Designing a Provider-facing Intervention for Patient-Reported Outcomes in Ophthalmology

by

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Dedication

In loving memory of my dear Grandma, *Kamala Devi Amma*

Dear *Ammumma*, with deep gratitude for the countless ways you have supported, influenced, and enriched my life, this dissertation is dedicated to you. Your memory lives on in my heart and inspires me to strive for greatness every day. I miss you deeply.

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Abstract

Visual impairments significantly impact individuals' quality of life, extending beyond visual acuity loss to various daily activities. Objective measures often fail to capture the comprehensive effects of eye conditions on patients' well-being. Patient-reported outcome (PRO) tools like the National Eye Institute's 9-item Visual Function Questionnaire (VFQ-9) assess the broader impacts of visual impairment on daily activities, mental health, and overall functional status, providing insights beyond traditional clinical measures. Despite the recognized value of PROs, challenges persist that prevent their routine use in clinical practice. At the organizational level, workflow integration is a primary challenge, while at the provider level, key challenges for PRO adoption are efficiency in their delivery to healthcare providers who have diverse needs and priorities. However, guidance for understanding user needs and designing prototypes for efficient delivery of PRO information in routine clinical practice is lacking in ophthalmology and many other contexts. This study employs User-Centered Design (UCD) methods to address the challenges associated with PRO reporting in routine ophthalmology practice. Through iterative prototyping and evaluation, this approach ensures that the designed PRO intervention meets the specific needs of the users. Aim 1 of the study characterizes variation in vision-related quality of life and changes related to patients' demographic factors to understand the potential impact of PRO information. Aim 2 identifies contextual factors, information needs, and preferences influencing providers' use of PROs in clinical practice. Aim 3 employs iterative prototyping and evaluation to design a PRO reporting tool for routine clinical practice and to formulate design

recommendations for such tools. Through collaborative design processes and iterative refinement, this research produces guidance for designing PRO reporting interventions to enhance patient-centered care in ophthalmology. By providing insights into contextual factors and provider needs, this study lays the groundwork for future advancements in provider-facing PRO reporting tools, with the ultimate goal of improving patient care and outcomes in ophthalmology.

Chapter 1 Introduction

"*It's obscene to let people go blind when they don't have to*." - Fred Hollows.

World Health Organization (WHO) estimates that the global magnitude of eye conditions and vision impairment is around 2.2 billion, of which about 1 billion are preventable or treatable.[1,2] It is estimated that around 90% of people with blindness are living in areas with limited access to healthcare services and treatment.[3] Steered by a demographic shift, especially population aging, the magnitude of vision impairment in the United States is expected to increase over the next few years[4,5] with a three-fold increase in the treatment cost estimated up to $376 billion.[6] Vision impairment may also create a substantial impact on one's physical,[2] social,[7] and emotional[7,8] well-being. Inequalities in prevention, treatment, rehabilitation services, poor infrastructure, shortage of trained workforce, and poor integration of eye care into health systems remain a significant challenge in addressing the eye care requirements.[1] A population health approach focused on patient-centered care processes can improve access to facilities, treatment, and rehabilitation services, thereby significantly reducing the magnitude of vision impairment.[9]

The Institute of Medicine defines patient-centered care as "care that is respectful of and responsive to individual patient preferences, needs, and values".[10] Patient-centered care prioritizes patients' preferences and it applies a biopsychosocial focus throughout the care process.[10] Patient-centered care can result in better patient-physician communication, improved care process, less anxiety among patients, reduced adverse outcomes,[11] shared ownership of the treatment plan,[12] better patient-provider relationships,[13] improved treatment outcomes, shared

decision-making,[14] and significant containment of healthcare costs.[15] Patient and family engagement are considered to be one of the key components in achieving quality and affordable patient-centered care.[14] Patient engagement can help in understanding the impact of treatment from the patient's perspective. However, meaningful engagement is considered to be challenging, mainly due to the difference in the level of health literacy among patients and their willingness to participate in the care process.[16,17] Care teams can overcome these challenges by using actionable data and implementing data-informed methods like shared decision-making interventions.[18] One such intervention that can facilitate shared decision making is patient-reported outcome measures (PROMs).

Patient-reported outcomes (PROs) are health outcomes self-reported by the patients regarding their health status or Health-related quality of life (HRQoL) or functional status associated with health care or treatment.[19] PROMs are standardized, validated tools used to capture PROs. These are self-reported questionnaires that patients complete without any external interpretation.[19] The physical status, disease status, functional status, psychological functioning, and social functioning of the patients can be captured by PROMs.[20] Using PROs along with other clinical interventions has shown to positively impact patient-provider communication and clinical decision-making.[21] A systematic review of controlled trials identified that integration of PRO in routine clinical care can facilitate frequent discussions on patient outcomes and emotional concerns of the patients about their conditions with the providers.[22] The 2015 U.S. federal financial incentive program[23] supports healthcare organizations to collect and assess PROs, which greatly increased the routine use of PROs.[24] Along with the widespread adoption of PROs in other specialties, ophthalmology has also witnessed a shift of focus from traditional

outcome metrics in clinical research and routine clinical care to treatment outcomes such as symptoms, overall quality-of-life (QoL), and vision quality of life.[25–27]

However, to effectively use the PRO data for clinical decision-making, it is vital to have a tool that can report these PRO data to providers at the right time in the right format. In modern healthcare, various digital interventions are used to report PROs in routine clinical practice. These tools can positively impact the use of PROs in routine clinical practice[28] and have various benefits including early identification of diseases, symptom monitoring, avoiding unwanted hospitalization, continuous tracking of quality-of-life,[29] and providing value-based care. Digital interventions with effective design workflow configuration can play a significant role by delivering actionable PROs to clinicians and improving patient-provider communication, care quality, and ensuring patient-centered care.[30] Due to the complex differences in the clinical problem of focus, administration (e.g., telephonic, self-administered, face-to-face interviews), and availability of resources (e.g., EHR, time, trained workforce), a PRO tool applied to one context might not be applicable in another.[31] A recent study on the barriers and facilitators of an electronic patient-reported outcome (ePRO) tool identified information overload, such as multiple graphical displays, as one of the significant barriers to its routine clinical use.[32] User-centered design (UCD) methods can help in identifying these kinds of barriers as it employs ethnographic methods[33] and design thinking approaches to create solutions.[34] UCD methods can aid in understanding information needs and visual display preferences of the users by iteratively developing, testing, and refining prototypes, which in turn can impact intervention effectiveness and stakeholder engagement.

The purpose of this research is, therefore, to understand the information content and delivery characteristics of a digital intervention for reporting PROs and provide design recommendations for such reporting tools to be used in routine clinical practice.

1.1 Patient-Reported Outcome Measures (PROMs)

PROMs are questionnaires used to measure the individual aspect of a medical condition, the outcome, and health status associated with that medical condition.[19] These questionnaires generally follow a scoring system consistent with the severity reported by the patients. Any significant changes in the collated score over time indicate a need for further analysis to determine the changes in the health status and health-related quality of life (HRQoL) of the patients.[35] The use of PRO data originated from clinical research to assess the impact of treatment and care from a patient's perspective. PRO data extracted from clinical trials are used to develop clinical guidelines, reimbursement-related decisions, and health policies.[28] Broadly, the uses of PROMs can be classified in three levels: (i) To improve physician-patient interaction (micro level), (ii) To compare and contrast the treatment effect across healthcare providers (meso level), and (iii) To inform policy-level decision making (macro level).[36]

With the growing emphasis on patient-centered care, healthcare providers have started to include patient-reported outcomes to incorporate patients' voices in routine clinical decision-making.[28] Incorporating PRO in routine care are said to have significant advantages for reimbursement related decision-making.[37] With the 2015 Medicare Access CHIP (Children's Health Insurance Program) Reauthorization Act (MACRA), and the shift from fee-for-service reimbursement to value-based payment models, health insurers have begun to explore how PROMs can fit within the value-based payment models.[38,39] Some of the key considerations while implementing routine PRO assessment are to determine (1) the goals for PRO collection,

(2) the context and target population, (3) the measures, (4) mode of PROMs administration, (5) mode of result reporting (6) aids for score interpretation (7) strategies for addressing feedback and issues related to PROMs, and (8) evaluation of the impact of the PRO intervention.[40] PROs for measuring performance and quality parameters in clinical practice are divided into five main categories such as (i) Health-related quality of life (HRQoL), (ii) Functional status, (iii) Symptoms and symptom burden, (iv) Health behaviors and (v) Patient experience. *Health-related quality of life (HRQoL)* measures physical, social, and emotional well-being associated with illness and its treatment. These could be generic or condition-specific measures. *Functional status* measures the patient's ability to perform activities of daily living such as physical function, cognitive function, and sexual functions. *Symptoms and symptom burden* captures symptoms such as fatigue and pain intensity, and symptom burden which is the sum of severity and impact of symptoms reported by patients. *Health behaviors* measure the actions that individuals take which affect their health and the behavior frequency. *Patient experience* measures the experience and satisfaction with overall healthcare service.[41]

1.2 The growing importance of PROs in delivering patient-centered care

From the earliest recorded history of health care,[42] the main focus of healthcare was noted to be centered around clinician needs and their overall limitations. This was known as the era of paternalism (the age of the physician). Later, around the 1940's, power started shifting slowly from providers to patients (known as autonomy, the age of the patients), and to bureaucracy around the 1970s (known as the age of payers).[42] Over the years the healthcare system has undergone a paradigm shift from being provider-centric to patient-centric.[43] However, in order to be a patient-centric health system, it is imperative to achieve and evaluate outcomes that matter most to the patients.[44] The role of PRO data in delivering patient-centered

care is crucial as it focuses on assessing health outcomes from the patient's perspective. PRO data are being used as a valuable tool for (i) screening common health problems, (ii) understanding and formulation of treatment goals that patients value (iii) revising treatment plans, and (iv) making lifestyle changes.[45] A systematic review identified that PRO implementation is mostly done at academic/tertiary care hospitals with adequate resources like systems and staff in place to deploy PRO tools.[46]

Incorporating PROMs in routine clinical care is vital in improving patient-provider communication, detecting and managing health conditions, and improving patient satisfaction. For example, integrating PRO data into routine clinical care can enable remote reviewing of patients six months post-surgery to determine their subsequent appointments based on their PROM score.[47] In orthopedics, PRO data have helped in reducing follow-up appointments by 70%.[48] However, for PROMs to be successful in clinical practice, measures must be reliable and valid. Some of the main resources available to assist in selecting valid PROMs are (i) The Australian Commission's lists of validated PROM,[36] (ii) The Standard Sets of the International Consortium for Health Outcomes Measurement (ICHOM),[49] (iii) The Patient-Reported Outcomes Measurement Information System (PROMIS) of the US Department of Health and Human Services,[50] and (iv) The Patient-Reported Indicators Survey initiative of the Organization for Economic Co-operation and Development (OECD).[51]

The development of electronic PRO (ePRO), i.e. a PRO that is collected electronically, and their integration within EHR[52] has increased their adoption and use in routine clinical care.[53] Another vital step the US government took, stressing the importance of patient-centeredness in healthcare, was creating the Patient-Centered Outcomes Research Institute (PCORI), authorized in the 2010 Patient Protection and Affordable Care Act.[54] The primary mission of PCORIs is to

integrate patient's voices in Patient-Centered Outcomes Research (PCOR), with PRO being a vital tool used for that purpose. The formation of PCORI was crucial in stressing the importance of stakeholders, including patients in comparative effectiveness research, that helps healthcare stakeholders to make informed decisions to improve healthcare at all levels.[55]

1.3 PROs in Ophthalmology

The use of PRO in ophthalmology started during the early 1950s. A 2001 study by Massof and Rubin noted that around 12 PROMs were developed and reported since 1980s.[56] However, a positive trend was witnessed over the years and more than 160 PROMs instruments are developed and used in ophthalmology currently.[28] Using PRO in routine clinical practice is highly relevant for patients with chronic health conditions like visual impairment, which profoundly impacts the patients' well-being and daily activities.[57] Recent years have shown significant progress in the development and use of PROMs in routine clinical care within ophthalmology.[58,59] PRO data are also used as a primary and secondary outcome in clinical research within ophthalmology.[28] In order to facilitate the collection of PROMs, various vision-related QoL measures have also been developed, including the Visual Function (VF)-14, Vision Core Module 1(VCM1), the National Eye Institute Visual Function Questionnaire (NEI-VFQ),[60] the Activities of Daily Vision Scale (ADVS), the Impact of Vision Impairment profile (IVI),[61] the Visual Symptoms and Quality of Life Questionnaire (VSQ),[62] and the EuroQoL.[63]

1.3.1 The use of PRO in routine clinical care in ophthalmology

In ophthalmology, PROs are used in various sub-specialties/services. PRO data are used in various ophthalmic conditions such as cataract[64] and glaucoma[65] as well as subspecialties including retina,[66] cornea,[67] and neuroophthalmology.[68] Within ophthalmology practice, PROs

are used in identifying the impact of particular diseases in the quality of life of patients,[68–70] treatment and management of various diseases,[66,71] and identifying the vision-related quality of life (VRQoL) associated with specific surgeries and treatments.[64,67,72] PRO data are collected/administered through various means like paper, electronic self-reported questionnaires, telephone,[73] face-face interviews etc. With the increased adoption of electronic health records, hospitals are migrating from paper-based to electronic platforms to collect PRO data.[32] PROMs administered via electronic platforms are comparable with measures administered on paper and can reduce costs.[74] However, it is imperative to have multiple modes of PRO administration, to allow the selection based on the choice of the users.[75] In terms of the implementation of PROMs to visually impaired people, PROM completion at home[76] prior to hospital appointments is more effective, and that caregiver or family member assistance with PRO completion does not introduce bias.[77]

Although the use of PRO data in routine clinical care is successfully implemented in many specialties, their use in routine ophthalmic practice is very limited.[57] A lack of robust vision-related PROMs is one of the significant barriers to the use of PROMs in routine clinical care, especially in pediatric ophthalmology practice.[70] Other key barriers include a lack of robust condition-specific PROs for common ophthalmic conditions like refractive error[69] and psychometric validity,[68,78] and failure to address the needs and preferences of stakeholders.[57] To overcome the psychometric limitations in some of the current ophthalmic PRO measures, "third generation - item banking" PROMs tools are being developed to address the quality-of-life parameters and yield parametrically distributed outcome measures. Item-banks are a set of questions that are statistically calibrated to measure different HRQoL dimensions. Item-banking is considered as more reliable and valid than traditional PROMs.[79] By using Computer Adaptive

Testing (CAT) methods to implement these item-banks, individually tailored PRO questions can be administered based on the response of the patient.[80] This has the potential to transform patient care by providing real-time information to providers for clinical decision making.[81] In spite of the plethora of benefits of integrating PRO in routine clinical care, the evidence is still lacking in ophthalmology around its successful integration and use in routine clinical practice.[28] Many studies have attempted to understand the stakeholder perceptions on the routine use of PRO in clinical care, the barriers and gaps in integrating PRO data into routine clinical practice.[82] However, only a few studies in ophthalmology attempted to understand the stakeholder perceptions, attitudes, and preferences for the routine use of PRO.[57]

1.4 Challenges in using PROs in routine clinical practice

Despite the potential benefits, such as improved communication, personalized treatment plans, and better patient outcomes, the implementation of PROs faces multifaceted challenges. These barriers span across patient, provider, and system levels, each presenting unique obstacles that can hinder the effective utilization of PRO data. Understanding these challenges is crucial for developing strategies to overcome them and for realizing the full potential of PROs in enhancing healthcare delivery. The following section delves into the specific challenges encountered at each level, as identified in empirical studies,[83] providing insights into the complexities of integrating PROs into daily medical practice.

1.4.1 Patient-level Barriers

At the patient level, several barriers impact the routine collection and use of PROs. One of the most common barriers is the time required for patients to complete PROMs. Given the frequent and time-consuming nature of various treatment appointments and procedures,

additional time required to fill out PROMs may be viewed negatively by patients, potentially leading to non-compliance or incomplete data.[84] Additionally, patient incapacity, such as physical or cognitive limitations, can hinder the completion of PROMs. Difficulties with using electronic devices to complete PROMs also present a significant barrier, particularly for older patients or those with limited technological literacy.[85] Furthermore, patients perceiving PROMs as irrelevant, often because they do not see a direct benefit to their care, also represents a significant challenge.[86,87]

1.4.2 Provider-level Barriers

Health professionals face their own set of challenges in integrating PROs into clinical practice. A primary barrier is the significant time required to educate patients about PROs,[87] administer PROMs, and follow up on the data collected.[88] Even when data is successfully collected, health professionals often lack the necessary knowledge or training to interpret and integrate these outcomes effectively into patient care.[89] This highlights the importance of training and continuous education in the use of PROs. Moreover, many clinicians are challenged by electronic PRO systems, which can be cumbersome and not seamlessly integrated into existing clinical workflows. These technical and knowledge-based barriers can diminish the perceived usefulness of PRO data, as health professionals may find the information redundant or irrelevant to immediate clinical decisions.[90] To address these challenges, experts recommend making PRO tools relevant and actionable, and emphasizes using a user-friendly interface with graphics, dashboards, threshold lines, and color codes to boost engagement and aid healthcare professionals in effectively interpreting and utilizing PRO data.[91,92]

1.4.3 System-level Barriers

At the system level, integrating PROs into routine clinical workflows presents substantial challenges. One major barrier is the lack of effective collection and integration of PRO collection and utilization within existing clinical practices and electronic health records (EHRs). Inadequate IT infrastructure often complicates the collection, storage, and retrieval of PRO data, leading to inefficiencies and missed opportunities for improving patient care.[93] Additionally, the inability to act on PRO data due to these integration issues can discourage ongoing use and reduce the potential benefits of this information.[94]

1.5 PRO Systems in Ophthalmology

Over the past decades, ophthalmology has shown increased adoption of information and digital technology tools. The past two decades, in particular, have shown a significant improvement in technology, transforming the diagnosis,[95] treatment, and management of various ophthalmic conditions, thereby improving care quality.[96] With around 2 billion people estimated to be over 60 years by 2050,[97] this can directly impact eye health, which calls for the need to leverage information technology for early detection and treatment of eye diseases[98] and to provide high-quality eye care overcoming geographical barriers.[99] Some areas of digital interventions used in ophthalmology are telemedicine[100] or teleophthalmology,[101] artificial intelligence[102] including deep learning, and machine learning.[103] In particular, these technologies play a vital role in diagnosing and monitoring ocular diseases like Diabetic Retinopathy,[104] early detection of Glaucoma,[105] and early identification of lesions to prevent Age-related Macular Degeneration (AMD),[106] and predict treatment requirement.[107]

Although there is limited evidence on PRO systems in ophthalmology, clinicians have noted the importance of PROs in routine clinical practice, as they provide crucial insights into

patients' subjective experiences and treatment outcomes.[57] PRO systems in ophthalmology have shown promise in improving the management of eye diseases. For instance, Nagino et al. (2023) demonstrated the equivalence of app-based and paper-based versions of the Ocular Surface Disease Index (OSDI) for assessing dry eye disease symptoms.[108] Providers also noted that an electronic patient record system would be optimal, facilitating clinicians' interpretation and minimizing time spent viewing data.[57] While there is increased evidence of using e-PROs in other specialties, it is crucial that the reporting tool matches the context and information needs of the users.[109]

1.6 Digital Interventions for reporting PROs in routine clinical practice

The development of digital computers and medical computing applications in the 1950s led to the introduction of information technology in healthcare.[82] Although the adoption of information technology is slower in healthcare than in other industries, various government policies and incentives have led to the widespread adoption of health IT tools like Electronic Health Records (EHR). The Health Information Technology for Economic and Clinical Health (HITECH) Act[110] of 2009 paved the way to the increased adoption of IT tools in healthcare by providing incentives for EHR[111] use. In the past decade, the healthcare industry has witnessed significant advances in digital interventions to deliver quality, affordable, and safe healthcare.[112] In order to mitigate the impact of the COVID-19 pandemic over other health services,[113] an increase in maturation and uptake of different digital platforms in healthcare was witnessed.[112]

Health information technology tools are complex electronic tools or platforms that provide information and support necessary to provide health services to patients.[114] Health information technology plays a key role in improving the quality of care delivery.[115] As stated by WHO, digital technologies for health use information and communication technologies to

address healthcare needs.[116] As defined by WHO, digital health interventions are "discrete functionality of digital technology that is applied to achieve health objectives".[117] Digital interventions play a significant role in various domains of healthcare like prevention, treatment, health promotion, self-management, health awareness, behavioral changes, self-management[118], and management of chronic conditions.[114,119] The term digital interventions is used broadly to include both the information systems and the interventions that they generate.[120] This research focuses on the latter, a reporting intervention to push the PRO information to the clinicians. In the case of PROMs, digital interventions can facilitate the involvement of patients in the care process, through completing the PROMs questionnaire and shared-decision making, thus delivering patient-centered care.[121]

Digital interventions for reporting patient-reported outcomes (PROs) have become increasingly significant in routine clinical practice, offering substantial improvements in patient care and clinical decision-making. These interventions utilize electronic systems to collect, store, and analyze patient-reported data, enabling real-time integration of this information into electronic health records (EHRs). The primary advantage of digital PRO reporting is the facilitation of continuous monitoring of patient health status, which enhances the ability of healthcare providers to make timely and informed decisions. Integrating PROs into clinical workflows can lead to improved patient outcomes, as healthcare providers can tailor treatments based on real-time patient feedback, ultimately enhancing patient satisfaction and engagement. For example, Chen et al. (2013) conducted a systematic review and found that the routine collection of PROs in oncologic settings led to significant improvements in patient management and outcomes, including better symptom control and enhanced quality of life.[122] Furthermore, digital PRO interventions support personalized medicine by capturing patient experiences and

outcomes that are not typically measured during routine clinical visits. This approach enables healthcare providers to address the specific needs and preferences of patients, fostering a more patient-centered care model. For instance, a randomized controlled trial demonstrated that electronic PROs in oncology practice not only improved symptom management but also enhanced patient survival rates.[123] The use of electronic PRO systems allows for the efficient capture and analysis of data, which can be readily accessed and utilized by healthcare providers to adjust treatment plans in a timely manner. Additionally, the integration of PRO data into EHRs helps in identifying trends and patterns in patient health over time, facilitating research and quality improvement initiatives within healthcare organizations. Jensen et al. highlighted that electronic PRO systems in cancer clinical care contributed to better communication between patients and providers, ensuring that patient-reported symptoms and concerns are systematically addressed.[53]

The Behavior Change Intervention Ontology (BCIO) is an important framework (Figure 1) that specifies the components of digital interventions, more specifically digital behavior change interventions. BCIO enables a systematic approach to defining and categorizing the components of the intervention, facilitating more consistent and effective intervention design, implementation, and assessment.

The key components of the BCIO include: (i) Intervention: The intervention comprises content and delivery aspects. Content refers to the specific elements included in the intervention. Delivery pertains to the methods and channels through which the intervention content is communicated to the target population. (ii) Mechanisms of Action: The mechanisms of action represent the processes through which the intervention exerts influence on behavior. (iii) Behavior: This refers to the specific target behavior the intervention aims to modify. (iv)

Context: This includes the target population and the setting in which the intervention is implemented. The population refers to any group of individuals for whom the intervention is designed. The setting encompasses the physical, social, and cultural environment where the intervention occurs. (v) Exposure: Exposure involves the reach and engagement of the intervention. Reach refers to the extent to which the intervention is delivered to the intended audience, and engagement pertains to the level of participation and interaction of the target population with the intervention.

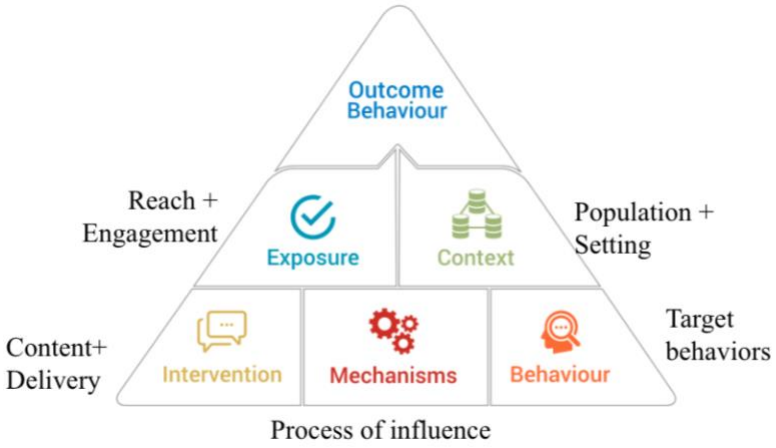


Figure 1: Behavior Change Intervention Ontology

By using BCIO, researchers and practitioners can identify and define various elements of intervention like the content, mechanisms of action, target behaviors, context, exposure and outcome behavior.[124]

1.7 User-Centered Design Methods

1.7.1 User-Centered Design (UCD) methods in healthcare

With the plethora of digital interventions in healthcare, the software development methodologies shifted from a traditional linear approach to an iterative process. This

methodology shift put users at the center of product design and development to improve quality, usability, and satisfaction with the product.[125] The term 'User-Centered Design' was first introduced and used by Donald Norman in 1986, providing a shift of focus from user testing to user involvement throughout the designing process.[126] A systematic review identified the evidence of UCD methods in healthcare dated back to 1992. However, there were only 4 studies reported until the year 2005.[127] Although the UCD approaches and principles were slower to be adopted in healthcare, a recent report from the US Agency for Healthcare Research and Quality (AHRQ) suggests user involvement as an effective way of optimizing the functionality, accessibility, and impact of any reporting intervention.[128] UCD methods are iterative processes that ensure users' perspectives are incorporated into the design process when developing products, services, or systems. UCD is a participatory approach that facilitates the co-design of an intervention by developers and users[129] in the following phases (Figure 2):

(i) Understanding the User: This phase focuses on users and the context of product use. Users are any persons who interact with or use the product for a purpose. Understanding the user also means understanding the needs, goals, strengths, limitations, context, and intuitive processes.

(ii) Develop/Refine Prototype: This is a multistage process that starts from creating a low-cost early prototype (with or without user involvement), further refined to the final prototype based on the users' information and visualization needs. For feedback reports, refinements can be done in terms of measures, data, and display.[130]

(iii) Usability Testing: ISO 9241-11 (1998) defines usability as the "extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use".[131] In this phase of UCD

methods, user observation is done through field trials to observe users' interactions with the prototype.[132] The concept of usability is not just about understanding the product's characteristics; instead, it focuses on the interaction between the user, their work, and the designed product.[133]

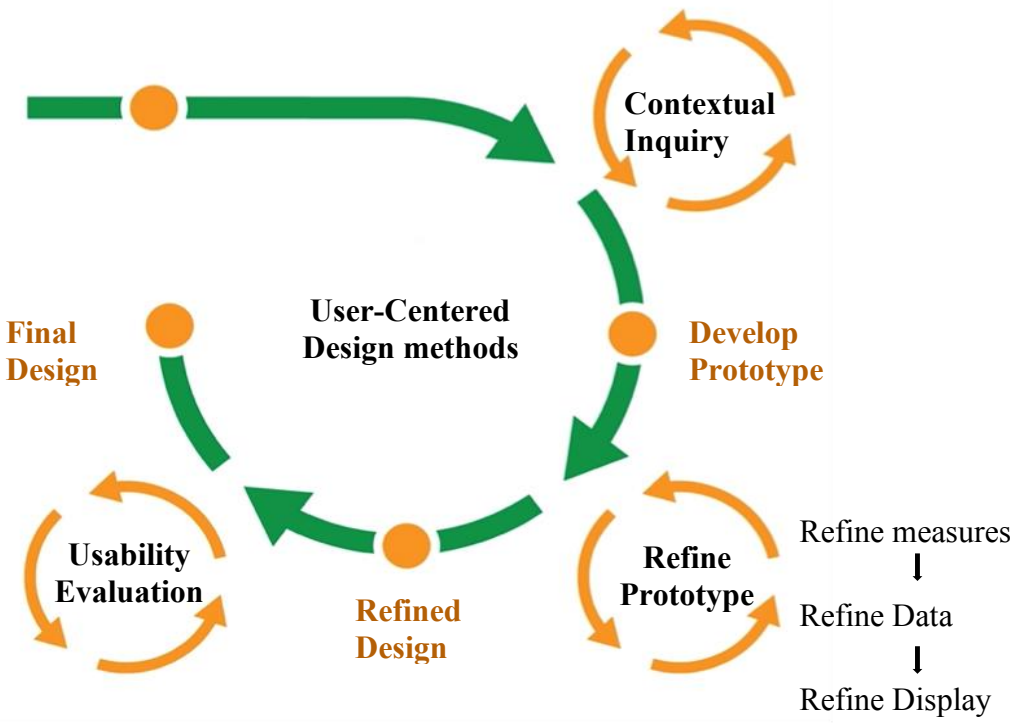


Figure 2: User-centered design framework

UCD methods are being widely used in the development of various interventions in healthcare. The ISO standard on ergonomics of human-system interaction outlines six principles for successful UCD methods: (i)Focus on an explicit understanding of users, tasks, and environments (ii) Involvement of users throughout the design and development of the product (iii) User-centered evaluation for the refinement of design (iv) Iterative process (v) User experience is addressed (vi) Focus on multidisciplinary skills and perspectives.[134]

1.8 Applying UCD methods for PRO data use in routine practice

Further highlighting the significance of methodology in the context of PROs, UCD methods are used in developing digital interventions for patients to report PRO.[135] Incorporating UCD practices in designing PRO reporting tools can aid in understanding display contents and graphical preferences of the users, which in turn can impact intervention effectiveness and better stakeholder engagement.[136] Incorporating UCD methods have shown to be helpful to understand how it influences the provider experience with the intervention.[137] A 2018 AMIA workshop highlighted the importance of incorporating UCD methods to understand the information needs at the clinician and system level for its PRO integration in routine practice.[138] In the UCD process, the qualitative methods can also aid in identifying the contextual barriers and facilitators towards the adoption of the intervention, thereby enabling the design of an intervention that fits the needs of diverse user groups.[139] Prior studies have mentioned the impact of integrating PRO in electronic medical records[140] by using UCD methodologies to understand the clinician's perspectives and concerns with integrating PRO in EHR[141].

Some of the critical concerns/barriers identified by stakeholders in integrating PRO data in clinical practice are: (i) lack of integration with the provider workflow,[139] (ii) information overload (iii) poor data visualization[142] (iv) Difficulty in interpreting PRO data and taking action, and (v) prolonged consultation time.[83] UCD methodologies are significant in this context, as these methodologies employ qualitative methods to enable understanding of the needs specific to each stakeholder type. Also, iterative cycles can help refine the prototype until the user needs and preferences are satisfied. The role of user-centered design methodologies to develop digital interventions has been well advocated in the literature.[24,143,144] However, we only found limited evidence that discussed the role of UCD methods in ophthalmology in the context of PRO.[145]

Although there is growing evidence of UCD methods for designing PRO tools in other specialties, our literature search did not yield any studies that mentioned UCD methods in designing a PRO reporting tool in ophthalmology.

Chapter 2 Research Study Design and Methodology

2.1 Research Aim:

The aim of this research is to understand the content and delivery characteristics of a provider-facing digital intervention for reporting PROs and develop design recommendations for such interventions to support decision-making and provide patient-centered care.

2.2 Research Questions:

We achieved the aim through the investigation of the following research questions:

Research Question 1: How does vision-related quality of life vary based on demographic factors such as age, gender, race, socioeconomic status, and ethnicity in a diverse patient population?

Research Question 2: What are the contextual factors, information needs, and preferences that influence the providers' use of PRO in clinical practice?

Research Question 3: What are the information content and delivery characteristics of an electronic health record (EHR) integrated patient-reported outcomes (PRO) report to be effectively utilized in routine clinical practice?

2.3 Research Design

We employed a mixed methods design (Figure 3) that involves a combination of quantitative and qualitative research methods to better understand the research problem.[146] The rationale behind using mixed-methods design is that, as this research will use UCD methods, a

combination of quantitative and qualitative methods and tools are needed to deeply understand the context-dependent needs and preferences of the providers. Qualitative analysis, in the context of a healthcare setting, is "the theoretical study and its corresponding use in investigation of a set of scientific methods, techniques and procedures, adequate to both describe and interpret the senses and the meanings given to the phenomena and also related to individuals' life (patients or any other participating person in the healthcare setting, such as family members, health professionals and community people)".[147] Qualitative study focuses on the participants' attitudes, experiences and behavior by asking open-ended questions such as 'how' and 'why', and thus provides a deeper insight into the problem.[148] Qualitative methods follow techniques such as participant observation, interviews, focus groups. This helps in exploring and understanding the participant's setting, their knowledge, behavior, opinions, preferences.[149] Quantitative methods employ systematic investigation of phenomena by collecting and analyzing numerical data to describe, predict or control variables of interest.[150] Quantitative research focuses on determining the relationship between an independent and a dependent(outcome) variable. Qualitative and quantitative methods can be used in ways that are complementary to each other in developing new knowledge to solve research questions.[151]

As this research is multifaceted that involves quantitative data analysis, prototyping, and user evaluation, a mixed methods design was identified as the most ideal for this study. As defined by Johnson et.al mixed methods research is "the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration".[152] For the purpose of this study, a three-phase mixed methods design was used. This design

involved three distinct and consecutive phases: (i) Collection and analysis of quantitative data (Research Question 1), (ii) Collection and analysis of qualitative data (Research Question 2); and (iii) Collection and analysis of qualitative data (Research Question 3). The combination of quantitative and qualitative research methods helped in providing a detailed insight into each step of the UCD process. In Phase 1(RQ:1), we conducted descriptive analysis to understand variations in VFQ-9 composite and domain scores based on demographic factors. In Phase 2 (RQ: 2) we conducted contextual inquiry to understand the VFQ-9 workflow and understand the information needs of the users. In Phase 3 (RQ: 3) we conducted iterative prototyping and evaluation to design the EHR-integrated digital intervention for reporting VFQ-9.

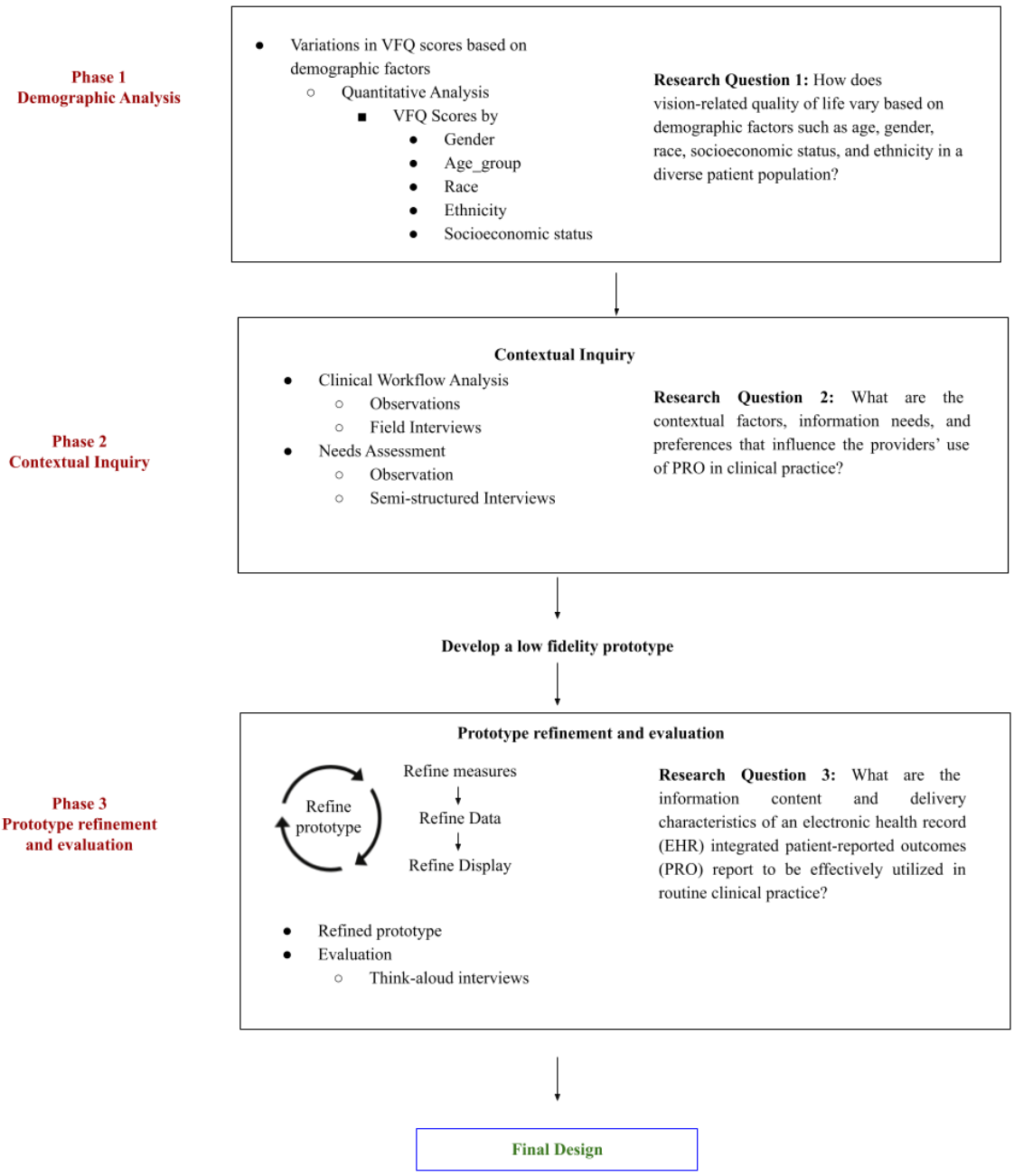


Figure 3: Research Design

2.4 Setting and Population

This research study took place at the University of Michigan W.K. Kellogg Eye Center. The Kellogg Eye Center (KEC) is a center for eye care and research located in Ann Arbor. The

center has over 100 clinical and research faculty and more than 500 employees in 10 different locations surrounding Ann Arbor. The center conducts more than 100,000 patient visits each year and features a comprehensive ophthalmology and cataract surgery clinic and eight subspecialty clinics. KEC also provides genetic counseling, ocular prosthetics, and ophthalmic photography for patients. Kellogg is an important referral center for the Midwest and beyond and conducts various clinical and research programs with the support from federal agencies and other foundations. The population in this study includes patients, staff and ophthalmologists at the Kellogg Eye Center.

The VFQ-9 is administered annually to all ophthalmology patients over 18 years at the KEC. This self-administered questionnaire captures essential aspects of visual function, including various domains such as general vision, mental health, and the ability to perform activities requiring near and distance vision. Patients can complete the VFQ-9 electronically through the patient portal before their appointment or in the clinic using a tablet or paper version. The VFQ-9 uses a variety of answer scales tailored to each question, generally ranging from six-level scales (e.g., "no difficulty at all" to "stopped doing because of your eyesight") to five-level scales (e.g., "none of the time" to "all of the time"). Each item is scored to reflect the level of difficulty or frequency of issues reported by the patients, with higher scores typically indicating better visual function and quality of life. The scores for individual items are converted to a 0-100 scale, where 0 represents the worst possible response and 100 represents the best possible response. To calculate the composite score, the scores of the individual items are averaged[153]. This composite score provides an overall measure of the patient's visual function and its impact on their quality of life. These scores provide valuable insights into how visual impairment affects

daily activities, emotional well-being, and social interactions, enabling clinicians to make informed decisions about patient care and monitor changes in visual function over time.

2.5 Methods

Through research question 1, we aimed to understand variation in VFQ-9 scores and related demographic factors. We stratified VFQ scores by various demographic factors such as gender, age group, race, ethnicity and Distressed Community Index (DCI) to understand how the VFQ scores changed differed on these demographic factors. The Distressed Community Index (DCI), developed by the Economic Innovation Group (EIG), measures the economic well-being and health of communities in the U.S. using indicators like poverty rates, median income, employment rates, and education levels. The DCI assigns scores from zero to 100, with higher scores indicating more distress. This tool aids policymakers, researchers, and community leaders in identifying areas with significant economic and social challenges, facilitating targeted interventions and resource allocation for economic recovery and improved quality of life.[154] At KEC, the DCI scores are calculated and prepopulated in the EHR for all patients. We also looked at the domain scores of VFQ-9 to understand how these domain level changes differed based on the demographic factors. In research question 2, we aimed to understand the contextual factors, information needs, and preferences that influence the providers' use of PROs in clinical practice. To better understand the context, we conducted clinical workflow analysis using observations, field interviews and semi-structured interviews with various stakeholders including front-office staff, technicians and clinicians. Qualitative semi-structured interviews conducted with clinicians were focused to understand their information needs and preferences for the provider facing PRO reporting tool. Based on the findings, we created an initial prototype for reporting VFQ-9 data to clinicians. In RQ 3, we conducted prototype evaluation which involved think-aloud semi-

structured interviews with providers. Iterative rounds of evaluations were conducted to refine the prototypes and create a final design and design recommendations based on the user requirements.

Through these phases, we engaged the clinicians in iterative user-centered design activities which informed the design of a provider-facing EHR-integrated reporting tool that displays the VFQ-9 scores of their patients.

Chapter 3 Understanding Variations in Vision-Related Quality of Life based on Demographic Factors: A Descriptive Study

3.1 Introduction:

Vision impairment encompasses a spectrum of visual deficits that can significantly impact individuals' daily lives and overall well-being.[2] From mild visual disturbances to severe blindness, vision impairment can affect various aspects of functioning, including mobility, communication, and independence. Vision impairment can thus substantially impact one's physical,[2] social,[7] and emotional[7,8] well-being and affects the quality of life.[155] In the realm of eye health, Vision-related Quality of Life (VRQoL) is a critical indicator of how visual impairments affect the everyday life of individuals.[156] Progressive conditions like diabetic retinopathy and age-related macular degeneration (AMD) have shown detrimental effects on VRQoL including emotional well-being, social interaction, and independence.[157]
By involving patients in the decision-making process, care teams can gain insights into the treatment's impact from the patient's perspective, thereby tailoring interventions more effectively to improve their quality of life.[158] Patient-reported outcome measures (PROMs) are vital tools in this context, helping to facilitate shared decision-making and ensuring that patient voices are incorporated into care planning and delivery.[35]

The National Eye Institute's nine-item Visual Function Questionnaire (VFQ-9) evaluates VRQoL by gauging individuals' perceptions of their visual function and its effects on their daily activities, emotional well-being, and independence.[159] The VFQ-9 (Appendix 1) comprises nine questions focused on specific domains of visual function. These questions assess various aspects

of vision-related quality of life, including general vision, mental health, near vision, distance vision, peripheral vision, and driving. Each question is designed to capture individuals' perceptions of their visual abilities and their impact on daily activities and emotional well-being. By addressing these domains comprehensively, the VFQ-9 provides valuable insights into the multifaceted nature of vision-related quality of life, enabling healthcare providers to tailor interventions and support strategies to meet the unique needs of individuals with vision impairment. By analyzing VFQ-9 scores and their domain scores, healthcare providers can gain valuable insights into the precise domains of visual functioning that drive alterations in quality of life of the patients. This understanding is instrumental in guiding interventions to enhance functional outcomes and overall patient well-being.

Understanding how VRQoL varies with demographic factors like age, sex, race, ethnicity, and socio-economic status is also crucial for tailoring interventions and improving patient outcomes. Research has shown that demographic variables such as age and gender can be used to predict individuals' quality of life with eye-related diseases. For example, a study on patients with macular edema undergoing intravitreal anti-vascular endothelial growth factor (VEGF) treatment revealed that demographic and clinical characteristics were predictive of vision-related quality of life.[160] Demographic factors play a pivotal role in shaping individuals' quality of life, influencing various dimensions of well-being across different population groups. Age, for instance, is a key demographic determinant, with older adults often facing unique challenges related to physical health, social support, and financial security.[161] As individuals age, they may experience declines in physical functioning and cognitive abilities, which can impact their overall quality of life. Gender also influences quality of life, as societal norms and expectations may shape individuals' experiences and opportunities differently based on gender

identity. Moreover, racial and ethnic disparities can significantly impact quality of life, with minority populations often facing barriers to healthcare access, economic opportunities, and social inclusion. Additionally, socioeconomic status, educational attainment, and geographical location are important demographic factors that influence quality of life, as they can affect access to resources, healthcare services, and social support networks. In a recent study investigating the impact of socioeconomic status (SES) on VRQoL in patients with primary open-angle glaucoma (POAG), researchers observed a significant influence of SES on VRQoL, highlighting the importance of understanding socioeconomic factors in shaping individuals' perceptions of vision-related quality of life.[162]

Building on this, our study delves into understanding how VRQoL differs based on the demographic variables and VRQoL, exploring how age, sex, race, ethnicity, and socio-economic conditions (as measured by the Distressed Community Index) affect the VFQ-9 scores. A first step towards understanding the utility of the PRO data for use by clinicians is to understand the distribution of the data and their variation across demographic categories to recognize the implications of using these PRO data to improve patient-centered care, both in terms of opportunities to intervene with a digital intervention, and to do so equitably. Addressing gaps in current research, this study aims to examine the variations in VRQoL based on key demographic variables. This research seeks to understand how the VRQoL changes based on the demographic factors and add to the knowledge base clinicians can draw upon to better understand potential VRQoL differences based on those demographic factors. By elucidating how VRQoL differ by demographic factors, this study aims to provide clinicians with additional insights that could influence future clinical practices. The findings may enhance clinicians' ability to consider demographic factors more comprehensively in their practice, potentially leading to improved

patient outcomes and satisfaction. This study also examines if there are significant differences in the VFQ-9 scores across demographic factors and across each domain. This study will inform the design of an EHR integrated provider-facing intervention to report VFQ-9 scores.

3.1.1 Objectives:

To understand the variation in vision-related quality of life, as measured by composite VFQ scores, and their domain-level score differences across demographic factors.

3.2 Methods:

3.2.1 Study Design and Data Source

We retrospectively analyzed a longitudinal dataset from a major university hospital's eye center in the midwestern United States. The dataset includes comprehensive patient records from September 2017 to September 2023, specifically focusing on individuals who completed the vision-related quality-of-life assessment using the Visual Function Questionnaire-9 (VFQ-9).

3.2.2 Population and Sampling:

Adult patients who visited the eye center between September 2017 and September 2023 were selected for inclusion in this study. Inclusion criteria required patients to have complete records, including VFQ-9 scores and detailed demographic information such as age, sex, race, ethnicity, and socio-economic status, quantified using the Distressed Community Index. Initially, our dataset comprised 135,655 patient records, accounting for multiple encounters for some individuals. To ensure the reliability and integrity of our analysis, we included only the first VFQ score for each patient and excluded records with missing or incomplete data. Additionally, pediatric patients were excluded from the analysis as VFQ-9 data were not collected for this

population. Following this refinement process, our final analytical sample consisted of 69,615 unique patient encounters. This approach enabled us to utilize a comprehensive dataset that adequately represents the diverse population visiting the eye center, ensuring that our findings are based on robust and complete data.

3.2.3 Data Collection:

The data were extracted from the hospital's EHR system, encompassing detailed demographic information such as age, gender, race, ethnicity, Distressed Community Index (DCI), and VFQ-9 scores. VFQ-9 composite scores, ranging from 0 to 100, were utilized as the primary outcome measure. To maintain data security, all information was accessed from a virtual sandbox environment, ensuring compliance with privacy regulations and safeguarding patient confidentiality.

3.2.3.1 Dependent Variable:

The primary dependent variable in our study was the VFQ-9 composite and domain scores. This score represents the overall vision-related quality of life as assessed by the VFQ-9, which evaluates various functional impairments and their impacts on an individual's daily activities and emotional well-being. The VFQ-9 composite score is calculated by averaging the scores of all the subscales/domains included in the questionnaire, providing a comprehensive measure of the patient's visual function and its effect on their quality of life.

3.2.3.2 Independent Variables:

Our analysis focused on age, gender, race, ethnicity, and the Distressed Community Index (DCI) as the independent variables. We categorized age into specific groups (e.g., 18-35, 36-55, 56-75, and over 75) to capture the potential variances in vision-related quality of life

across different life stages. Race and ethnicity were classified according to standard national classifications. Additionally, we stratified the Distressed Community Index, a measure of economic and social hardship, into quartiles.

3.2.3.3 Statistical Analysis:

We calculated descriptive statistics for all demographic variables. For categorical independent variables including age groups, gender, race, ethnicity, and socioeconomic status quantified by the DCI quartiles, we calculated frequencies and percentages. This helped in understanding the distribution of these demographic factors within our study population. We used the Mann-Whitney U test for non-parametric testing of independent variables with two groups and the Kruskal-Wallis test for variables with more than two groups to determine if the differences observed among the groups were statistically significant.

3.2.4 Ethical Consideration:

This study was approved as exempt by the Institutional Review Board at the University of Michigan (HUM00201862)

3.3 Results:

3.3.1 Descriptive analysis: Patient Demographics and Characteristics:

Table 1 presents the distribution of demographic characteristics among the participants in this study. We analyzed a sample of 69,615 unique participant encounters, and the demographic breakdown showed a predominance of females, constituting 59.3% of the sample, compared to 40.7% who were male. The age distribution reveals that the largest group was those aged 56-75 years, representing nearly half of the population at 49.6%, followed by the 36-55 years age group at 23.7%. The youngest cohort, 18-35 years, comprised 11.9%, while the oldest, those above 75,

accounted for 14.7%. The racial composition was majority White at 81.1%, with Black or African American at 9.3%, Asian at 6.5%, and smaller percentages for American Indian or Alaska Native (0.3%), Native Hawaiian or Other Pacific Islander (0.1%), and other races (2.7%). The ethnicity of the participants was predominantly non-Hispanic or Latino, making up 97.2% of the sample. Socioeconomic status, gauged by the Distressed Community Index (DCI), showed that 55% of the sample resided in the least distressed communities (Quartile 1), with descending representation through more distressed quartiles: 25.3% in Quartile 2, 9.9% in Quartile 3, and 9.7% in Quartile 4. In our analysis, all demographic factors were treated as categorical variable, whereas the VFQ composite score was treated as a continuous variable.

Demographic Factor	**Count (%) N=69,615**
Gender	
Female	41,251 (59.3%)
Male	28,364 (40.7%)
Age group	
18-35	8,305 (11.9%)
36-55	16,496 (23.7%)
56-75	34,551 (49.6%)
Above 75	10,263 (14.7%)
Race	
White	56,436 (81.1%)
Black or African American	6,502 (9.3%)
Asian	4,499 (6.5%)
American_Indian or Alaska Native	242 (0.3%)
Native Hawaiian or Other Pacific Islander	54 (0.1%)
Other	1,882 (2.7%)
Ethnicity	
Hispanic/Latino	1,950 (2.8%)
Not Hispanic/Latino	67,665 (97.2%)
Distressed Community Index (DCI)	
Quartile 1 (Low distressed community)	38,298 (55%)
Quartile 2	17,627 (25.3%)
Quartile 3	6,915 (9.9%)
Quartile 4 (Highly distressed community)	6,775 (9.7%)

Table 1: Descriptive Statistics of Demographic Factors

3.3.2 VFQ Scores by Demographic factors:

We observed significant differences in vision-related quality of life as assessed by VFQ-9 scores when examining demographic factors. Table 2 shows the VFQ-9 mean scores of the population by gender, age group, race, ethnicity, and DCI quartiles.

N=69615	**Mean**	**Median**	**SD**	**IQR**	**pvalue**
Gender					p<0.05
Female	80.8	86.7	17.5	18.9	
Male	81.8	86.7	17.1	18.3	
Age Group					p<0.05
18-35	86.4	92.2	15.6	15.5	
36-55	82.2	86.7	16.7	18.3	
56-75	81.0	86.7	16.5	18.3	
above75	76.3	81.7	20.7	24.5	
Race					p<0.05
White	81.5	86.7	17.0	17.2	
Black or African American	76.7	83.9	20.3	24.5	
Asian	85.0	89.4	14.1	15.6	
American Indian or Alaska Native	74.7	81.1	20.5	29.0	
Native Hawaiian or Other Pacific Islander	79.5	84.4	19.0	24.4	
Other	79.7	84.4	18.0	19.4	
Ethnicity					p=0.09
Hispanic/Latino	80.3	86.7	18.1	19.4	
Non-Hispanic	81.2	86.7	17.3	17.8	
DCI Quartile					p<0.05
Q1	83.3	87.2	15.4	16.7	
Q2	81.1	86.7	17.2	18.9	
Q3	75.7	81.7	20.3	26.4	
Q4	75.0	81.7	21.3	27.2	

Table 2: VFQ scores by demographic factors

We observed significant differences in the mean VFQ score within each demographic group (Figure 4).

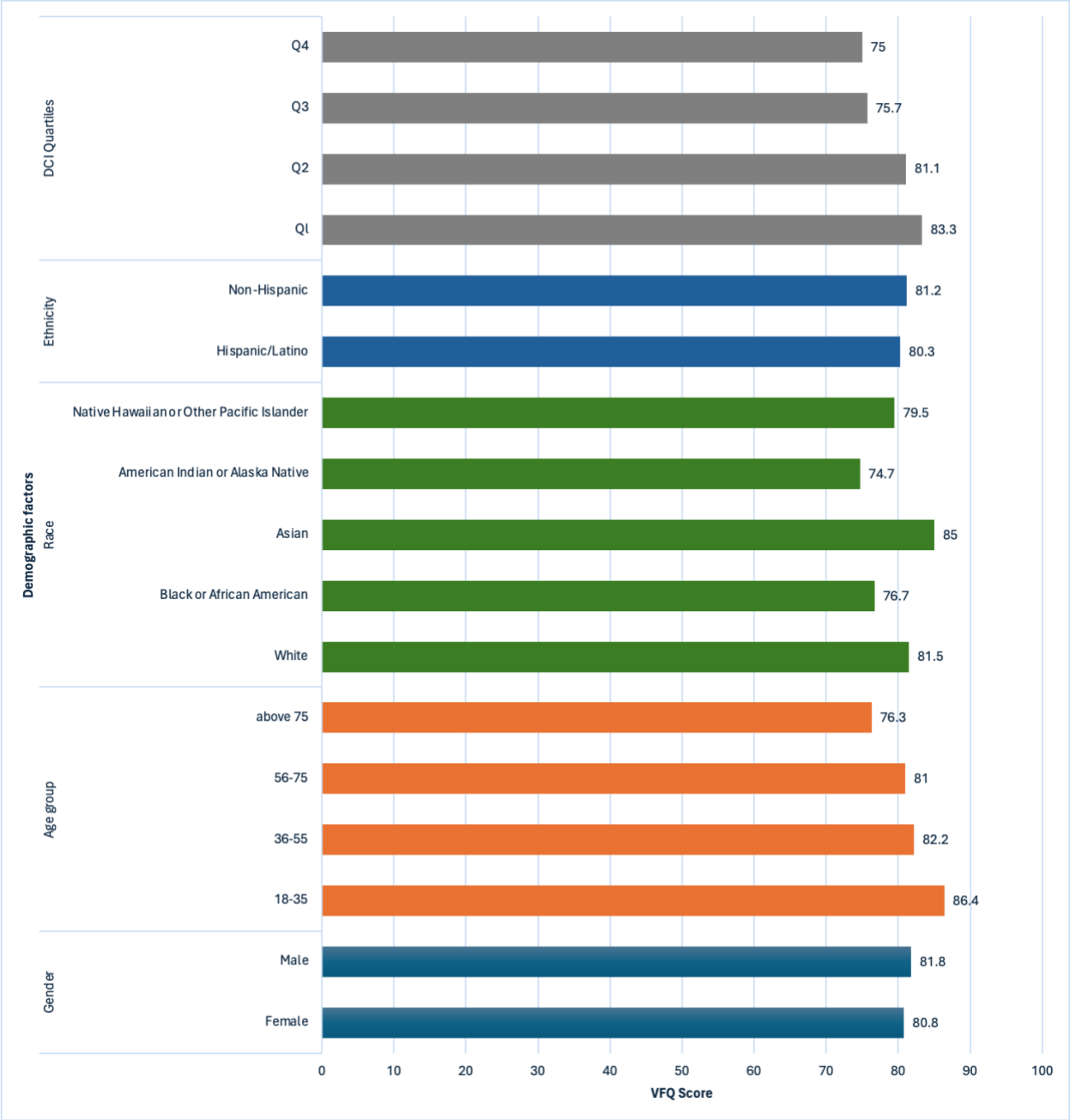


Figure 4: Average VFQ scores stratified by demographic factors

Overall, the mean VFQ-9 score for the entire cohort was 81.3. When stratified by gender, we noticed that males exhibited slightly higher mean score of 81.8 compared to women at 80.8. Significant variations were evident across racial categories, with Asian participants reporting the

highest mean score of 85, followed by White participants at 81.5, while Black participants reported a lower mean score of 76.7, and American Indian participants had the lowest at 74.7. Ethnicity also played a role, with Hispanic individuals showing a slightly higher mean VFQ-9 score of 86.66 compared to non-Hispanic individuals at 86.67.

Age stratification revealed that younger participants aged 18-35 had the highest mean VFQ-9 score of 86.4, followed by those aged 36-55 at 82.2, and subsequently, participants aged 56-75 and above 75 reported mean scores of 81 and 81.67, respectively. All groups had high median scores above 80, indicating generally good quality of life (Figure 5). The younger age groups, 18-35 and 36-55, had slightly higher median scores and less variability compared to the older groups. The number of outliers increased with age, suggesting greater variability in vision-related quality of life among older populations.

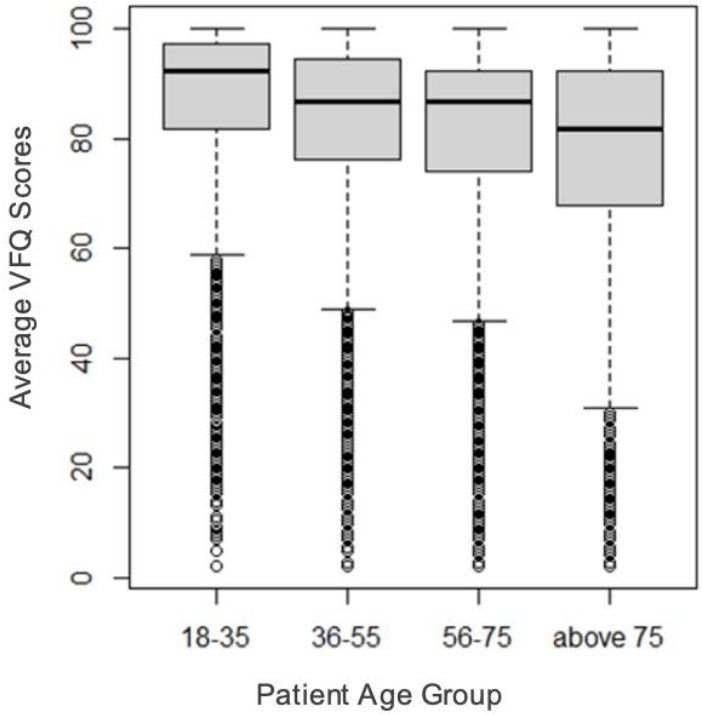


Figure 5: Average VFQ scores stratified by patient age group

Additionally, differences in VFQ-9 scores were observed across socioeconomic strata as indicated by DCI quartiles, with participants in the first quartile demonstrating the highest mean score of 83.3, followed by those in the second quartile at 81.1 and subsequently decreasing scores in the third and fourth quartiles at 75.7 and 75, respectively. These findings underscore the multifaceted relationships of gender, race, ethnicity, age, and socioeconomic status with vision-related quality of life.

Statistical tests were conducted to assess if the score differences observed across each group are significant. The Kruskal-Wallis test revealed significant differences in VFQ-9 scores across age groups ($\chi^2 = 1567.7$, $p < 0.001$), racial categories ($\chi^2 = 436.9$, $p < 0.05$), and DCI quartiles ($\chi^2 = 1342.9$, $p < 0.05$). Additionally, Mann-Whitney U tests showed significant differences in VFQ-9 scores between genders ($W = 564676696$, $p < 0.05$). However, when comparing VFQ-9 scores between Hispanic and non-Hispanic individuals, the Mann-Whitney U test did not reveal a statistically significant difference ($W = 64464259$, $p = 0.08$). These findings highlight the complex relationship between demographic factors and vision-related quality of life, with ethnicity being the exception in this analysis.

3.3.3 VFQ subdomain scores stratified by demographic variables:

In addition to examining overall VFQ scores, we conducted an analysis of VFQ subdomain scores stratified by demographic variables. This analysis allowed us to assess how specific aspects of vision-related quality of life varied across different demographic groups (see Table 3). To investigate the associations between demographic factors and VFQ subdomain scores, we utilized statistical tests tailored to the nature of each variable. Specifically, we employed the Kruskal-Wallis test to assess differences in subdomain scores across race, age groups, and Distressed Community Index (DCI) quartiles. For gender and ethnicity, we utilized

the Mann-Whitney test to compare subdomain scores between groups. These tests enabled us to comprehensively explore the relationship between demographic variables and VFQ subdomain scores in our study population.

	Average VFQ Scores by domains									
N=69615	**Mean VFQ Score**	**General Vision**	**Mental Health**	**Near vision (Reading)**	**Near Vision seeing well up close**	**Distance Vision**	**Driving**	**Role Limitation**	**Peripheral Vision**	**Near Vision (Finding Objects crowded shelf)**
Total Patient Population	81.2	70.2	64.9	74.5	76.8	84.5	89.2	91.9	89.4	89.5
Gender										
Female	80.8	70.0**	64.4***	74.2**	76.7	82.9***	88.6***	91.5***	89.4	89.7***
Male	81.8	70.4**	65.5***	75.0**	76.9	87.0***	90.1***	92.4***	89.4	89.2***
Age Group										
18-35	86.4	72.8***	68.7***	87.2***	89.4***	90.6***	91.4***	94.9***	90.6***	91.9***
36-55	82.2	70.0***	64.1***	74.6***	77.4***	87.7***	91.2***	93.4***	90.3***	90.7***
56-75	81.0	70.4***	64.8***	73.1***	74.8***	83.7***	89.9***	92.4***	89.9***	89.7***
above 75	76.3	67.7***	63.2***	69.0***	72.5***	77.3***	81.8***	85.1***	85.2***	84.8***
Race										
White	81.5	70.6***	65.8***	74.7***	76.4***	84.4***	89.5***	92.4***	89.7***	89.9***
Black or African American	76.7	66.1***	57.0***	69.2***	75.5***	82.1***	84.9***	86.8***	84.7***	84.3***
Asian	85.0	71.1***	67.3***	80.7***	83.9***	90.2***	92.1***	93.7***	93.5***	92.4***

	Average VFQ Scores by domains									
N=69615	**Mean VFQ Score**	**General Vision**	**Mental Health**	**Near vision (Reading)**	**Near Vision seeing well up close**	**Distance Vision**	**Driving**	**Role Limitation**	**Peripheral Vision**	**Near Vision (Finding Objects crowded shelf)**
American Indian or Alaska Native	74.7	66.3***	57.1***	67.6***	69.7***	76.5***	82.7***	86.6***	83.1***	83.0***
Native Hawaiian or Other Pacific Islander	79.5	69.6***	65.7***	69.9***	76.9***	80.6***	85.6***	89.4***	89.4***	88.9***
Other	79.7	68.6***	59.3***	73.5***	77.8***	84.8***	87.7***	89.5***	88.4***	87.7***
Ethnicity										
Hispanic/Latino	80.3	68.8***	60.3***	74.1	78.4***	84.7	88.3*	90.9*	88.7	88.4*
Non-Hispanic	81.2	70.2***	65.0***	74.5	76.8***	84.5	89.2*	91.9*	89.4	89.5*
DCI Quartile										
Ql	83.3	71.9***	67.7***	76.8***	78.6***	86.7***	91.3***	93.7***	91.6***	91.7***
Q2	81.1	70.0***	64.7***	74.4***	77.1***	84.4***	89.2***	91.8***	89.4***	89.3***
Q3	75.7	65.8***	57.5***	68.8***	71.4***	78.7***	83.6***	87.6***	83.4***	84.2***
Q4	75.0	65.2***	57.0***	67.6***	71.7***	78.7***	82.9***	85.8***	82.9***	83.0***

*** p-value<0.001, ** p-value < 0.005, *p-value < 0.05

Table 3: VFQ subdomain stratified by demographic factors

In our analysis of mean VFQ scores by subdomains we found that of all the subdomains, mental health had the lowest mean score (64.9), followed by general vision (70.2) across the entire sample. (Figure 6)

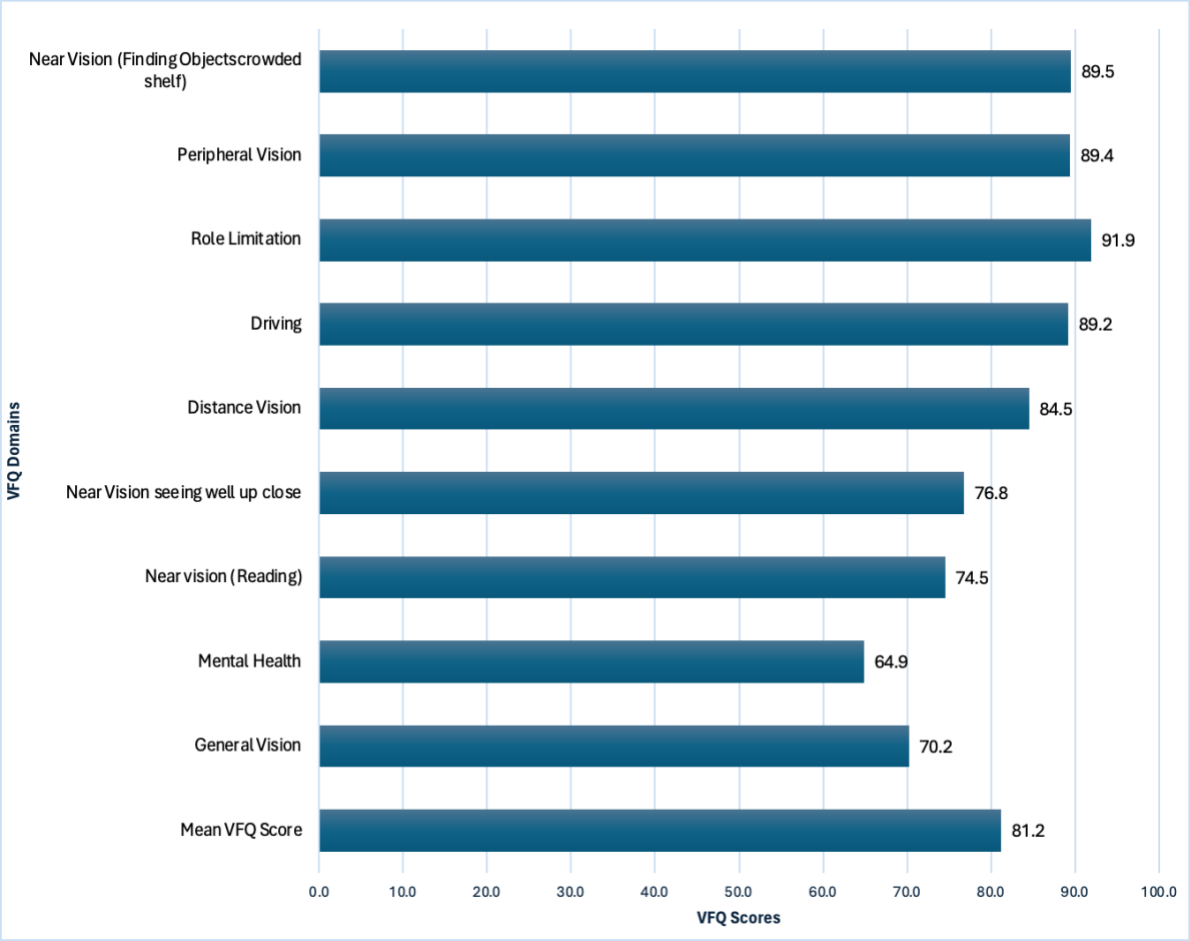


Figure 6: Average subdomains scores for the population

When stratified by age groups, we observed that all subdomain scores decreased as the age increases. (Figure 7).

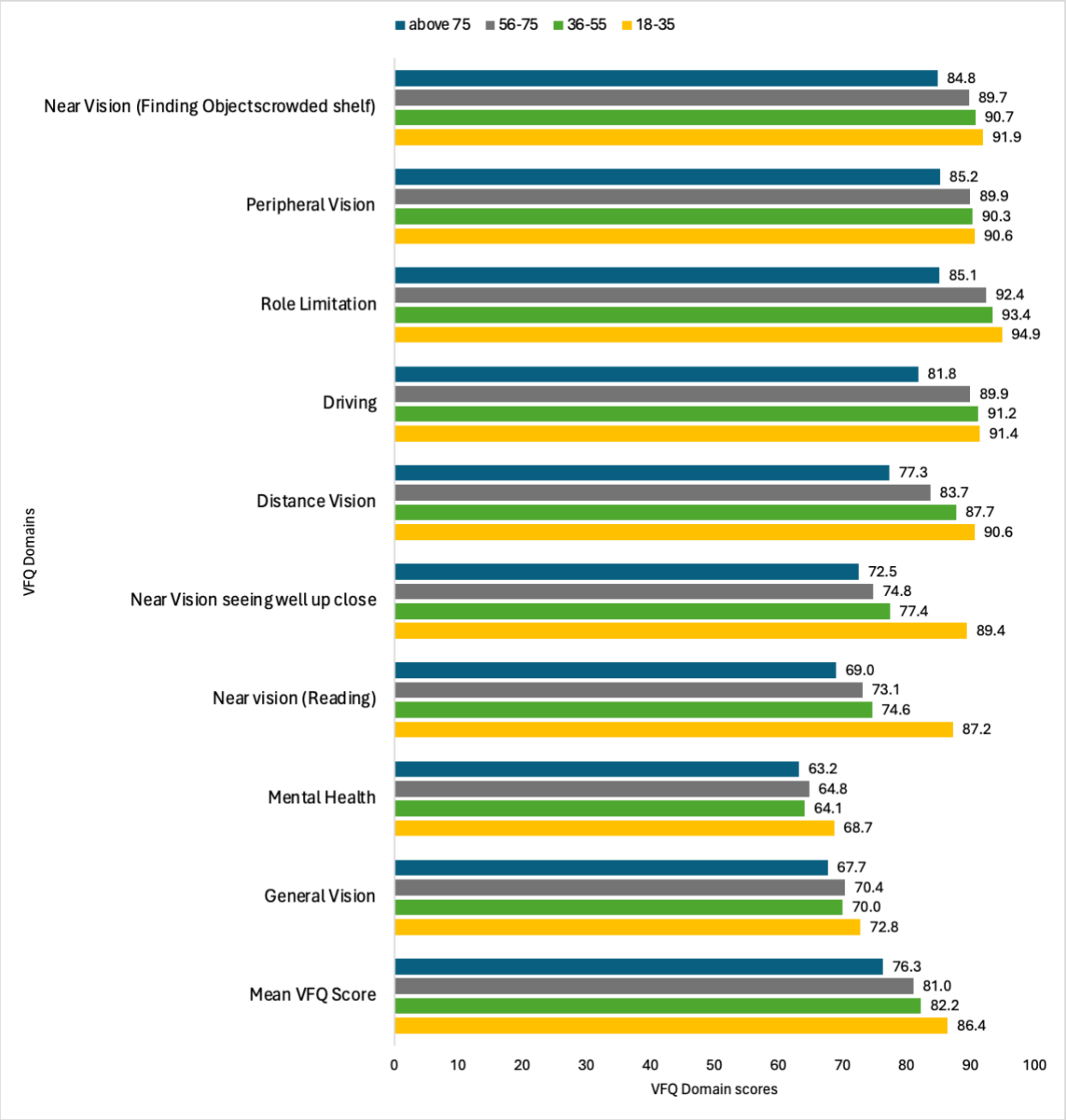


Figure 7: VFQ subdomain scores stratified by age groups

Specifically, we noted a trend of lower mental health-related quality of life across age groups, with mean scores for the mental health subdomain declining from 68.7 for 18-35 age group to 63.2 for those above 75. (Figure 8)

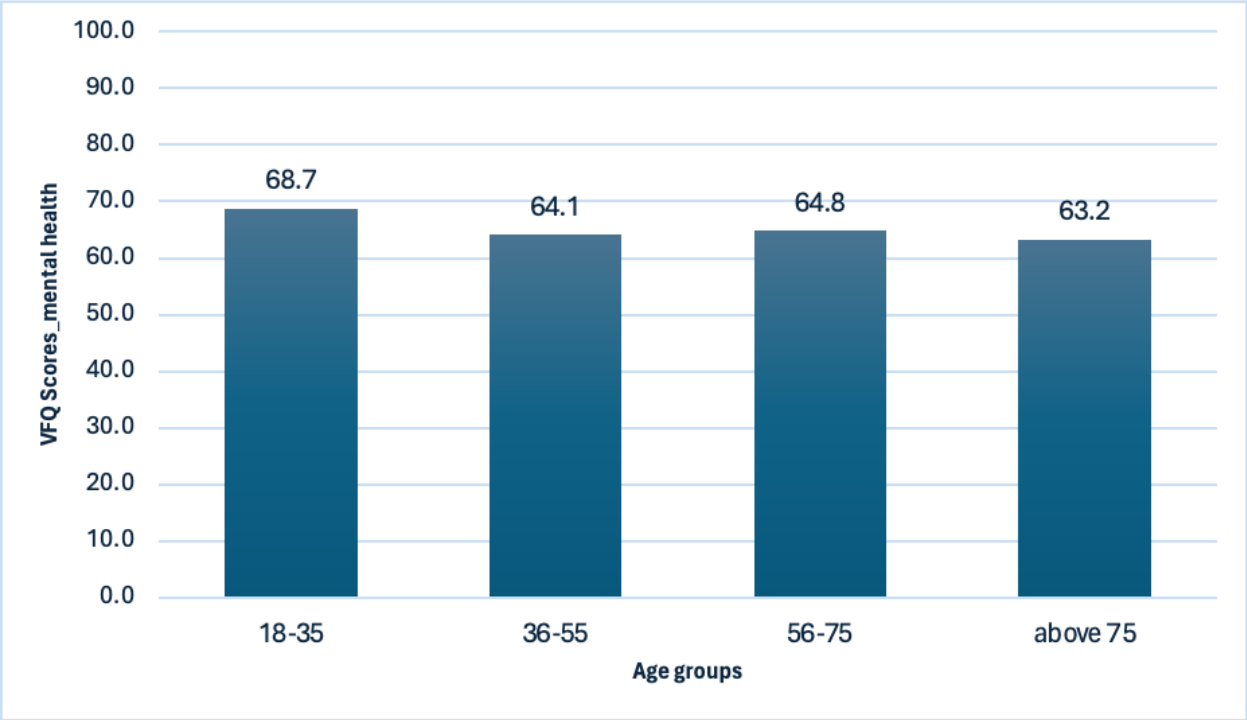


Figure 8: VFQ subdomain mental health scores stratified by age groups

Furthermore, when considering race, Black and American Indian participants exhibited the lowest mean scores for the mental health subdomain, with scores of 57 and 57.1, respectively (Figure 9).

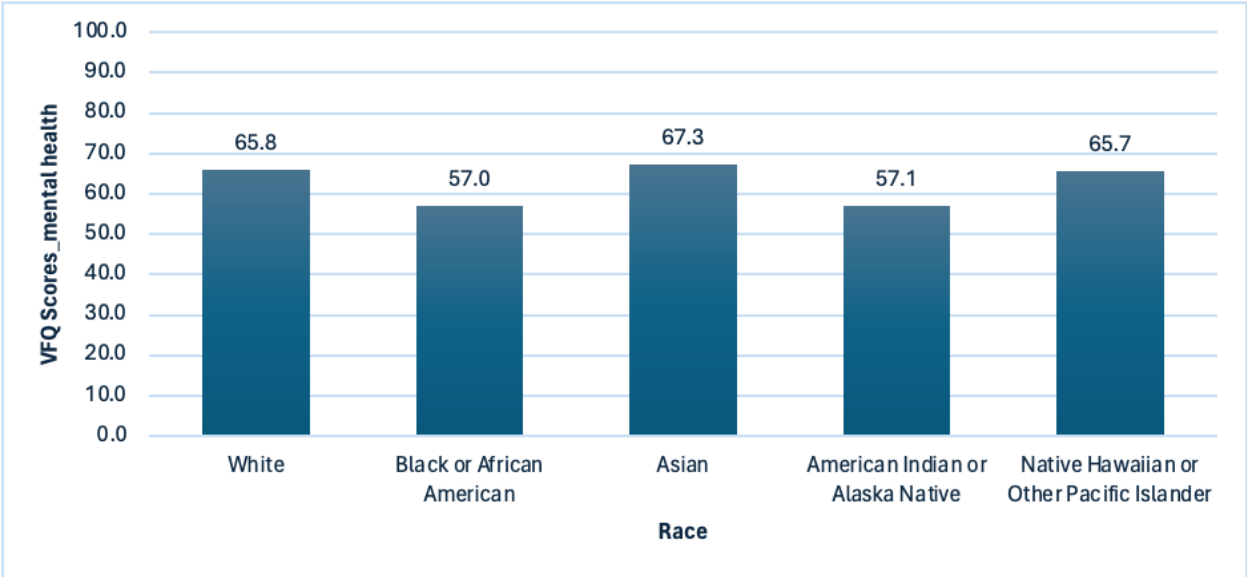


Figure 9: VFQ subdomain scores by race

3.4 Discussion:

Our study looked at the variations in VFQ-9 composite and subdomain scores, in a large sample from a Midwest university hospital's eye center. Significant variations in VFQ-9 composite and domain scores were evident across demographic groups. Notably, age-stratified analysis revealed a decline in VRQoL as age increased, with younger individuals reporting higher VFQ scores compared to older age groups. Racial disparities were also notable, with Asian participants reporting the highest VFQ scores, followed by White individuals, while Black and American Indian participants exhibited lower scores. Similarly, ethnicity played a role, with Hispanic individuals reporting slightly higher VFQ scores compared to non-Hispanic counterparts. Socioeconomic status, as measured by the DCI score, showed varying impacts on VRQoL across quartiles, with individuals in less distressed communities reporting higher VFQ scores.

Our study also highlights the importance of examining VFQ subdomain scores for the patient population. Well-being/Mental health emerged as a particularly salient subdomain, with the lowest mean score observed as compared to other domains. We also observed significant variations within other domains of VFQ-9 like General vision, Distance vision, Near Vision, Peripheral vision, Role limitation and Driving.

Our findings emphasize the importance of incorporating VFQ composite and subdomain scores into routine clinical assessments. By providing clinicians with a more nuanced understanding of patients' VRQoL, including specific domains of visual function, our study necessitates the need for a reporting tool that can deliver these subjective measures for shared decision making. Our study has the following limitations. Although we looked at the variations in VFQ scores, we did not look at the impact of these demographic factors on VFQ-9 composite

and domain scores. Moreover, our study sets the stage for future research exploring provider-facing interventions, such as EHR-integrated tools, aimed at enhancing the reporting and utilization of VFQ subdomain scores in clinical decision-making. Subsequent analyses should include an analysis of the relationship between VRQoL and visual acuity, to identify opportunities to inform clinicians about unexpectedly low VRQoL scores, when visual acuity is normal would also be conducted in the future. We anticipate that future analyses are also needed to better understand the relationship between mental health and visual acuity.

Chapter 4 Using Patient-Reported Outcomes (PROs) in Routine Ophthalmology Practice: A Contextual Inquiry

4.1 Introduction:

Visual impairments profoundly influence an individual's quality of life and extend beyond the loss of visual acuity to affect various aspects of daily living.[163] In ophthalmology, visual acuity is often used as the primary metric for assessing a patient's visual function.[164] However, such objective measures fail to fully indicate the broader effects of eye conditions and their treatments on patients' vision-related quality of life (QoL).[165]

Patient-reported outcomes (PROs) can provide a comprehensive assessment of the broad impact of eye conditions on patients' quality of life, delivering direct insights into their symptoms, functional status, mental health, and overall well-being.[31,69] In the context of ophthalmology, the National Eye Institute's 9-item Visual Function Questionnaire (VFQ-9) is a validated PRO instrument designed to capture the patient's perspective on how their vision impairment affects their daily life, activities, and overall well-being, making them an essential tool for assessing the quality of life-related to visual function.[153] By focusing on key areas of visual function, VFQ-9 provides information about the personal experiences of those with visual impairments, emphasizing the patient's perspective in assessing visual health outcomes.[159]

Incorporating PROs in routine clinical care have shown to be useful in detecting and managing health conditions, improving patient-provider communication, and improving patient satisfaction.[58,71] Therefore, PROs like the VFQ-9 hold considerable value in clinical practices,[159]

providing insights into the broader effects of visual impairment on daily life aspects that clinical assessments do not capture.[166]

For PROs to be effectively utilized in routine clinical practice, PRO data must be easily accessible and readily available during patient care. EHR-integrated PROs can enable more standardized and efficient PRO documentation, use, and workflows.[138,167,168] However, incorporating PROs into clinical settings presents significant concerns, such as increased workload, the clinical relevance of PROs, interruptions to existing workflows, and insufficient data visualization capabilities.[83,168] The successful integration and adoption of an EHR-integrated PRO system depends on careful consideration of the workflow and the needs of stakeholders, as well as potentially tailoring the PRO intervention to meet diverse needs.[94,169] While there are studies focused exclusively on provider perspectives[30,170] for using PROs in clinical practice, there is limited evidence of a comprehensive approach to exploring the workflow, stakeholder perspectives, and the requirements for effective collection, reporting, and use of PRO information in routine clinical practice.[171]

Contextual Inquiry (CI) is a user-centered research method that aims to uncover users' true needs by observing and interviewing them in their work environments.[172] This method is foundational in understanding the complex conditions surrounding users' tasks, which can then inform the redesign of work processes and the development of tailored user interfaces. CI combines direct observation with partnership and focused inquiry to ensure a deep, accurate comprehension of users' needs in their "real world" contexts. Key concepts of CI include: (i) Context: This encompasses all the factors that influence users' work, such as their physical environment, social interactions, organizational culture, and the tools they use. Understanding these factors is essential to grasp the full scope of users' needs and challenges. (ii) Partnership:

Traditional interviews often fail to capture detailed needs because users might not articulate the subtleties of their tasks. CI addresses this by involving users as co-investigators, which helps obtain a more accurate and complete understanding of their requirements, and (iii) Focus: CI is directed by a specific focus that narrows the research to a particular area of interest, facilitating the collection of detailed and relevant data.[173]

Therefore, this study employs a contextual inquiry approach to examine the clinical workflows, stakeholder perspectives, and information needs related to using PRO data in routine clinical settings. We aim to inform the development of integrated VFQ-9 reporting systems within EHRs.

4.2 Methods:

4.2.1 Setting and Context:

The study was conducted at a major eye center located within an academic medical center in the Midwestern United States. Starting in 2017, the center began incorporating the National Eye Institute's 9-item Visual Function Questionnaire (VFQ-9) into the Electronic Health Records (EHR) for all patients aged 18 and above on an annual basis.

4.2.2 Participants:

Participants in this study included front office staff, technicians, managers and ophthalmologists. Our observations included front office staff and technicians in their clinical settings, specifically looking at how they collected and entered VFQ-9 scores into the EHR. Along with the technicians and front office staff, we also interviewed the managers to understand the operational challenges in collecting and reporting VFQ-9 data. We conducted semi-structured interviews with clinicians who have engaged with VFQ-9 scores within the EHR system, aiming

to capture their perspectives and information needs to use VFQ-9 scores in their routine clinical practice. We selected stakeholders for interviews using a purposive sampling method, focusing on individuals directly involved with the VFQ-9 process.

4.2.3 Study Design and Approach:

Our study employs a contextual inquiry approach grounded in user-centered design principles to ensure a detailed examination of the integration and utilization of the VFQ-9 within clinical workflows (Figure 10).

First, we performed clinical workflow analysis to map out the processes involved in collecting and reporting the VFQ-9 data within the clinical setting. As part of the clinical workflow analysis, we also carried out observations and semi-structured interviews with front office staff and technicians to understand the process involved in collecting and reporting VFQ-9 data. Then, we conducted semi-structured interviews with clinicians to understand their perspectives and the information needed to use VFQ-9 data in routine clinical practice.

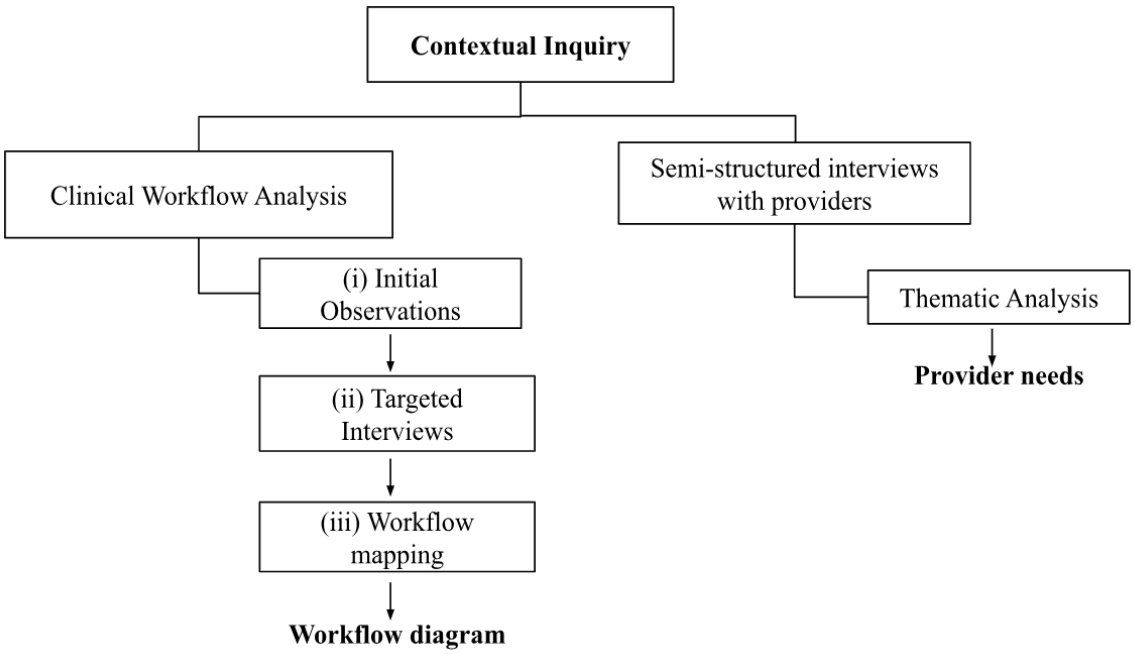


Figure 10: Overview of the Contextual Inquiry Approach

4.2.4 Clinical Workflow Analysis:

We implemented a 3-step process for the workflow analysis. This included (1) initial observations of the clinical environment to gain a comprehensive understanding of the VFQ-9 workflow, (2) targeted interviews with stakeholders involved in the VFQ-9 process to elucidate their perspectives and identify specific challenges, (3) workflow mapping to visually represent the VFQ-9 workflow.

(1) Initial Observations:

The initial observations involved systematically evaluating and documenting the VFQ-9 workflow within the clinical environment. We conducted 40 hours of direct observation across various clinical settings within the eye center to capture real-time interactions and processes related to the VFQ-9 collection, data entry into the EHR, and PRO reporting to a dashboard. This step enabled us to understand how the questionnaire is integrated into daily operations across clinical specialties. We gathered information on how the VFQ-9 is administered, how the data is entered into the EHR, how it is reported, and who utilizes the reports.

(2) Targeted Interviews:

Additionally, we carried out field interviews with diverse stakeholders involved in the VFQ-9 process. This group included front office staff (n=6), who often serve as the first point of contact for patients; technicians (n=6), who are crucial in administering the VFQ-9 and ensuring its completion; and managers (n=3), who oversee the operational aspects of VFQ-9 integration. These interviews were designed to explore their experiences, identify any challenges they face in their roles concerning the VFQ-9, and collect their recommendations for process improvements.

(3) Workflow mapping

The workflow mapping step visually represented the collection, integration, and reporting processes of the VFQ-9 data within the clinical setting. Creating a detailed map of how VFQ-9 data moves through various stages—from patient entry to data utilization—helped identify challenges in the current workflow. The visual nature of workflow mapping allowed the research team and stakeholders to pinpoint bottlenecks and areas identified through observation and targeted interviews where the current VFQ-9 process could be improved. By synthesizing information from diverse sources, this step provided a comprehensive view of the challenges and opportunities within the existing workflow.

4.2.5 Semi-structured interviews

After the clinical workflow analysis, we focused on understanding the clinician's perspective and information needs for using VFQ-9 scores in routine clinical practice. We conducted semi-structured interviews with clinicians (n=9) who had direct experience with VFQ-9 data within the EHR system. The interviews were transcribed verbatim, and we conducted thematic analysis to develop common themes related to information needs, and challenges for the use of VFQ-9 data. We aimed to understand the perspective of clinicians and their specific information needs for using VFQ-9 data in routine clinical practice. By employing this multifaceted, hands-on approach, our study not only aimed to map out the existing workflows and interactions surrounding the VFQ-9 but also sought to identify areas for improvement.

4.2.6 Data Collection and Analysis:

Clinical workflow analysis was conducted over a period of one month during February 2023. Direct observation and field interviews with front office staff and technicians were

conducted over a period of five weeks between February and March of 2023. Semi-structured interviews with the clinicians were conducted from 2020 to 2023. Study participants were recruited via email, face-to-face, and through referrals from the managers of each clinic. Verbal consent was obtained from all participants prior to conducting the interviews. Participants were fully informed about the purpose of the study, the nature of their participation, and their right to withdraw at any time without any consequences. We collected field notes for all observations and interviews with front office staff, technicians, and managers. Additionally, semi-structured interviews with clinicians were recorded, transcribed verbatim, and later edited for clarity. We conducted a thematic analysis of field notes and interview transcripts to systematically develop and categorize key themes.

4.2.7 Ethical Consideration:

This study was reviewed and determined to be not regulated by the Institutional Review Board at the University of Michigan (HUM00228979)

4.3 Results:

4.3.1 Clinical Workflow Analysis

4.3.1.1 Initial observations

Based on the workflow analysis, we created a flowchart that presents the clinical workflow around the collection and reporting of VFQ-9 within the eye center. (Figure 11). The flow chart presents the VFQ-9 workflow from how the data is collected to how it is reported in the EHR.

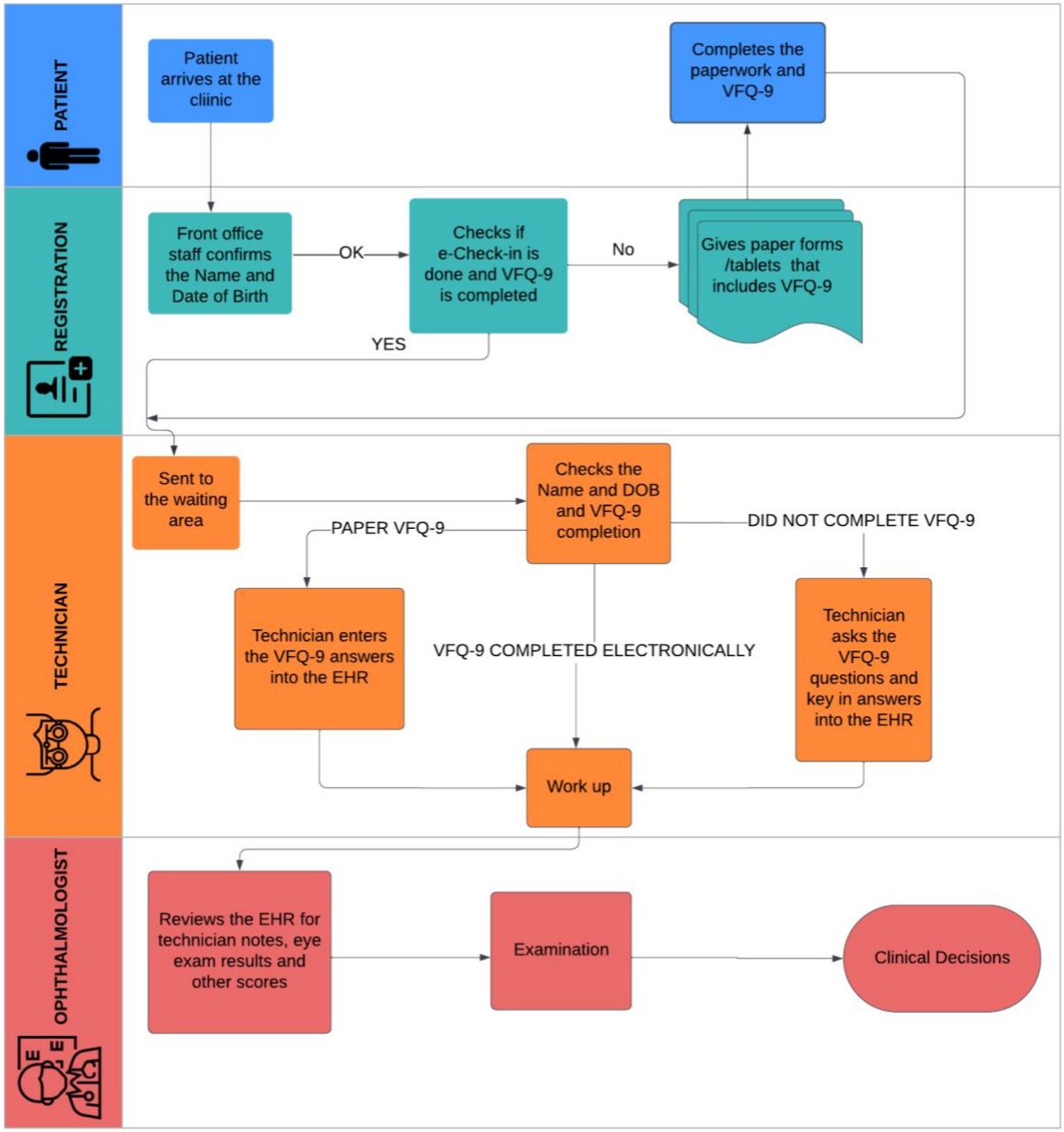


Figure 11: Clinical workflow mapping of VFQ-9

Based on the field interviews conducted, we identified the following challenges in collecting and reporting PROs (Figure 12).

(i) Low patient engagement with the portal

Participants noted that the primary challenge in collecting VFQ-9 data is related to the low engagement with the portal, as some patients could not fill out the forms because of their existing visual conditions. For example, a front office staff member said, "*Completing the VFQ forms can be a real challenge for some of our patients, particularly those with eye conditions that impair their vision, like glaucoma. It's especially tough for them due to the progressive nature of their conditions.*"

(ii) Inadequate accessibility features within the portal:

Managers reported the need for accessibility options within the patient portals, like text-to-speech. They noted that these improvements would assist visually impaired patients in completing the VFQ-9 through the portal and improve the portal usage rate. For example, a participant said, "To support all our patients, incorporating accessibility options like text-to-speech into our portal is essential. This can enable patients with visual impairments to navigate and complete the VFQ-9 independently, increasing overall usage rates of our portal and improving portal usage rates".

(iii) Limited font size in both paper and portal versions of the VFQ-9

A staff member noted that increasing font sizes in the portal and on printed VFQ-9 forms can also help patients with varying degrees of visual impairment access and complete the questionnaire more comfortably. "*There should be options to increase the font sizes on the portal, and we also need additional printed VFQ-9s with larger fonts. This will greatly benefit people with visual impairments, making it easier for them to complete the forms comfortably."*

(iv) Limited availability and use of tablets:

Staff highlighted that tablets are limited in availability and use, and most clinics use paper VFQ-9 forms. Even in clinics that do utilize tablets, during times of high patient volume, there are not enough devices to go around or no convenient charging facilities for tablets, leading staff to resort to paper VFQ forms. For example, one staff member said, *"In our clinic, we do not have an adequate number of tablets; if the patients do not complete VFQ during their online check-in, we give paper forms."*

Another staff member added, "*Most clinics use paper VFQ forms. In the clinic where they use tablets, we have a limited number of devices. And we just don't have enough to go around on busy days. So, we give paper VFQ-9 forms, which means more manual data entry for our technicians.*"

(v) Increased workload

Technicians reported increased workload due to the limited use of patient portals and tablets to fill VFQ-9 as another bottleneck. Patients who have not completed the VFQ-9 during online check-in are given paper VFQ-9 forms in most clinics. This increases the workload of technicians who must manually input VFQ-9 data into the EHR. The technicians added that the use of tablets, however, could automate this data entry, effectively reducing the technicians' workload. One of the technicians stated, *"It would be great if all patients could fill out the VFQ-9 through the portal or tablet here at the clinic. When they don't, we're manually entering their responses from the paper forms into the EHR, and that takes up a lot of our time, especially during a busy clinic day"*

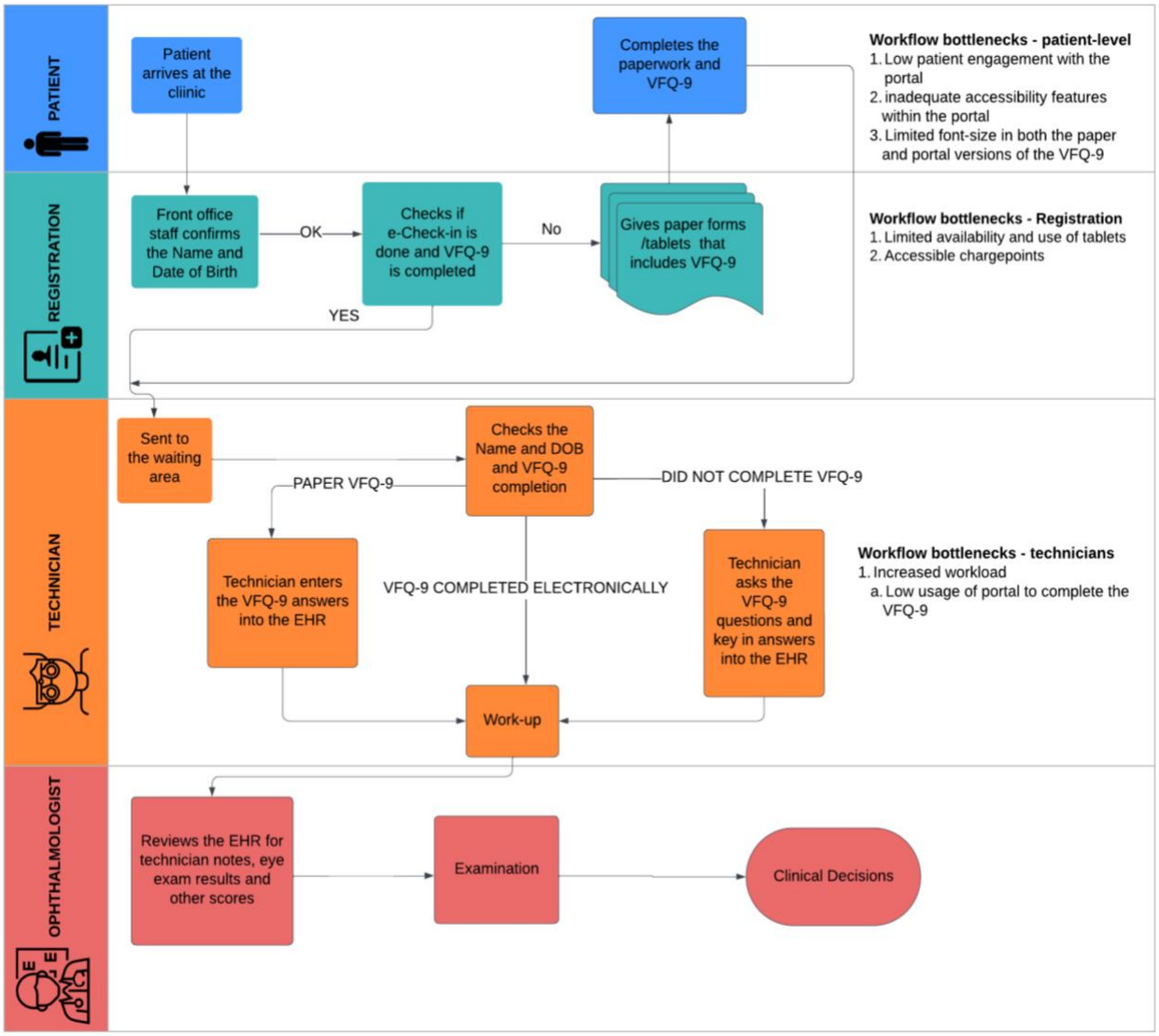


Figure 12: Bottlenecks identified in the workflow map of VFQ-9

4.3.1.2 Semi-structured interviews with providers:

The interviews with the clinicians lasted 30 minutes on average, ranging from 20-42 minutes. During the interviews, providers shared their perspectives on VFQ-9, including its significance, some of the current challenges associated with using them for clinical decision-making, and their needs for using VFQ-9 scores in routine clinical practice. Based on the analysis, we identified four main themes: (i) Theme 1: VFQ for Improved Patient Communication and Engagement, (ii) Theme 2: Challenges and Limitations in using VFQ-9, (iii)

Theme 3: Information needs for using VFQ-9, and (iv) Theme 4: Educational Needs on VFQ-9 Clinical Utilization. Appendix B outlines the themes identified in our study and includes representative quotes from providers to illustrate these themes.

VFQ for Improved Patient Communication and Engagement:

Theme 1: VFQ-9 helps in understanding patient's perspectives of their vision

During the interviews, providers consistently highlighted the significance of the Visual Function Questionnaire (VFQ) in their clinical practice. One provider noted, "*Some people are just a lot more sensitive to little imperfections in their vision compared to other patients. And so I get to know them a little better with the VFQ-9. More of their perception of what it's like outside of the exam room, like what it's like to live their life with their vision. (010)*"

The providers emphasized that the VFQ is crucial for gauging patients' perceptions of their vision-related quality of life, offering invaluable insights beyond traditional clinical measures. Another provider noted, "*For me, it's a really good thing to know before I walk into a patient about how their perceptions of how severe their eye problems are affecting them. When we take a history, sometimes we really don't have a relative severity compared to other patients and compared to sort of perfect health. So I found them (VFQ-9) incredibly useful*" (003). This emphasis on the VFQ underscores its role as a diagnostic tool and a medium for fostering more meaningful and informed conversations between providers and patients.

Providers also highlighted the effectiveness of the VFQ-9 due to its concise and targeted nature. *"[VFQ-9] is one of the more accessible questionnaires because of its length. Most people can complete it in three or four minutes. Most patients, especially with something like glaucoma, which is the majority of my patient population, are deeply concerned with their long-term ability*

to continue doing all of their daily functional activities. And this questionnaire gets at those things. (001)"

According to the feedback gathered, the VFQ's ability to capture the subjective impact of vision impairments on daily activities enables providers to tailor their care approaches more effectively, ensuring that treatment plans align with patients' needs and concerns. A provider shared, "*I see some conditions that don't manifest as clinical signs that I can see on examination. And really a lot of that is subjective, so specifically for my world, dry eye, a lot of people can have very little clinical signs on eye exam, but they can be very symptomatic and very functionally impaired. So, the VFQs are invaluable in capturing the patient's subjective experience, allowing us to tailor treatments more effectively to their specific needs. (003)"*. This acknowledgment of the VFQ's importance reflects its integral role in enhancing patient-centered care by bridging the gap between clinical assessments and the patient's experience.

Theme 2: Challenges and Limitations in using VFQ-9:

This theme captures the logistical and practical challenges encountered by healthcare providers when implementing the VFQ-9 into clinical practice. These challenges primarily revolve around the additional time and workload required, perceived inefficiencies in the current workflow, and the timing of VFQ completion to optimize patient care.

Providers expressed concern that incorporating the VFQ into their routine assessments significantly increases their clinic time and workload. This is especially pertinent in fast-paced clinical settings where time is limited. One provider articulated this challenge by stating, "*The challenge is time. The time it takes for me to look at it. [...] In some clinics, the technicians actually take time during the visit to answer the question, [...], and record their answers. And*

nobody likes that because it takes technician time, increases workload, and delays clinic visits." (006)

The workflow associated with the VFQ administration has been identified as another critical challenge. Providers feel that the current process could be streamlined for efficiency. A representative quote that highlights this says, "*It's tough because [...] sometimes the patients aren't even finished with the questionnaire by the time the technician is done working them up. So they're usually finishing the questionnaire while they're waiting to see me. [...]. So then it's not available to me in the EHR when I'm actually seeing the patient. [...] so it's not available to me unless I go through the paper and add up. I don't even know how it works everywhere, but the whole workflow should be streamlined"*. (009)

Many providers suggest that having the VFQ completed before the patient's visit could alleviate some of these challenges, allowing for a more focused and efficient use of consultation time. One clinician noted, "*The technicians are administering the [VFQ] questionnaire often. Even still, that's [...] three or four minutes, sometimes in a busy clinic, the technician will move through 100 patients. So that's literally hundreds of minutes of asking these questions. I think if patients could complete this prior to their visits, that would be great." (001)*

Theme 3: Information Needs for Using VFQ-9

This theme addresses the critical information needs identified by healthcare providers to optimize the use and interpretation of VFQ-9 in clinical settings. Providers emphasized the importance of quickly accessing VFQ scores within the EHR. A clinician noted, "*I actually have no idea where even to find the results of the VFQ. I don't know where to find it in EHR. That's how little we use it. But if it was there and readily available, yeah, I'd review it." (007)*

Providers underscored the need to show changes within each domain of visual function, such as General vision, Well-being/mental health, near vision, distance vision, driving, role limitation, and peripheral vision, as captured by VFQ scores, for a more detailed insight into patient conditions. A clinician remarked, "*It's important to see changes within each VFQ-9 domain so that we can tailor our approach to precisely address the areas where patients are experiencing difficulties.*"

Most providers emphasized the necessity of time point and time series data to monitor VFQ scores longitudinally. "*It's nice to know what it [VFQ score] is that day, but we can also hit if there's a trend button or a graph button where we can trend it over time, and I think both of those will be helpful." (009).* Another provider noted, "*I think, [...] it would also be nice to have these trends over time within each patient so that we can see people's VFQ score over time [...] like this is where they were this year, this is where they were last year. And I think that would be helpful." (003).*

The need for simple and straightforward visual representations of VFQ data was emphasized to facilitate quick interpretation. A provider mentioned, "*In terms of visualization, the simpler the better. I need to be able to look at it in like 5 seconds and take it in. However, that works. (006)*"

Lastly, aligning VFQ results more closely with exam scores, such as visual acuity scores and Intraocular Pressure, was mentioned as a way to better correlate subjective patient experiences with objective clinical measurements. A clinician highlighted, "*If I can view the VFQ data [...] side by side with the clinical data [...], for example, visual acuity and intraocular pressure are things that just pop up right in front of you when I open a patient chart. If this [VFQ score] was right there alongside them, I have visual acuity, intraocular pressure, and*

VFQ. Then it went in the face, and I couldn't miss it even if I'm moving fast; it would be impossible to miss this." (002). Another provider said, *"And there's a snapshot that shows you trends in intraocular pressure (IOP) over time. I think the most useful place for it [VFQ Scores] would be in that trend over time snapshot window with IOP. (001).*

Theme 4: Educational Needs for VFQ-9 Utilization

This theme underscores the need for continuous internal educational initiatives on the clinical utility of VFQ scores. It highlights two main areas of focus: (i) the need for enhanced education regarding the clinical utility of VFQs and (ii) the promotion of continuous discussions on the VFQs' clinical benefits via internal education platforms.

The gap in knowledge regarding how PROs, like VFQs, can be leveraged in clinical practice to enhance patient care was a concern. A provider expressed, "*I think that a lot of this conversation around VFQ gets sequestered in the research community, [..] I think getting information about the clinical utility of VFQs out to clinical providers [...] could be helpful.*" (001). Another provider added, "*I think tailoring why VFQ is helpful with clinical examples to each subspecialty is probably a nice way to go about doing it. [...] Tailoring to the specific subspecialty makes the VFQ much more powerful. [...] Because I don't know how clinically meaningful a VFQ score is to a specific clinical condition. And I think that clinical meaningfulness would come from being able to talk about VFQ's clinical utility to clinicians so that they can't ignore it; except now, it is like, go find it!". (008)*

Continual education and dialogue on the application and benefits of VFQs and PROs within the healthcare team were recommended. *"Showing clinicians the utility of this VFQ scores related to the traditional outcomes that they're familiar with, like in grand rounds, journal clubs, educational forums [...] and to be able to talk about this from an educational standpoint*

and demonstrate to people that it can actually impact their patient care would be helpful. I mean, I see it in my own work, but I think that sort of ongoing dialogue is really important." (003).

Another provider noted, *"We have different seminars like we have a fall seminar, a midwinter one, and a spring one. And that is well attended. So maybe there could be someone who could talk for 15-20 minutes about VFQ; I feel like you could cover it enough to help us understand why we should care about it" (010).*

4.4 Discussion:

This contextual inquiry into the use of the National Eye Institute's 9-item Visual Function Questionnaire (VFQ-9) within routine ophthalmology practice at a major eye center has uncovered significant insights into information needs and challenges for PRO integration. The clinical workflow analysis helped in understanding the workflow challenges in collecting the VFQ-9. At the patient level the workflow bottlenecks identified are (i) Low patient engagement with the portal (ii) Inadequate accessibility features within the portal, and (iii) Limited font-size in both the paper and portal versions of the VFQ-9. At the front-office, limited availability and use of tablets were identified as the bottlenecks. Technicians noted that a significant challenge was increased workload due to the low usage of the portal by patients.

Our thematic analysis yielded the following themes: Theme 1: VFQ helps in understanding patient's perspectives of their vision, Theme 2: Challenges and Limitations in using VFQ-9, Theme 3: Information needs for using VFQ-9 and Theme 4: Educational Needs for VFQ-9 Utilization.

Further exploration within our study revealed that operational challenges, such as inadequate patient portal features and the physical limitations of tablet use in clinical settings, significantly hinder the collection and utilization of PROs. In our study, providers articulated

their specific needs for integrating VFQ-9 within the EHR system. They emphasized the importance of the VFQ-9 as a vital tool for capturing patients' subjective experiences of vision impairments, which are only sometimes apparent through clinical examination alone.[174] However, providers faced significant challenges in effectively using VFQ-9 scores due to workflow inefficiencies and limitations within the EHR system. They highlighted the need for quicker access to VFQ-9 results to minimize disruptions during patient consultations and improved visualization of VFQ-9 scores within the EHR to facilitate easier interpretation and integration into clinical decision-making processes.[30] Consistent with previous studies, providers also highlighted the necessity of continuous training and the development of tailored educational resources to enhance understanding and effective use of PRO/VFQ-9 scores.[168] These insights are crucial for developing more refined systems that support the nuanced needs of both patients and healthcare providers.

Our findings align with existing literature emphasizing the value of PROs in enriching clinical assessments and patient care. Studies, such as those by Valderas et al.,[109] have similarly identified the integration of PROs into clinical practice as a method to improve the accuracy of patient health assessments and treatment outcomes. However, unlike most studies that focus on the theoretical or small-scale implementation of VFQ in clinical practice,[175] our inquiry comprehensively analyzes the implementation across a large, specialized clinical setting. This contextual inquiry uniquely contributes to understanding the practical challenges and adjustments needed for successful PRO integration in healthcare workflows.

A notable strength of this study is the use of a comprehensive approach to capture a holistic view of the VFQ-9 integration process from multiple stakeholder perspectives. A limitation of our research is the exclusion of direct patient feedback, which could provide deeper

insights into patient perceptions and the usability of PRO tools. Our findings illustrate a range of barriers and information needs for the use of VFQ-9 but do not necessarily represent these characteristics for ophthalmology clinics more broadly.

Future studies should include patient interviews to understand their experiences and preferences regarding PRO completion and integration into their care. Despite these limitations, our methodology—combining observations, workflow analysis, and stakeholder interviews—offers a robust framework for identifying critical areas for improvement in designing tools for collecting and using PRO within clinical practice.

4.5 Conclusion:

This contextual inquiry into the VFQ-9 integration at a major ophthalmology center has identified challenges associated with patient visual impairments, inadequate hardware resources, and limitations in the current EHR systems to manage and display PRO data effectively. The results of our study revealed significant insights into the VFQ-9 integration process, which are crucial for designing a more efficient system for reporting PRO data in routine clinical practice. Moreover, the study highlights operational issues, such as inefficient patient portal features and the cumbersome physical use of tablets within clinical environments, which impede the optimal collection and use of PROs. Our findings suggest a need for system improvements to enhance access to and the usability of PRO data and ongoing provider education to maximize the benefits of PROs in clinical settings. Importantly, to advance the utility of PROs in enhancing patient care, future efforts should prioritize direct patient input to better align the system's capabilities with the users' needs. This is important not only in Ophthalmology but also across any health system as patients with visual impairment see all kinds of providers and applies to all the other care they receive from other specialties as well. This approach will ensure that the system's

design and functionalities closely match the actual needs of its users, making PRO tools more practical and effective in clinical settings. This study provides valuable insights into the dynamics of PRO integration. It lays the groundwork for more effective implementations in the future, potentially leading to more patient-centered and nuanced healthcare solutions in ophthalmology.

Chapter 5 Designing and Evaluating an EHR-Integrated PRO Reporting Tool for Ophthalmology: A User-Centered Design Approach

5.1 Introduction:

In recent years, the healthcare landscape has undergone a profound transformation, shifting towards a model of care that places patients at the center of decision-making and treatment planning.[176] At the heart of this movement lies the concept of patient-centered care, which emphasizes the need to engage patients in their own care journey, recognize their individual preferences, and address their unique needs and concerns.[43,177] Patient-reported outcomes (PROs) have emerged as a key mechanism for capturing patients' subjective experiences and perspectives and offer a more holistic and patient-centered approach to assessing healthcare outcomes.[177]

The integration of PROs into routine clinical practice, especially in specialized fields like ophthalmology, has garnered significant attention for its potential to improve patient care and treatment outcomes.[178] In ophthalmology, the National Eye Institute Visual Function Questionnaire (NEI-VFQ) has proven to be a valuable tool for evaluating vision-related quality of life (VRQOL).[179] The NEI-VFQ-9 (Appendix 1) is an abbreviated 9-item PRO measure often used in clinical settings due to its simplicity and practicality.[153,180] It consists of nine questions that cover various aspects of visual function, including general vision, near vision, distance vision, peripheral vision, mental health, role limitation, and driving. The VFQ-9 is a valuable

tool in ophthalmology, providing clinicians with a comprehensive understanding of how a patient's visual impairment affects their daily life.

Despite the emphasis on PROs in clinical care, several challenges remain, including the need for standardized measurement tools, efficient data collection and reporting methods, and seamless integration into existing workflows.[168] Integrating PRO data into the EHR systems allows healthcare providers to gain real-time access to patient-reported information, allowing for more personalized and patient-centered care delivery.[167] However, the successful implementation of PROs depends on the data being accurately integrated into EHRs, easily accessible, and interpretable.[181] Given that the utility of PROs is context-specific, reporting systems must be tailored to meet the unique needs of users and their contexts.[182] User-centered design (UCD) is thus instrumental in this process, ensuring that the end-user's experience is the focal point throughout the development of these systems.[183]

UCD methods have been successfully used to develop electronic patient-reported outcome measures (ePRO) tools, demonstrating their effectiveness in enhancing user experience and satisfaction with new systems.[184] By actively involving end-users in the design process, UCD methodologies enable developers to gain valuable insights into the usability, functionality, and relevance of PRO reporting tools.[135] Through iterative prototyping and user testing, designers can identify potential usability issues,[185] gather feedback on design elements, and make informed decisions about refinement and optimization. This iterative approach enhances the final product's usability and effectiveness and fosters greater acceptance and adoption among end-users.[186]

In our previous study (Aim 2), we employed contextual inquiry to understand the users and their information needs. This comprehensive approach incorporated workflow analysis,

observations, and semi-structured interviews. These activities facilitated a grounded understanding of the existing system and user needs, directly informing the design of initial low-fidelity prototypes. By leveraging UCD principles, this study seeks to develop design recommendations for PRO reporting interventions that meet providers' unique needs and preferences to deliver patient-centered care in the field of vision health.

5.2 Methods:

5.2.1 Setting:

This study was conducted at a leading eye center within a major university hospital in the Midwest region of the United States. The center collects Visual Function Questionnaire (VFQ-9) scores annually from all patients aged 18 and older, which are then integrated into the hospital's EHR system. Recruitment and data collection for this study spanned from May 2023 to March 2024, facilitating the development of design recommendations for enhancing the VFQ-9 report integration within the clinical setting.

5.2.2 Participants:

Participants in the study were providers who either regularly interacted with or expressed willingness to engage with VFQ-9 scores within the EHR system. Eleven providers from the eye center were selected through purposive sampling to participate in the design study, some of whom were chosen based on their valuable insights from earlier research involvement. The inclusion criteria were specifically aimed at providers involved in adult patient care, aligning with the patient age group eligible for VFQ-9 assessments. Pediatric ophthalmologists were excluded from the study because they do not use the VFQ-9, as it is not administered to children. Providers who opted out of participating in the study design process were also excluded. This

strategic selection process was done to gather comprehensive, practical insights that would drive the development of a more functional and user-friendly VFQ-9 reporting format.

5.2.3 Design process:

This study used a user-centered design (UCD) framework[130] (Figure 13), which is comprised of a three-stage design process to design a VFQ-9 report using input from the end users. The UCD framework was chosen for its emphasis on understanding and addressing the needs of the end users, thereby ensuring the development of a usable and effective solution. The three stages of UCD methods include (1) Contextual Inquiry, (2) Developing /refining the initial prototypes, and (3) Usability evaluation.

5.2.3.1 Developing / Refining the Initial Prototypes:

The process of developing and refining the VFQ-9 feedback report prototypes involved several iterative steps. Initially, low-fidelity sketches were created to explore design features and gather initial feedback from users. These sketches served as a foundation for generating ideas and refining the prototypes. The prototypes underwent iterative refinement through collaborative design sessions based on user feedback, requirements, and information needs.

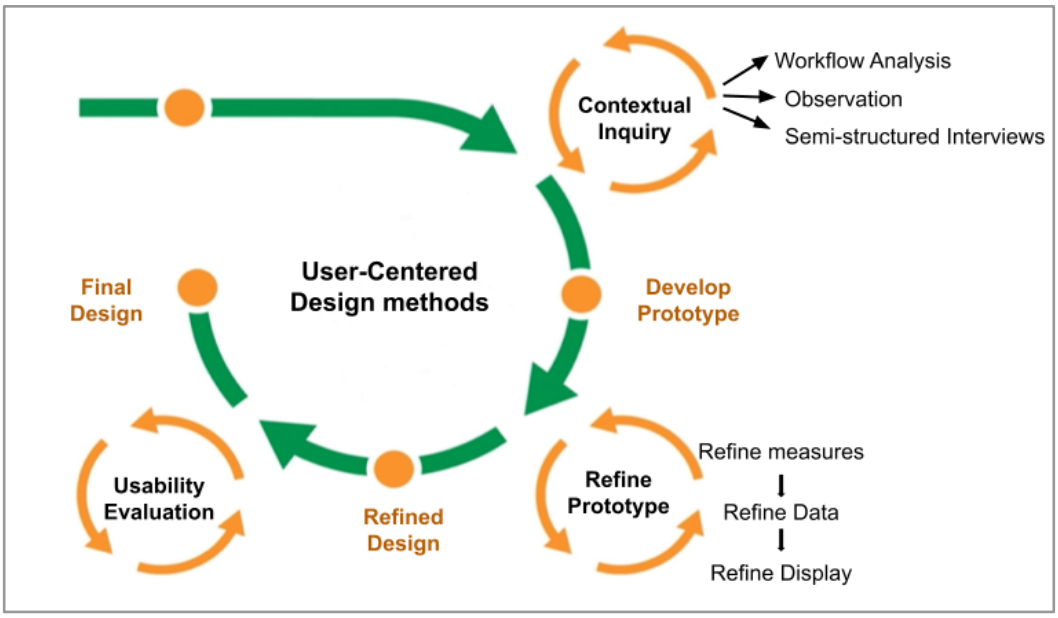


Figure 13: User-centered design process for feedback reports

5.2.3.2 Usability Evaluation:

Usability evaluation was conducted to assess the effectiveness and usability of the VFQ-9 reporting intervention prototypes. This involved conducting think-aloud semi-structured interviews, where participants were asked to verbalize their thoughts and reactions as they interpreted the prototypes. To ensure the prototypes met the users' needs, iterative rounds of evaluations were carried out, allowing for continuous refinement. Feedback from these sessions was analyzed to identify usability issues, which informed subsequent modifications to enhance the interface and functionality of the prototypes. The study also employed user stories, a technique commonly used in agile software development, to capture the nuanced requirements and experiences of end-users. User stories are succinct narratives that focus on the user's perspective, detailing their needs and the desired outcomes from interacting with a system.[187] To create the user stories, we extracted quotes from the interview transcripts and transformed them into a structured format: 'As a [type of user], I want [an action] so that [a benefit/value].' This

process involved carefully analyzing the transcripts to identify key user needs and preferences and then rephrasing these insights into concise, actionable narratives. Each user story succinctly captured the perspective of the clinicians, detailing their specific requirements and the desired outcomes from interacting with the VFQ-9 report system. Alongside thematic analysis of interview transcripts, user stories helped provide a qualitative depth to the research, enabling the iterative refinement of the prototypes to meet the specific needs and contexts of the healthcare providers.

5.2.4 Data Collection:

The data collection period spanned from May 2023 to March 2024, during which multiple rounds of design sessions and interviews were conducted to gather feedback and refine the prototypes. We conducted semi-structured interviews via Zoom using interview guides with open-ended questions to capture participants' thoughts and reactions to the VFQ-9 report prototypes. All interviews were recorded, and the data were transcribed verbatim. The transcripts were then edited for clarity and anonymized to remove any identifying information. Participant IDs were assigned to maintain confidentiality and facilitate data management.

5.2.5 Data Analysis:

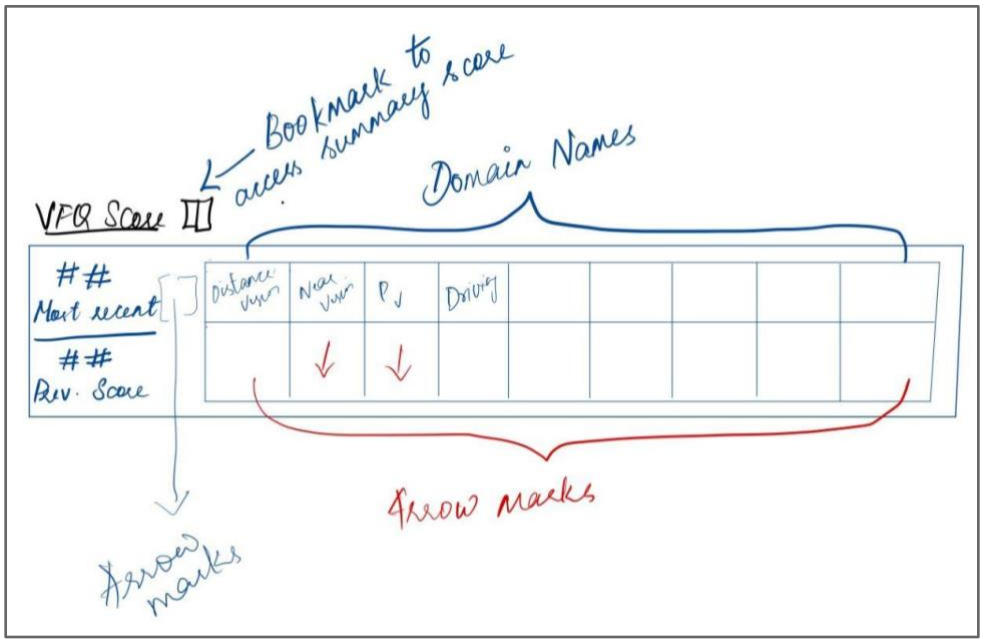
We analyzed the data collected from the think-aloud semi-structured interviews using thematic analysis to identify recurring patterns, themes, and insights regarding the usability and effectiveness of the VFQ-9 report prototypes. Thematic analysis involves a systematic process of coding, categorizing, and interpreting the qualitative data to uncover meaningful themes and patterns within the participants' responses. This process allowed for the identification of key issues, concerns, and preferences related to the VFQ-9 report prototypes.

5.2.6 Ethical considerations:

The study complied with ethical guidelines and was determined to be exempt by the University of Michigan's Institutional Review Board (IRB) (HUM00201862) due to the minimal risk involved.

5.3 Results:

We developed initial prototypes based on the needs identified from the contextual inquiry and our understanding of the users. These prototypes were rough sketches (Figure 14) co-created with two providers who actively utilize the VFQ-9 in their clinical practice. Based on provider needs and requirements, we made the following changes to the display.



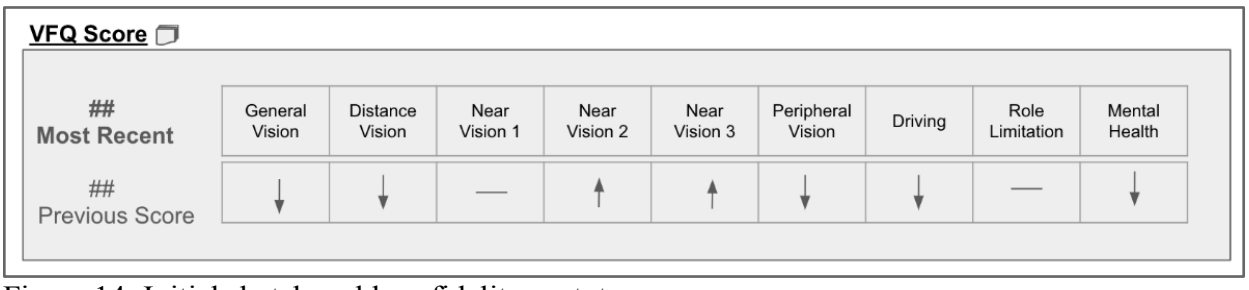


Figure 14: Initial sketch and low-fidelity prototype

The current VFQ-9 report provides a single composite score which providers identified as insufficient for a detailed clinical analysis and decision-making.

Also, the VFQ-9 sub-domain results are represented in an ordinal scale format. While informative, providers noted that this is challenging to interpret quickly and effectively during consultations.

Clinicians emphasized the need for visualizations that quickly convey changes in the composite score and individual domains. In response, the prototype was updated (Figure 15) to display the latest composite scores next to previous ones, with domain score fluctuations marked by intuitive upward or downward arrows.

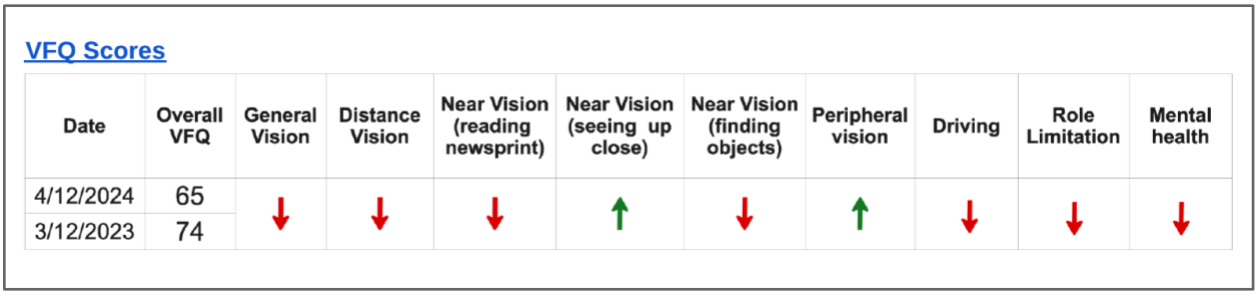


Figure 15: Prototype 1 (Snapshot report)

5.3.1 Usability evaluation:

We conducted 1:1 usability evaluation session with nine participants using think-aloud semi-structured in-person and via Zoom interviews. Each participant was asked to read through the VFQ-9 report prototypes and verbalize their thoughts and reactions as they attempted to understand and interpret the information presented. This think-aloud method was instrumental in capturing insights into the participants' cognitive processes as they interacted with the reports. The interviews were recorded and transcribed verbatim, followed by a thematic analysis to distill the key insights.

Participants expressed the need for an easily interpretable data presentation. One provider mentioned, "*If you are interested, you can delve into the VFQ-9 data. But for a quick look, [...] we want a quick and easily interpretable report here. I should be able to review key data points and changes at a glance. This is nice."*

Providers appreciated having visual aids like up/down arrows and color coding in the report, which helped them quickly interpret the data. One provider noted*, "I did like the colors because I can easily visualize[...] which areas were decreased, which areas were increased. This could really speed up my data interpretation."* Another mentioned, *"It was easier to quickly glance at the colors. The green and the red give an easier, quick interpretation."*

They also highlighted the importance of displaying positive and negative patient score trends. *"I don't want to be depressed and only see the bad stuff. I also want to see the good stuff or the stable things. It's all about stability, like our goal is always stability,"* mentioned one clinician. Furthermore, another clinician highlighted, *"So overall score is really nice to have. And I like the comparison between the most recent and the previous. I like seeing changes where things have improved, not just having the decreased categories."*

Addressing the needs of colorblind users was also a concern raised. "I*f people are colorblind, obviously red and green don't work very well. So having the up/down arrow is also important*," stated one participant, indicating the need for an inclusive design.

Participants desired a more streamlined report with less clicking and faster access to information. *"And it should be on one page. The overall VFQ Score, trend, domain scores, and their trends should all be on just one page. The more you can shove on one page, the better [...] Every time I click, I have to wait, and the computers don't always work well. [...] You're trying to decrease the clicks already. So I think making only one click is better."* shared a provider.

Another suggested, *"If you click on VFQ Score[heading], I would want to be able to see the trends of the subdomains and the total composite score, all in one page."* Based on the needs, we added created another prototype (Figure 16)

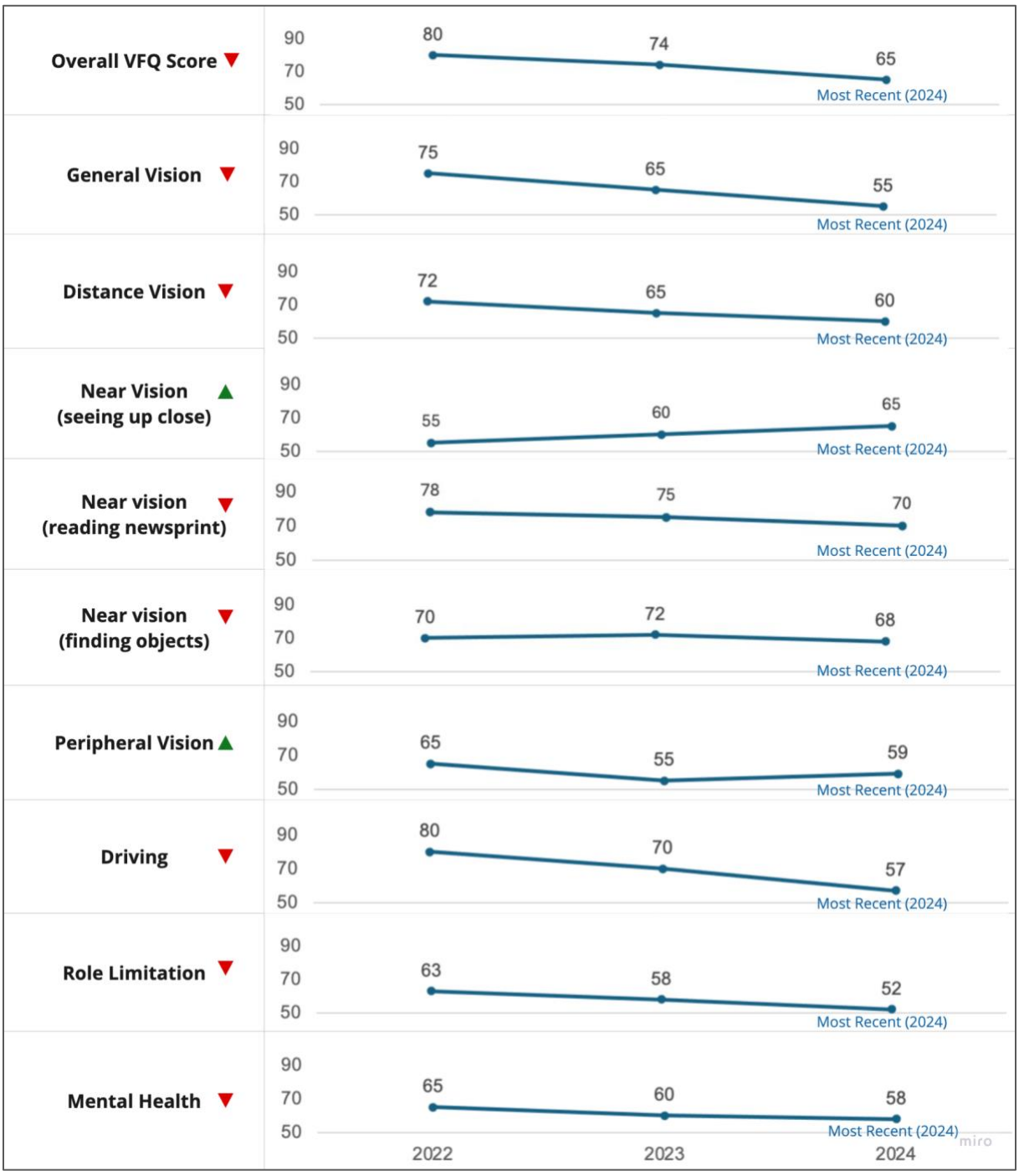


Figure 16: VFQ-9 summary report and trend data

Another provider added on the importance of displaying domain-specific scores. *"The overall score isn't the most telling factor[...]it's like asking someone's height and weight combined into one number. For instance, if two people both have a combined height and weight of 312, one could be tall and slim, the other short and heavy[...]they're completely different. Similarly, combining all VFQ domain scores into one doesn't accurately reflect distinct aspects of a patient's vision[...] it obscures critical details about specific domains. So, I need domain-specific scores to effectively assess and address different areas of visual impairment."*

Some participants suggested the integration of the VFQ scores into commonly used screens to enhance visibility and utility in clinical decision-making. *"You know how there's an overview of the vision and IOP in other screens as well[...] I would need it [VFQ-9 scores] like that, too. It's nice to have the vision and the pressure outside of here [eye exam screen]; it would also be nice to have this VFQ-9 on multiple screens to have visibility. We will be able to use it better that way,"* a participant expressed. Another clinician added, "*I currently do not look at the VFQ-9 scores. But if the scores are moved into a space that I look at more often, it would [..] change the way [...] I use this information to inform my clinical decision-making. If it's more in the space that I'm used to looking at to make decisions. [...] It's probably better."*

In response to the requirement, we also created some prototypes with VFQ-9 integrated into multiple screens

From this analysis, we developed user stories (Table 4) that captured the participants' needs and preferences.

Story	As a	I want	So that
1	provider	VFQ-9 summary data on a single page	I can access all data at once without having to do multiple clicks
2	provider	the VFQ-9 report to visually display both improvements and declines	I can assess the overall stability and changes in patient conditions for a balanced understanding.
3	provider	changes in the VFQ score to be color-coded like green for improvement and red for decline	I can easily distinguish between areas of improvement and decline, making data interpretation faster.
4	provider	domain-specific VFQ-9 scores	I can effectively assess and address different areas of visual impairment, ensuring targeted and precise treatments.
5	provider	a trend for VFQ-9 scores across multiple visits	I can assess the effectiveness of interventions and observe long-term changes in the patient's visual function.
6	provider	an easily interpretable VFQ-9 report	I can efficiently review key data points and changes at a glance, optimizing time during consultations.
7	provider	VFQ-9 scores integrated into the screens I use most often	I can effectively correlate the scores with clinical data.
8	provider	the report to include up/down arrows in addition to color-coding	providers who are colorblind can also interpret the score changes

Table 4: User stories

These stories were then mapped (Figure 17) to the elements of the final design to ensure that all user feedback was effectively incorporated. This approach ensured that the redesigned VFQ-9 report prototypes met user requirements for a more intuitive and comprehensible tool.

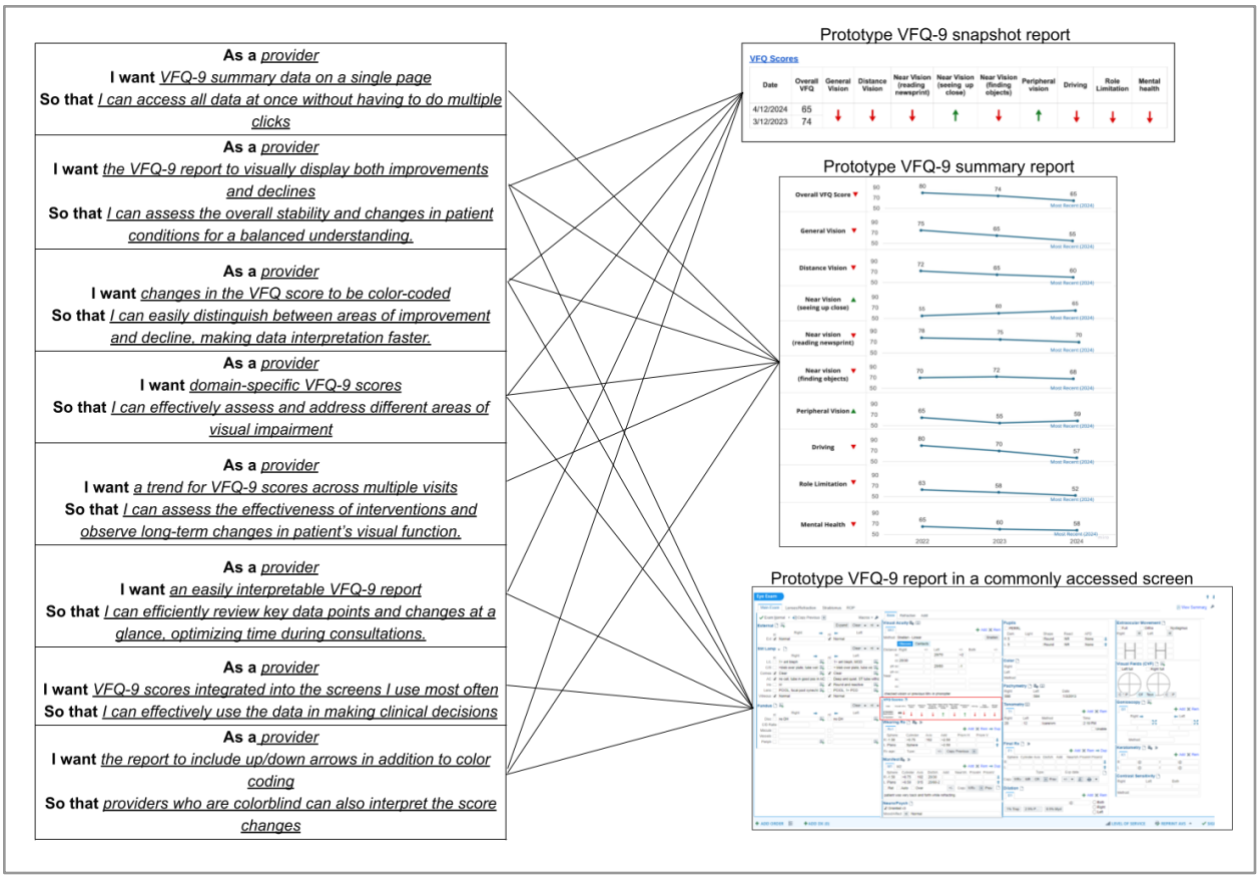


Figure 17: User story mapping with the prototypes. Lines indicate that a prototype satisfies the requirement.

5.4 Discussion

Our study focused on designing an intervention to report and use PROs in clinical practice. We found that providers highly valued specific design features aimed at enhancing usability. For example, providers preferred visual aids like arrows and color coding to interpret changes in patient data quickly. This preference underscores how critical user feedback is in shaping design decisions, which in turn improves the practical utility and efficiency of clinical consultations. Such insights highlight the significant impact of direct user involvement on the overall effectiveness of healthcare technologies.

The integration of patient-reported outcomes (PROs) into routine healthcare practices to enhance patient-centered care has been emphasized in the current research.[188] Studies, such as those conducted by Basch et al., have demonstrated that effective use of PROs in routine clinical care can lead to improved patient satisfaction and treatment outcomes.[167] However, these studies also highlight a significant gap in the integration of PRO tools into daily clinical workflows, often due to the inaccessibility of PRO data within clinical interfaces.[189] Our study addresses this gap by showcasing how user-centered design can facilitate the integration of PROs into EHR systems, thereby ensuring that these tools are not only accessible but also have the potential to enhance user engagement and satisfaction, which are critical for the adoption and effective use of PROs in clinical practice.

While there is a solid foundation for the value of PROs in clinical settings, there remains a disconnect between the availability of PRO data and its routine use during clinical decision-making.[190]. Despite the availability of sophisticated PRO measures, their adoption is often hindered by system design and user interface challenges.[46,191] Our study offers recommendations (Table 5) for designing EHR-integrated interventions that support the reporting and use of PROs. As the clinicians in our study suggested, healthcare providers may potentially make more informed and timely decisions by integrating VFQ-9 scores into commonly used interfaces within the EHR. This approach has the potential to improve the usability of PRO data and enhance the overall quality of patient care. Looking forward, our research suggests a roadmap for future EHR system designs that prioritize user-friendliness and accessibility, ensuring that PROs become integral components of clinical practice rather than peripheral elements.

Moreover, the study underscores the importance of tailoring the tool to the specific context and user needs, including considerations for colorblind users, which highlights the

necessity of inclusive design in digital interventions. By addressing these unique user requirements, the redesigned VFQ-9 report aims to enhance usability for all clinicians, thereby encouraging broader adoption and more effective utilization. The process of mapping user stories to design elements was key to ensuring that all identified needs were met in the final designs.

Our study has several limitations. The study's focus on a single clinical setting may limit the generalizability of our results to other contexts or specialties. Additionally, the enthusiasm and specific suggestions of users who are already familiar with the VFQ-9 might not represent the broader range of potential end-users. Future studies should examine the application of UCD principles across various healthcare settings and with different types of PROs to validate our findings and explore their broader implications. Our findings suggest that involving users in the design process is not merely beneficial but essential for developing technologies that enhance patient care and clinical efficiency. Our study advocates for a paradigm shift towards more inclusive and participatory design practices in healthcare IT, aiming to bridge the gap between technology development and clinical utility.

Intervention Content

- The intervention should include composite and domain-specific PRO scores to provide detailed insights into specific areas of visual function.
- The PRO scores should be available as a snapshot report for quick viewing of the scores
- The PRO summary score data should be presented on a single page for quick and comprehensive review.
- The PRO scores should be integrated into the EHR screens that clinicians use most often to streamline access to patient-reported outcomes.

Delivery characteristics

- The PRO report should be integrated into the EHR, enabling clinicians to quickly access and act on the data.
- The report should visually display both improvements and declines in patient-reported outcomes.
- The visualization should implement color-coding for changes in PRO scores, using green to indicate improvements and red to indicate declines.
- The report should show trends for PRO scores across multiple visits to track patient progress over time.
- The report should include up/down arrows in addition to color-coding to clearly indicate increases and decreases in PRO scores for quick comprehension.

Table 5: Summary of design recommendations for provider-facing EHR- integrated intervention for PRO reporting in Ophthalmology

5.5 Conclusion:

This research demonstrates the potential benefits of applying user-centered design methodologies to the refinement of clinical reporting tools in ophthalmology. By engaging end-users in the design process and incorporating their feedback through iterative prototyping and evaluation, we developed VFQ-9 report prototypes that significantly improve upon the existing

system. These prototypes not only meet the specific needs of clinicians but also have the potential to enhance the overall usability and effectiveness of PROs in clinical practice.

As healthcare continues to evolve towards more patient-centered approaches, the integration of enhanced PRO tools like the VFQ-9 into clinical workflows becomes increasingly vital. The insights from this study provide a valuable framework for future developments in PRO tool integration within ophthalmology. The implications for practice are clear: more intuitive, accessible, and comprehensive PRO tools have the potential to transform patient care by enabling more informed and patient-centric clinical decision-making.

Further research should explore the long-term impact of these redesigned tools on clinical outcomes and patient satisfaction. Additionally, expanding this approach to other fields of medicine could yield significant benefits across the healthcare system, promoting a more holistic and nuanced understanding of patient health and treatment outcomes.

Chapter 6 Discussion

This dissertation aimed to advance our knowledge on the application of UCD principles in the design of an EHR-integrated provider-facing reporting tool for PROs in ophthalmology. The integration of PROs into routine clinical practice faces significant challenges, including systems that fail to align with healthcare providers' specific needs, leading to data overload, and disruption of workflows.[138] This often results in the underutilization of PRO data, despite its potential to deepen understanding of patient conditions and improve treatment outcomes.[158]

User-centered design offers a solution by aligning the development of the intervention with the actual needs, preferences, and daily operations of healthcare providers. This research not only aims to design a tailored reporting tool for ophthalmologists but also to establish design recommendations for similar tools in the field. By focusing on the end-users, our study offers practical and impactful solutions, that have potential to enhance the adoption and effectiveness of PROs in ophthalmology and serve as a model for similar initiatives in other medical specialties.

In Chapter 1 of this dissertation, we established a foundational understanding of PROs,[190] their routine use in clinical practice, and the prevailing challenges associated with their integration.[192] The review highlighted that while PROs hold significant potential to enhance patient-centered care, their implementation often faces barriers such as poor system integration and lack of user-friendly interfaces. The literature also explored how digital interventions could facilitate the delivery of PROs[193] by improving accessibility and interaction, ultimately enhancing the efficiency of clinical workflows. Additionally, the review underscored the critical

role of user-centered design (UCD) in developing digital interventions. By prioritizing the needs and preferences of end-users, UCD emerges as an essential approach for creating interventions that are not only effective but also widely adopted in clinical settings.[136,183] This synthesis of existing knowledge framed the subsequent research questions and methodology, guiding the development of a tailored, user-centered PRO reporting tool aimed at addressing the identified gaps and enhancing the application of PROs in ophthalmology.

Utilizing the VFQ-9 as a measure, in Chapter 3, through Research Question 1, we explored how vision-related quality of life varies based on demographic factors such as age, gender, socioeconomic status, and ethnicity. The results demonstrated significant differences in the quality of life based on the demographic factors, aligning with broader healthcare research that indicates the impact of demographics on health outcomes. Additionally, we analyzed how each of the seven domains within the VFQ-9 such as General Vision, Near Vision, Distance Vision, Peripheral Vision, Driving, Mental Health and Role limitation varied across our study population and their demographic characteristics. This analysis was critical to determine if significant differences existed between the domains, and to determine if there is value in displaying these domain-level score changes to clinicians for each patient. When we analyzed VFQ-9 data, we found that the average composite score for the total population was 81.2, indicating a relatively good vision-related quality of life. However, domain-specific analysis revealed significant disparities; the average score for mental health was notably lower at 64.9, followed by general vision at 70.2. This variation highlights the critical need for clinicians to have access to detailed domain-specific data, which can greatly improve the personalization of patient care. This study offers a novel perspective exploring variations in quality-of-life scores based on demographic factors within the field of Ophthalmology. This is crucial as it enables

clinicians to tailor interventions more effectively by understanding which aspects of vision-related quality of life are most affected by patient demographics. By providing detailed insights into domain-specific responses, this research enriches the existing knowledge base, helping to develop personalized care strategies that address the unique needs of diverse patient populations, and ultimately improving treatment outcomes.

In Chapter 4, we conducted a contextual inquiry to understand the workflow, user information needs and preferences to use VFQ-9 within routine clinical practice at the eye center. Our findings revealed that integrating PROs like the VFQ-9 is feasible and beneficial for enhancing communication and decision-making between patients and providers. However, significant operational challenges were uncovered, such as low patient engagement with digital tools for completing the VFQ-9 questionnaire, inadequate accessibility features within the patient portal, and the limited availability of devices to collect the VFQ-9 in clinical settings. These significantly hindered the collection of PROs. During semi-structured interviews providers emphasized the importance of capturing subjective experiences of vision impairments which is not always evident through clinical examination. Yet, they faced significant challenges with workflow inefficiencies and EHR system limitations that hindered the effective use of VFQ-9 scores. Providers stressed the need for quick access to VFQ-9 results and improved visualization within the EHR to minimize disruptions and facilitate easier interpretation during patient consultations. The importance of continuous training and tailored educational resources was also underscored to enhance the understanding and effective use of PRO/VFQ-9 scores. These insights are vital for developing refined systems that meet the nuanced needs of both patients and healthcare providers, promoting better adoption and usability of PRO tools.

In Chapter 5, to answer Research Question 3, we delved into the design and functionality of the PRO report integrated within the EHR system, focusing on creating a tool that both aligns with clinician needs and support in clinical decision-making. The final design of the PRO reporting tool was the result of an extensive, iterative process based on direct feedback from end-users. This user-centric approach ensured that each iteration of the tool was progressively refined to better meet the practical demands of daily clinical use. The interface of the PRO report is streamlined to present complex data in a clear, digestible format, reducing cognitive load and enabling quick interpretation. By simplifying the presentation of data, the tool can help clinicians quickly assess critical patient-reported outcomes in a busy clinical setting where time is limited, and data utility is paramount. Further, the design process paid special attention to integrating the PRO tool within existing workflows of the EHR system, aiming to ensure that accessing and utilizing PRO data does not disrupt the natural flow of patient consultations. The tool features intuitive navigation and is embedded within the usual EHR environment, which reduces the learning curve and resistance often associated with new technology adoption. To enhance usability and effectiveness, the tool also incorporates visual aids such as graphs and color-coded arrows, that highlight areas of concern or significant changes in a patient's health status over time. These visual aids are designed based on clinician feedback, which indicated a preference for at-a-glance information that could be easily discussed with patients during consultations. By thoroughly aligning the PRO reporting tool's design with user feedback, the tool can not only support the effective use of PROs in ophthalmological care but can also contribute to a more responsive and efficient healthcare delivery system.

6.1 Through Learning Health System Lens:

Using the Learning Health System (LHS) lens, we identified the elements of LHS within this work. As defined by the Institute of Medicine (IOM), an LHS is "a system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families as active participants in all elements, and new knowledge is captured as an integral by-product of the care experience".[194] Successful integration of PROs hinges on robust governance, seamless integration into clinical workflows, and effective reporting mechanisms. Specifically, the generalizable guidelines to adopt an LHS approach to integrating PROs across the healthcare organization highlight the importance of defining clear objectives, developing IT strategies, establishing formal governance structures, and fostering continuous learning and multidisciplinary engagement.[195]

By continuously leveraging the existing infrastructure and engaging in iterative learning cycles, our study aims to support real-time data analytics, enhance patient care, and foster a culture of continuous improvement. This aligns with the core principles of an LHS, where data, technology, and clinical practice intersect to generate and apply evidence-based insights in a continuous feedback loop. Our provider-facing intervention exemplifies the practical application of the learning cycle (Figure 18), where data is translated into knowledge, knowledge is applied in practice, and practice informs further data collection.

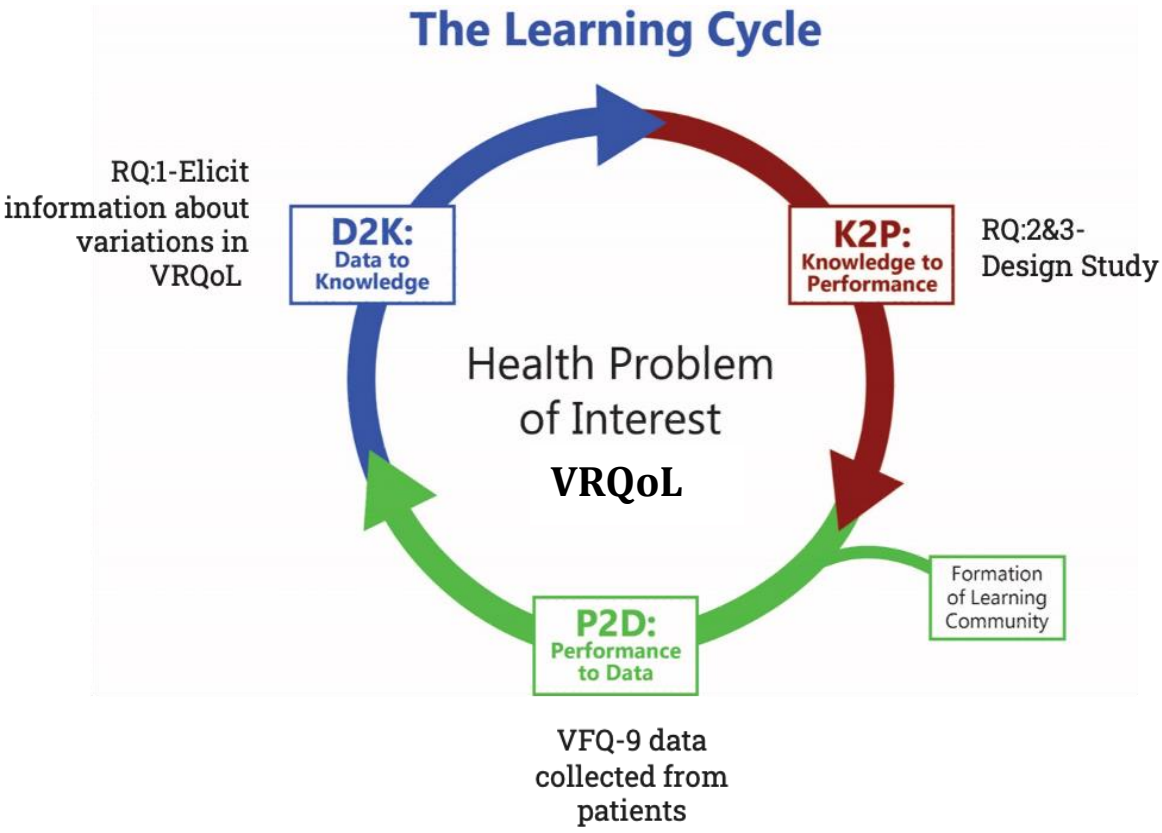


Figure 18: Through the LHS Lens

Practice to Data (P2D): VFQ-9 PRO data is routinely collected and reported, indicating the patients' experience of their health. This ongoing data collection can help facilitate understanding of the impact of interventions and identify areas for further improvement through analysis in the following stage of the cycle.

Data to Knowledge (D2K): We analyzed VFQ-9 PRO data and additional patient data to identify variations in the scores, transforming raw data into actionable knowledge.

Knowledge to Practice (K2P): To integrate the knowledge derived from PRO data into clinical practice, we designed a provider-facing digital intervention that presents PRO data to clinicians for decision-making. Features like single-page summaries, color-coded score changes, and trend visualizations enable clinicians to quickly interpret patient-reported outcomes and make informed decisions.

Once these interventions are implemented, new performance data are collected in the subsequent P2D phase as the cycle continues. This feedback loop can help promote a culture of continuous learning and improvement. We notice that as this study aligns with the core principles of LHS, where continuous learning and adaptation drive meaningful improvements in healthcare delivery, there is a potential for an eye center to become a learning health system, that responds to patient needs and fosters innovation in ophthalmic practice.

6.2 Future Work

This dissertation sets a foundation for future work in using PROs in routine clinical practice in Ophthalmology. While this study explored how quality of life scores change based on demographic factors, further research could expand these analyses to study how these demographic factors can predict VFQ scores. This would help to develop predictive models that could be integrated into clinical decision-making processes, allowing for more personalized patient care. Understanding these predictive relationships could also aid in designing targeted interventions that preemptively address potential declines in vision-related quality of life, enhancing both preventative care and treatment outcomes. In Chapter 4, we conducted a contextual inquiry to understand the workflow challenges and user needs related to a PRO reporting tool in routine clinical care. While this involved observations and interviews with several key stakeholders, patient perspectives were not included. Future research should seek to integrate patient viewpoints to deepen understanding of the challenges they encounter when completing the PRO questionnaire. Capturing these insights is crucial for identifying necessary improvements in the patient portal, which would support patients to more easily and effectively complete the VFQ-9. Additionally, future studies should aim to include a national-level sample of clinicians to understand the broader spectrum of information needs and preferences for using

PROs in routine clinical practice. This expansion would provide a more comprehensive view of the diverse clinical environments across the country, enhancing the generalizability of our findings. By gathering insights from a wide range of geographical locations and healthcare settings, we can better tailor the PRO reporting tools to meet the varied demands of clinicians nationwide, ensuring that the developed solutions are adaptable and effective across different contexts.

Appendix A: Visual Function Questionnaire 9

Q1. General vision (6-level)
At the present time, would you say your eyesight (with glasses or contact lenses, if you wear them) is: 1) excellent, 2) good, 3) fair, 4) poor, 5) very poor, or 6) are you completely blind?
Q2. Well-being/mental health (5-level)
How much of the time do you worry about your eyesight? 1) None of the time, 2) a little of time, 3) some of the time, 4) most of the time, or 5) all of the time.
Q3. Near vision, reading normal newsprint (6-level)
How much difficulty do you have reading ordinary print in newspapers? 1)No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, 5) stopped doing because of your eyesight, or 6) stopped doing this for other reasons or not interested in doing this.
Q4. Near vision, seeing well up close (6-level)
How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, sewing, fixing things around the house, or using hand tools? 1) No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, 5) stopped doing because of your eyesight, or 6) stopped doing this for other reasons or not interested in doing this.
Q5. Distance vision, going downstairs at night (6-level)
Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? 1) No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, 5) stopped doing because of your eyesight, or 6) stopped doing this for other reasons or not interested in doing this.
Q6. Driving (6-level)
How much difficulty do you have driving during the daytime in familiar places? 1) No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, stopped doing because of your eyesight, or 5) stopped doing this for other reasons or not interested in doing this.
Q7. Role limitation (5-level)
Are you limited in how long you can walk or do other activities such as housework, childcare, school, or community activities because of your vision? 1) All of the time, 2) most of the time, 3) some of the time, 4) a little of time, or 5) none of the time.
Q8. Peripheral vision (6-level)
Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along? 1) No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, 5) stopped doing because of your eyesight, or 6) stopped doing this for other reasons or not interested in doing this.
Q9. Near vision, finding objects on a crowded shelf (6-level)
Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? 1) No difficulty at all, 2) a little difficulty, 3) moderate difficulty, 4) extreme difficulty, 5) stopped doing because of your eyesight, or 6) stopped doing this for other reasons or not interested in doing this.

Appendix B: Table-Themes and Representative Quotes from Provider Interviews

Table B.1: Themes and representative quotes from provider interviews

Themes	Codes	Representative Quotes
Theme 1: VFQ for Improved Patient Communication and Engagement	VFQ helps in understanding patient's perspectives of their vision	"Some people are just a lot more sensitive to little imperfections in their vision compared to other patients. And so I get to know them a little better with the VFQ. Just more of their perception of what it's like outside of the exam room, like what it's like to live their life with their vision."
	VFQ is short and specific	"[VFQ-9] is one of the more accessible questionnaires because of its length. Most people can complete it in three or four minutes. Most patients, especially with something like glaucoma, which is the majority of my patient population, are deeply concerned with their long-term ability to continue doing all of their daily functional activities. And this questionnaire gets at those things."
	VFQ helps in improving conversations with patients	"I see some conditions that don't manifest as clinical signs that I can see on examination. And really a lot of that is subjective. So specifically for my world, dry eye, a lot of people can have very little clinical signs on eye exam, but they can be very symptomatic and very functionally impaired. So, the VFQs are really invaluable in capturing the patient's subjective experience, allowing us to tailor treatments more effectively to their specific needs."
Theme 2: Challenges and Limitations in Using VFQ-9	VFQ increases time/ workload	"The challenge is time. The time it takes for me to look at it. [...] In some clinics, the technicians actually take time during the visit to answer the question, [...], and record their answers. And nobody likes that because it takes technician time, increases workload, and delays clinic visits."
	The current VFQ workflow is not ideal	"It's tough because [...] sometimes the patients aren't even finished with the questionnaire by the time the technician is done working them up. So they're usually finishing the questionnaire while they're waiting to see me. [...]. So then it's not available to me in the EHR when I'm actually seeing the patient. [...] So it's not available to me unless I go through the paper and add up. I don't even know how it works everywhere, but the whole workflow should be streamlined".

Themes	Codes	Representative Quotes
	VFQ not completed prior to the visit	“The technicians are administering the [VFQ] questionnaire often. Even still, that's [...] three or four minutes, sometimes in a busy clinic, the technician will move through 100 patients. So that's literally hundreds of minutes of asking these questions. I think if patients could complete this prior to their visits, that would be great.”
Theme 3: Information needs for using VFQ-9	VFQ results should be easily accessible within the EHR	“I actually have no idea where even to find the results of the VFQ. I don't know where to find it in EHR. That's how little we use it. But if it was there and readily available, yeah, I’d review it.”
	Need domain-specific VFQ scores	"It's important to see changes within each VFQ-9 domain so that we can tailor our approach to precisely address the areas where patients are experiencing difficulties."
	Need time point and time series data for VFQ results	“It's nice to know what it [VFQ score] is that day, but we can also hit if there's a trend button or a graph button where we can trend it over time, and I think both of those will be helpful.”
	Need simple and quick-to-interpret visualization	“In terms of visualization, the simpler, the better. I need to be able to look at it in like 5 seconds and take it in. However, that works."
	Need VFQ results closer to Visual Acuity scores	“If I can view the VFQ data [...] side by side with the clinical data [...], for example, visual acuity and intraocular pressure are things that just pop up right in front of you when I open a patient chart. If this[VFQ score] was right there alongside them, I have visual acuity, intraocular pressure, and VFQ. Then it went in the face, and I couldn't miss it even if I'm moving fast; it would be impossible to miss this.”
Theme 4: Educational Needs for VFQ Utilization	Need more education on the clinical utility of PROs	"I think tailoring why VFQ is helpful with clinical examples to each subspecialty is probably a nice way to go about doing it. [...] Tailoring to the specific subspecialty makes the VFQ much more powerful. [...] Because I don't know how clinically meaningful a VFQ score is to a specific clinical condition. And I think that clinical meaningfulness would come from being able to talk about VFQ’s clinical utility to clinicians so that they can't ignore it; except now, it is like, go find it!”
	Promoting Ongoing Dialogue on the Clinical Utility of VFQs/PROs through Internal Education Platforms	“We have different seminars like we have a fall seminar, a midwinter one, and a spring one. And that is well attended. So maybe there could be someone who could talk for 15-20 minutes about VFQ; I feel like you could cover it enough to help us understand why we should care about it”

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