeling disconnected from other research staff makes it hard to find resources for role and learn from more experienced staff.” These concerns about the need for more information sharing across study groups hinder effective study implementation.

Time constraints emerged as a significant process-oriented barrier, impacting effective research conduct. Time was cited as a barrier in 11 of 47 statements (23.4%). Most simply stated variations of, “I don’t have time,” while others referenced limited availability of academic time. Time constraints, compounded by clinic volume, posed challenges in allocating time for research activities. Efforts to improve time constraints are acknowledged, with a shared sentiment of having a substantial to-do list and a need for effective time management.

> With providers primarily focused on clinical care, research is of interest to them, but is not necessarily a strength nor readily accessible to them as it may be in other clinical areas. They often lack experience in fully considering all aspects of a research study and rely heavily on support staff…. They are also rather isolated from working with other disciplines, and when they do work with other disciplines, it's typically bench scientists and engineers, where study activities that involve human interaction are atypical.

SQ3: What barriers to clinical research care delivery, if any, are outcome-oriented?

Outcome-oriented barriers were the least referenced throughout the study resulting in 16.9% (20/118) statements. These statements resulted in three emergent meaning units: recruitment and retention, external sponsor factors, and financial efficacy.

Research participant recruitment, enrollment, and retention in clinical trials emerged as a critical focal point, comprising 65% (13/20) of generated statements within the category. Statements made from 8/18 participants suggested that enrollment is a barrier for many reasons, some resulting from process-oriented time management issues, outcomes-oriented financial benchmarks, or structure-oriented staffing shortages. Clinical research enrollment is featured as a prominent outcomes concern in the literature and is further confirmed in ophthalmic clinical research. Three respondents each shared a similar frustration with retaining participants, offering barriers related to participants cancelling or not showing up to scheduled appointments. Follow-up, and strategies to improve recruitment outreach, are offered as priorities. One respondent offers the following suggestion of top priorities.

> Recruitment. Working to find better ways to reach out to potential research participants. Satellite offices, someone to help preview and flag charts…find ways to make our research volunteers know how much they are valued. I know this can be tricky as you need to be very careful about incentives. We would be nothing without our volunteers. I know there are ways to accomplish this, paying close personal attention to someone goes a long way.

Another respondent suggests that there should be an "all patients are part of research orientation" to help improve enrollment outcomes, reinforcing its importance. Another respondent offers the following experience.

> The broad limitations in my experience are related to modest commitment from clinicians and connection between clinic visits to recruit subjects, and to the roles

> of study coordinators. That is, there has been only tacit support of subject recruitment from the section leadership so clinic resources (understandably limited these days but was also the case before Covid) are not involved in identifying candidates. Also, in my experience, [department-based clinical trial] coordinators are much more focused on general study conduct but have little insight into subject recruitment strategies owing to large administrative burdens from studies and lack of a presence when patients are in the building. Trying to consent people after they leave [their standard care clinic visits] is a very low yield approach. We signed up for an important industry sponsored trial but zero patients were recruited [resulting in]… a large financial loss.

This statement blends into a second outcomes-oriented barrier, financial efficacy, revealing challenges associated with clinical trial costs.

Financial efficacy had only two generated statements throughout the study, but each made unique points. One respondent stated, "We have turned down important clinical trials because our cost with [centralized institutional departments] have been prohibitive of moving forward unless the PI wants to use [their own department-based research] funds sometimes in excess of $60,000." This respondent is referring to projections offered during the budgeting phase of clinical trial development, where the internal costs of participating in research are projected to be higher than revenue received. The second statement confirms this thought when the respondent states, "The cost of doing research often exceeds budgeting constraints."

This financial strain intersects with structure- and process-oriented themes, but with a slightly different perspective. Structure-oriented barriers are related to internal support for independent research and prevent the development of new research. This outcomes-oriented barrier results in a decision to not participate in existing research, impacting the overall quality of care in the clinical research domain.

Lastly, five statements were generated regarding external research sponsor challenges. One participant reflects on these sponsor-based delays and their effect on clinical research outcomes.

> I think some of the burdens encountered can be dependent on sponsor involvement. If they provide regulatory start-up checklists, regulatory binders, case report forms, etc. then study activity can run much smoother. If they are not provided by the sponsor, it takes additional coordinator time to create these things that are necessary for smooth study implementation.

Other comments included mismatches in sponsor and site timelines, and sponsor's not having all required documents ready or finalized when reaching out to begin the study activation phases, "[creating] rework during startup and delays site activation." Another respondent raises concerns of "sponsor mission creep that bog down study teams with responsibilities that go beyond work on clinical trials." Examples were not provided but may be referring to requests for data or information that may be beyond what is prescribed in a study protocol. Each of these are presented as factors that reduce the ability for a clinical research program to operate efficiently, reducing its ability to provide clinical research care.

RQ. What barriers to ophthalmic clinical research care delivery are experienced by ophthalmic clinical research professionals?

The study identified significant structural barriers affecting clinical research care delivery. Key issues include challenges in workforce implementation, organizational infrastructure, and limited resources for underfunded programs. Staffing concerns emphasized the need for qualified personnel and the adverse effects of turnover on study activation and subject recruitment. The overall organizational structure, exampled by the centralized administrative departments, has a demonstrable effect on study teams. Despite obstacles, some respondents highlighted the crucial support provided by dedicated regulatory personnel for efficient study delivery.

Process-oriented barriers focused on specialized expertise in ophthalmic clinical research, clear communication, and cooperation among team members, and managing time constraints. Process-oriented statements emphasized the complexity of ophthalmic clinical research, stressing the unique expertise required for clinical and diagnostic testing. Secondary discussion highlighted disconnection among research staff, hindering resource location, knowledge transfer, and task efficiency. Time constraints impacted the effective conduct of research due to clinic volume and a substantial to-do list.

Outcome-oriented barriers identified three meaning units: recruitment and retention, external sponsor factors, and financial efficacy. Recruitment and retention were the most cited barriers and highlighted challenges in enrollment due to time management, financial benchmarks, and staffing shortages. Financial efficacy highlighted concerns about prohibitive institutional costs impacting trial participation decisions and exceeding

budget constraints. External sponsor challenges displayed the impact of sponsor involvement on delayed study implementation, contributing to reduced efficiency in clinical research programs.

Summary

This study has shown that ophthalmic CRPs and ophthalmic clinical research programs face many of the same challenges presented in the existing literature. Concepts such as lack of time, enrollment, cost, and limited resources in workforce development guided by increased protocol complexity were all supported by the findings of this study. Additionally, this study showcased the unique challenges in ophthalmology, providing insight into the dual role of CRPs as medical and research professionals. Ophthalmic clinical research care delivery is heavily impacted by proper staffing levels and the experience and technical skill of the CRPs in carrying out complex ophthalmic research diagnostic testing. Ophthalmic CRPs provide multiple examples of increased need within their specialty and the increase in their overall workload.

Chapter 5 will provide further interpretive detail of the findings, discuss the limitations of the study, provide recommendations for further research, and describe the implications of this study, including the potential impact for positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

This descriptive-interpretive qualitative study aimed to explore the barriers to ophthalmic clinical research care delivery as experienced by ophthalmic CRPs. A web-based, asynchronous, anonymized, open-ended survey study was conducted with ophthalmic CRPs to explore their experiences in delivering clinical research care in ophthalmology as viewed within Donabedian's (1988) quality-of-care framework, using a descriptive-interpretive qualitative approach.

Following data collection and analysis of 18 ophthalmic CRPs, the key findings reinforced existing literature, describing considerable barriers to ophthalmic clinical research care delivery among the three categories of Donabedian's quality-of-care framework: structure, process, and outcomes.

The most significant findings demonstrate workload imbalance issues due, in part, to difficulty maintaining a high-quality staffing environment exasperated by increasingly complex clinical research protocols. The unique role of specialized expertise necessary for ophthalmic CRPs in clinical research delivery further complicates these challenges. Chapter 5 will provide the interpretation of the findings, study limitations, recommendations for future research, and implications for positive social change.

Interpretation of the Findings

Ophthalmology is a medical specialty that employs a wide range of medical professionals with specific expertise in vision and eye care. Over 7 million Americans live with uncorrectable vision loss, with long-term projections showing up to 10 million

Americans will be affected by blindness or visual impairment by 2050, contributing to economic burden, reduction in the labor force, and increased stress on health care services (CDC, 2020; Flaxman et al., 2021).

Ophthalmic clinical research is delivered by a diverse group of ophthalmic professionals, including physicians, technicians, imaging specialists, and regulatory and administrative staff. This study has demonstrated that ophthalmic CRPs experience the same barriers and burdens in clinical research care delivery as CRPs in other major disease group programs. The literature identified several themes: recruitment and retention, cost, quality, workload management, burnout, and protocol complexity. These themes were mentioned by ophthalmic CRPs in this study and helped confirm that these barriers are not unique to a specific program but are embedded into the profession. Ophthalmic CRPs have an additional barrier to care delivery in the form of advanced technical expertise and training unique to ophthalmic clinical research.

Workload, Burnout, Complexity, and Assessment

The literature review in Chapter 2 described several critical studies detailing the struggles of increasing protocol complexity, the effect of complexity on workload, and the effect of workload on staff turnover and feelings of burnout. Workload can be linked to the increased complexity of clinical research, which includes increased procedures per visit, increased visits per participant, and difficulty in measuring CRP workload capacity (Brennan et al., 2019; Getz & Campo, 2017; Jones et al., 2020; Malik & Lu, 2019; Mascaro et al.,2021; Milani et al., 2017; Morin, 2019).

Participants in this study confirmed these challenges, with most of the response statements referring to challenges in maintaining adequate staff and appropriate training and the difficulties in maintaining high-quality, experienced, and specialized staff required to carry out complex ophthalmic clinical research protocols. Structurally oriented staffing issues, including staff turnover, were reported to increase individual workloads beyond capacity and affect process- and outcomes-oriented issues such as site activation and study recruitment. The process-oriented barriers, including the increasing complexity of ophthalmic clinical research, were also frequently reported by respondents, confirming challenges in the literature. Unique to this study, however, was the additional mention of the need for high-quality CRPs and those highly trained and proficient in ophthalmic testing. These traditionally clinical tasks are performed by CRP staff, adding a significant layer to a high workload. Additionally, many participants in ophthalmic clinical research have some degree of visual impairment, adding to the logistical complexity of informed consent and conducting multiple clinical research tests.

Enrollment

Enrollment was another significantly mentioned barrier in the literature. Current research suggested that participants per study has been decreasing despite an increase in registered sites per trial and increasing recruitment periods (Brøgger-Mikkelsen et al., 2022). Additional research supports that increasing protocol complexity, limited research assistance and institution resources, and protected time for investigators are significant contributors to low enrolling sites (Dickens et al., 2020; Feuer et al., 2022). Failures to meet study enrollment goals are also shown to have a disproportional effect on the

recruitment of women and minorities (Carcel & Reeves, 2021; Duma et al., 2018; Vaswani et al., 2020; Vuong et al., 2020).

While enrollment, recruitment, and retention were the most discussed outcomes-oriented barriers, this study did not uncover any data that supports an effect on women and minority recruitment into clinical research studies. However, the underlying causes of protected time, limited institutional resources, and increasing protocol complexity are revealed in detail. This study supports existing literature in revealing significant enrollment related barriers in common with other disciplines.

Cost and Quality

Cost was not offered as a barrier as frequently as the literature would lead one to expect. However, this study does confirm that costs and operational expenses are significant structure- and outcomes-oriented considerations. The literature describes cost-associated barriers in terms of pharmaceutical research and development and the costs of conducting a clinical trial as a multi-billion-dollar industry, costing as much as US$102 million per clinical trial (Moore et al., 2020; Rennane et al., 2022). Locally, participating sites have many costs to consider, generally stemming from the cost of labor (Chen et al., 2021; Moore et al., 2020). This study helps to confirm that limited resources, institutional infrastructure, and concerns of financial efficacy are occasionally prohibitive and indicate a desire for increased structural support for underfunded and investigator-initiated projects.

Donabedian's Quality-of-Care Framework

Donabedian's (1988) quality-of-care framework provided an interesting approach to exploring barriers related to ophthalmic clinical research care delivery. Donabedian's quality-of-care framework is designed to identify areas for improvement in care delivery through its useful way of categorizing and measuring aspects of health care quality. Applying Donabedian's framework to ophthalmic clinical research care delivery is not an obvious use-case; however, the results from this study do identify actionable barriers to clinical research care in a clear and organized manner. The categorization of meaning units into structure-, process-, and outcomes-oriented barriers provided the study with a clear narrative and allowed for a more nuanced understanding of the experiences offered by the survey respondents.

Limitations of the Study

There is a lack of comprehensive literature on clinical research care delivery, and less literature describing ophthalmic clinical research delivery. This study presents the first known exploration into the experiences of ophthalmic CRPs and is thus subject to many limitations. A significant limitation in this specific study was the dropout rate. Of the 76 invitees to the survey instrument, 43 consented to participate, but only 18 completed the questionnaire. There are two potential explanations: 1) the open-ended survey design was more of a time commitment than participants anticipated when first showing interest, and 2) due to the anonymized nature of the study, there is a possibility that individuals may have opened more than one link, consenting more than once, but

only completing one survey. Although possible, it is unlikely that a single participant completed multiple surveys and the responses showed no evidence that this was the case.

Anonymous responses added another layer of complexity in the form of source and quality control. Measures were put in place to ensure only those eligible to participate were allowed to do so; however, no system is entirely secure. Additionally, verifying any of the scenarios volunteered by respondents was impossible. The generalizability and transferability of the findings may be constrained due to the single-site nature of the project, a relatively low number of respondents, and a narrow focus on a specific population.

Lastly, an intentionally mitigated limitation of this study was my role within the clinical research program, which introduced the potential for bias. While unlikely, my position in the organization could have influenced responses. The research design was intended to minimize any potential appearance of coercion.

Recommendations

There is much potential for research in clinical research care delivery. The available literature on the subject is limited and difficult to find. Since ophthalmology is a minor discipline when compared with other clinical research programs, there is a noticeable gap in all research related to ophthalmic CRPs.

A significant challenge emergent in the literature and reinforced by this study is a need to quantify the complexity of a clinical research protocol to assign and balance workload management appropriately. Protocol complexity, testing frequency, and visits are significant restrictions to recruitment, enrollment, and retention in clinical research

studies. Staffing, training, and specialized expertise are limiting factors in clinical research care delivery. Future studies should focus on efforts to understand and address these issues across disciplines and particularly in ophthalmology.

Potential research studies that could be conducted are:

- A qualitative study using focus groups and structured interviews of ophthalmic CRPs.
- A quantitative study to measure and compare changes in ophthalmic protocol complexity over time.
- A mixed-methods study to determine the most significant factors in clinical research complexity to apply weights and ratings scales measuring protocol complexity and workload capacity.

Implications

The findings of this study have the potential to make significant advancements in the field of clinical research, especially for ophthalmology programs in academic medical centers. The study has identified several areas of need, and Donabedian's (1988) quality-of-care framework presents those areas in targetable categories. This study uncovered previously unidentified barriers to care delivery. The insights gleaned from this study can inform practice and policy changes, mitigate burnout, improve workload balance, and augment the capacity to deliver high-quality clinical research care.

The findings of this study could have significant implications for positive social change at the organizational and individual level. Addressing the challenges in ophthalmic clinical research care delivery improves operational efficiency and may help

move investigational treatments from research to clinic, ultimately enhancing patient outcomes (Brennan et al., 2019). The findings also support a need to address the well-being of CRPs, enhancing their quality of life, and supporting high-quality care. Lastly, this study demonstrates a need for more research in the clinical research operational field, potentially identifying solutions to these growing challenges.

Conclusion

In summary, this study highlights the challenges of ophthalmic CRPs in clinical research care delivery. The increasing prevalence of vision issues in the US, coupled with projected rises in blindness and visual impairment, demonstrate a sense of urgency in addressing barriers in ophthalmic clinical research care delivery.

Ophthalmic CRPs face challenges common in clinical research programs, emphasizing widespread concerns across the research industry, particularly concerning protocol complexity, staffing, workload management, cost, and enrollment. Ophthalmic CRPs face additional challenges, including the demand for advanced technical expertise, compounded by complexities inherent in a visually impaired patient population. Ultimately, this study provides a foundation for advancing clinical research care delivery in ophthalmology and contributing to broader healthcare research and practice.

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Appendix A: Email Invitation

Subject Line: Online Survey for Clinical Research Professionals in Ophthalmology

Dear Colleague,

This study is being conducted to explore the barriers to clinical research care delivery through the experiences of ophthalmic clinical research professionals. For this study, you are invited to describe your experiences regarding the structures, processes, and outcomes of clinical research care.

About the study:

- This is a web-based, asynchronous, anonymous, open-ended survey that should take 30-60 minutes to complete.
- No identifying information will be collected, and all responses will remain completely anonymous.

Volunteers must meet these requirements:

- 18 years of age or older
- Working as a clinical research professional in ophthalmology for the last 6 months

This survey is part of the doctoral study for James Green, a Ph.D. student at Walden University. The invitation will be active from DATE to DATE.

To participate, please click the link below that will lead you to the survey space.

Appendix B: Word Clouds by Question

Q1. Barriers and burdens

Q2. Complexity

Q3. Capacity factors

Q4. Top priorities

Q5. Effective practice

Q6. Additional considerations