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PrEYEmary Care Optical Coherence Tomography: Increasing Adherence to Retinopathy Screening

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Abstract

Background: Diabetic retinopathy (DR) is a leading cause of preventable blindness in working age adults in the United States. Nonadherence to screening recommendations persists due to significant barriers. Early detection is crucial to mitigate economic burdens and improve patient outcomes. This quality improvement project aimed to increase DR screening access for patients with diabetes at an urban Midwest safety net clinic by implementing an optical coherence tomography (OCT) screening program. Methods: A 12-week, cross-sectional study design using convenience sampling to recruit adult diabetic patients, type-1, or type-2, at a Midwest primary care clinic. Intervention involved retinal imaging scans of participants to complete annual screening per the American Diabetes Association (ADA) annual recommendations. Results: Among the 375 active patients with diabetes, there was a statistically significant improvement, (p value = 0.03), in screening rates among eligible participants, when compared pre-intervention rates. Conclusions: OCT is a useful tool to increase access and improve adherence to annual DR screening recommendations.

Key Words: Diabetic eye exam, diabetic retinopathy, tele-retinal screening, fundoscopic imaging, optical coherence tomography, quality improvement.

Acknowledgements: I would like to thank my project advisors Dianne Slager DNP and Clay Reeves DNP for their guidance, insight, and mentorship during project development and implementation.

Introduction

DR affects around 4 million individuals in the United States (US) and is the leading cause of blindness among working-aged adults.[1] Despite its prevalence, DR often goes undiagnosed until its advanced stages, emphasizing the need for comprehensive screening protocols.[1,2] The slow, often asymptomatic progression of DR not only compromises the quality of life for affected individuals but also exacts a significant economic toll contributing to millions in healthcare costs annually.[2,3] With the prevalence of diabetes in the US projected to increase, proactive measures, such as preventative screenings, are essential for early detection and intervention.[4] Eppley et al.[2] and Coney[4] identify limited access to eye care professionals due to transportation and financial constraints as a significant barrier to screening adherence among underserved and minority diabetic populations. An et al.[5] further elucidate the impact of social and educational factors, such as lower health literacy and lack of awareness about DR on adherence rates. Research reveals lower screening compliance among Black and Hispanic individuals compared to White, non-Hispanics.[1] Dilated fundus exams, the gold standard for DR diagnosis, are typically conducted by eye specialists.[6] OCT is a non-invasive imaging technique utilizing light waves to produce detailed images of the retina and optic nerve. Recent advancements in OCT technology have eliminated the need for direct eye contact or pupil dilation during scanning, resulting in a more efficient and safe process for patients. Consider also that OCT scans can typically be completed within five to ten minutes, further enhancing its accessibility and usability in clinical settings.[7] A comprehensive approach to DR management including a thorough physical exam, dilated eye exams or high-quality fundoscopic images, and primary care follow-up is crucial in alleviating the burden of this life-altering sequalae.[6] In a prospective cross-sectional study involving 329 patients, Laotaweerungsawat et al.[8] investigated the efficacy of OCT imaging in distinguishing stages of DR within an urban safety-net hospital

diabetic population. Their findings suggest that fundoscopic OCT imaging is equally effective in discerning DR severity groups in this setting as it is in tertiary referral centers.

Theoretical Framework

The Chronic Care Model (CCM) served as the framework to design the integration of technology and electronic medical record (EMR) systems as well as staff and patient education to support clinical decision-making in the care of patients. The use of regular patient engagement and empowerment activities helped to reinforce self-management strategies. In addition, community mobilization for preventive services and support of marginalized populations completes the comprehensive approach to chronic care management and use of the CCM.

The quality improvement (QI) project implemented a primary care-based OCT DR screening program at a midwestern safety net clinic. The provision of onsite OCT screening aimed to enhance patient outcomes by addressing the need for effective DR screening and management in underserved communities.

Institutional Review Board

This quality improvement study was conducted using data obtained for clinical purposes and underwent extensive consultation with the Institutional Review Board (IRB) of Grand Valley State University. This project was determined to be quality improvement (QI) by the university's Institutional Review Board (IRB), thus eliminating the need for informed consent. This study was conducted in accordance with ethical standards.

Methods

At risk participants were identified by medical staff during diabetic care appointments. Based on participant preference, patients were either scheduled for a return appointment or scanned in the primary care office during their visit using the OCT device. Images produced were later interpreted by an off-site optometrist providing analysis and follow-up recommendations. Images with final interpretation were then added to the patient EMR. OCT reports were uploaded into the patient EMR and were categorized using the most recent guidelines for DR screening from the International Council of Ophthalmology[9] and ADA[6].

Participants

This cross-sectional study recruited 32 participants using a convenience sampling of patients with diabetes seen at a clinic over 12 weeks. Inclusion criteria included adults over the age of 18 with a diagnosis of DM type-1 or type-2 that had not completed recommended diabetic eye exams within the prior 12 months. The minimum age of participants was 37 years, and the maximum was 74 years. All participants received verbal patient education regarding American Diabetes Association (ADA) screening recommendations for diabetic retinopathy.

Data Collection

Participants were scanned and an OCT report was generated, incorporated into the patient EMR, and any resulting ICD-10 code was added to the problem list. ICD-10 codes indicating referral were referred to an area ophthalmology residency clinic for follow up. Data was stored securely on a password-protected desktop housing the OCT software, with EMR access available for seamless document uploading.

Measures

Gender, age, race, and ethnicity were collected for aggregate descriptive statistics.

Analysis

A pre-implementation, retrospective chart review was conducted using the EMR to determine the number of retinal exams performed during the same three-month calendar period one-year prior to implementation of onsite OCT. It was determined that of the 375 active diabetic patients at the clinic from December 8th, 2022 to March 5th, 2023, 19 (5%) were compliant with ADA DR screening recommendations. This pre-implementation dataset was collected, analyzed, and compared to post-implementation data to determine the difference in proportions in scanning adherence from post OCT intervention.

Results

The three-month intervention data collection period for this study occurred from December 8th, 2023 to March 5th, 2024. During this time, 32 participants meeting inclusion criteria received scans equating to an adherence rate of 8.5%. The mean age of participants was 56 years with 15 (47%) being male. Additionally, 31 (97%) had no prior record of an OCT scan and 31 (97%) were Hispanic. An independent samples z proportion test was conducted to compare pre- and post-intervention DR screening adherence rates. The post implementation analysis was performed using IBM SPSS version 29 and results indicate a statistically significant difference, (p value = 0.03), demonstrating an improvement in screening adherence following the implementation of the OCT intervention. At the 90% confidence interval, p value = 0.06, the analysis demonstrated sufficient evidence that the odds of DR screening adherence post-implementation are between 1.09 and 3.09 times greater than pre-implementation. This indicates an increased likelihood that participants will adhere to screening protocols after clinic based-

OCT scanning was introduced. underscoring the effectiveness of the intervention in promoting adherence to an essential healthcare practice.

Discussion

This QI project sought to improve diabetic retinal screening access, particularly for at-risk minority populations, by implementing a clinic-based OCT program that aligns with the ADA standards of care recommendations for annual DR screening[6]. Despite ADA recommendations, adherence to DR screening continues to be an issue especially among vulnerable patient populations. OCT is a new modality that demonstrates efficacy in DR diagnosis. Through focused QI efforts, this study demonstrated both clinically and statistically significant improvements in screening adherence. However, this study has limitations that must be discussed. The relatively small sample size, single-center design, and homogeneity of participants may limit the generalizability of these findings to broader patient populations and healthcare settings. Additionally, the short data collection period may not capture long-term participant adherence patterns or the sustainability of the intervention beyond the study period.

New Contribution to the Literature

Through the implementation of streamlined processes and evidence-based interventions, this study achieved statistically significant improvements in access and adherence rates to annual diabetic retinal exams. This research contributes to the current body of literature by demonstrating the effectiveness of an OCT based program in overcoming barriers to access and promoting adherence to DR screening among underserved minority patients in an urban Midwest safety net clinic. The results of this QI project support the use of clinic-based OCT programs to enhance diabetic eye care by improving screening access.

Conclusion

Future research should prioritize larger-scale, longitudinal studies to evaluate clinic-based OCT program effectiveness in improving diabetic retinal screening adherence across diverse settings. The pursuit of qualitative research on patient perspectives can further inform interventions that promote screening adherence and identify access barriers. This study highlights improved screening adherence but underscores the need for further research to address limitations and enhance program effectiveness and sustainability.

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Increasing Adherence to Diabetic Retinopathy Screening: PrEYEmary Care Based Optical Coherence Tomography

Henry Peña

DNP Project Final Defense

April 23rd, 2024

Acknowledgements

Advisory Team

Dr. Dianne Slager, DNP, FNP-BC

Dr. Clay Reeves, DNP, NP-C

Site Mentor

Volunteer Optometrist

Objectives for Presentation

- Examine the phenomenon of diabetes and diabetic retinopathy (DR).
- Explore DR screening modalities in people with diabetes.
- Explore, synthesize, and discuss:
    - Organizational assessment
    - Literature review findings and use of optical coherence tomography for DR screening
    - Project Implementation
    - Implications for practice

Diabetes Introduction and Background

The numbers

- Total: 38.4 million people with diabetes,11.6% of United States (US) population (CDC, 2023).
- Projected to increase to 55 million by 2030 (Coney, 2019).
- Diagnosed: 29.7 million, including 29.4 million adults (CDC, 2023).
- Undiagnosed: 8.7 million people, 23.0% are undiagnosed (CDC, 2023).

Diabetic Retinopathy Introduction and Background

Diabetic Retinopathy

- DR is a leading cause of blindness and accounts for nearly 80% of legal blindness in US adults aged 20-74 (CDC, 2022).
- 8.6% of diabetics over the age of 45 had DR (CDC, 2022).
- 9.60 million diabetics in the US had DR in 2021 (Lundeen et al., 2023).
- DR Incidence is projected to increase to 10 million by 2030 and 14.6 million by 2050 (CDC, 2022).
- 1.84 million people diagnosed with diabetes had vision-threatening diabetic retinopathy in 2021 (Martinez et al., 2019).

American Diabetes Association (ADA) Standards of Care-Retinopathy

- “People with Type 1 should have an initial dilated and comprehensive eye within 5 years after the onset of diabetes”.
- “People with Type 2 should have an initial dilated and comprehensive at the time of the diabetes diagnosis”.
- “Programs that use retinal photography to improve access to diabetic retinopathy screening can be appropriate screening strategies for diabetic retinopathy”.
- “Promptly refer individuals with any level of diabetic macular edema, moderate or worse non-proliferative diabetic retinopathy, or any proliferative diabetic retinopathy to an ophthalmologist”.

(ADA, 2022, p.24)

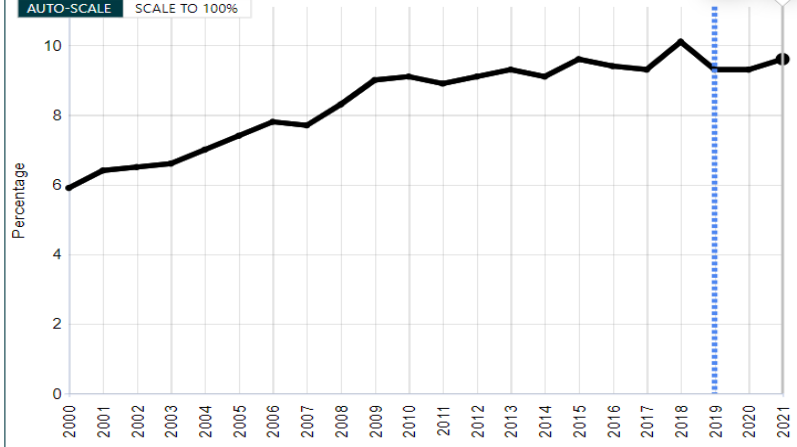
United States Crude Percentage Diagnosed Diabetes Adults 18+

Total | Age | Ethnicity | Education | Stratifications

Total

Percentage for 2021
Total - **9.6**

AUTO-SCALE | SCALE TO 100%



Major changes to the survey methods in 2019

Horizontal dotted line indicates "No Data", "Suppressed Data" or both.

Year	Total		
	Percentage	LL	UL
2000	5.9	5.6	6.2
2001	6.4	6.1	6.7
2002	6.5	6.2	6.8
2003	6.6	6.3	6.9
2004	7.0	6.7	7.4
2005	7.4	7.1	7.8
2006	7.8	7.3	8.2
2007	7.7	7.3	8.2
2008	8.3	7.8	8.7
2009	9.0	8.6	9.5

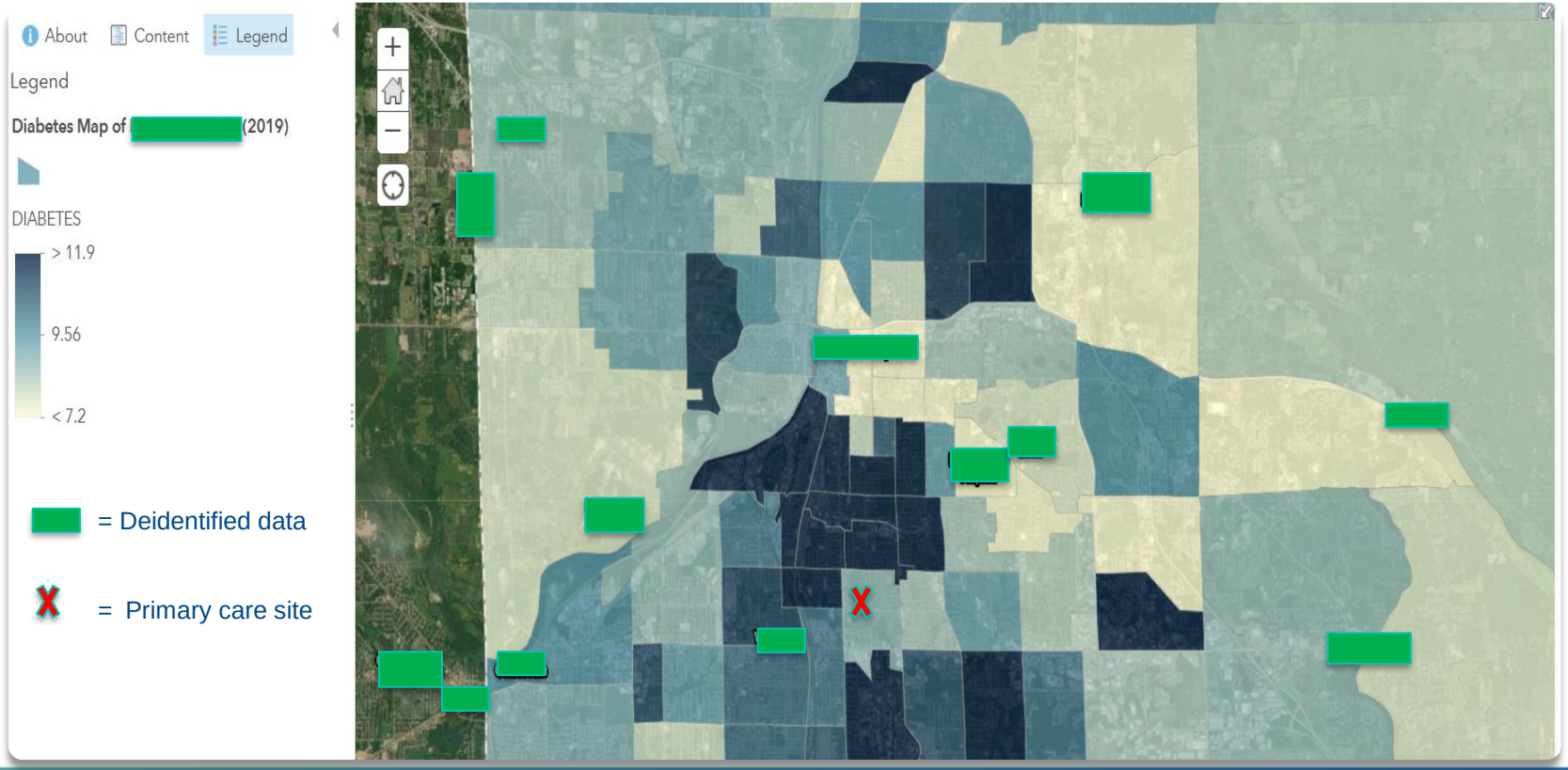
Showing 1 to 10 of 22 entries Previous 1 2 3 Next

Major changes to the survey methods in 2019

* indicates 'No Data', ** indicates 'Suppressed Data', LL - Lower Limit, UL - Upper Limit

(CDC, 2022)

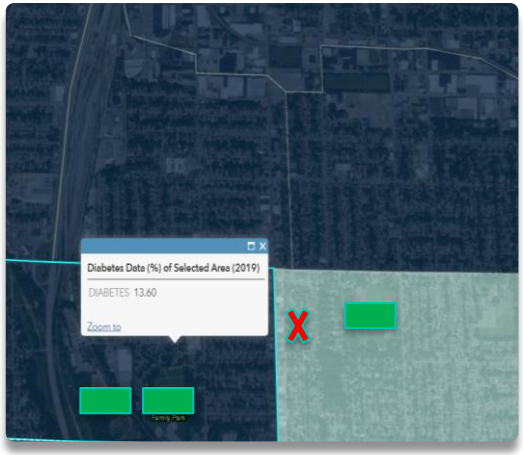
County Level Percent Diabetes



(YYYY, 2022)

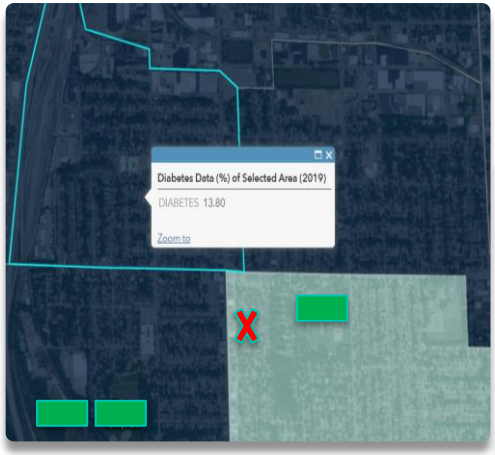
Grand Valley State University

Neighborhood Percent Diabetes



Area 1

13.60%



Area 2

13.80%

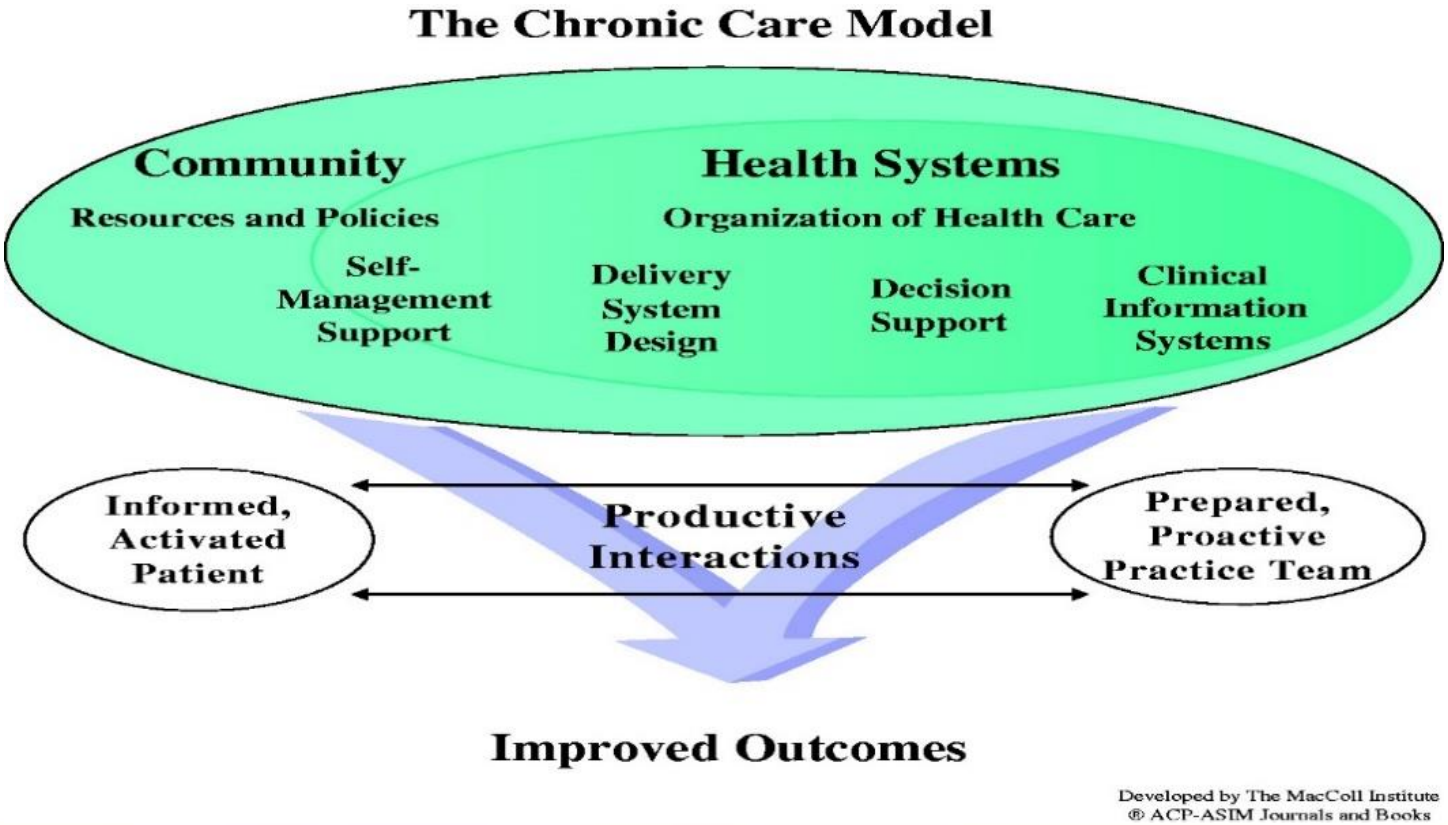
Area 3

16.30%

= deidentified data

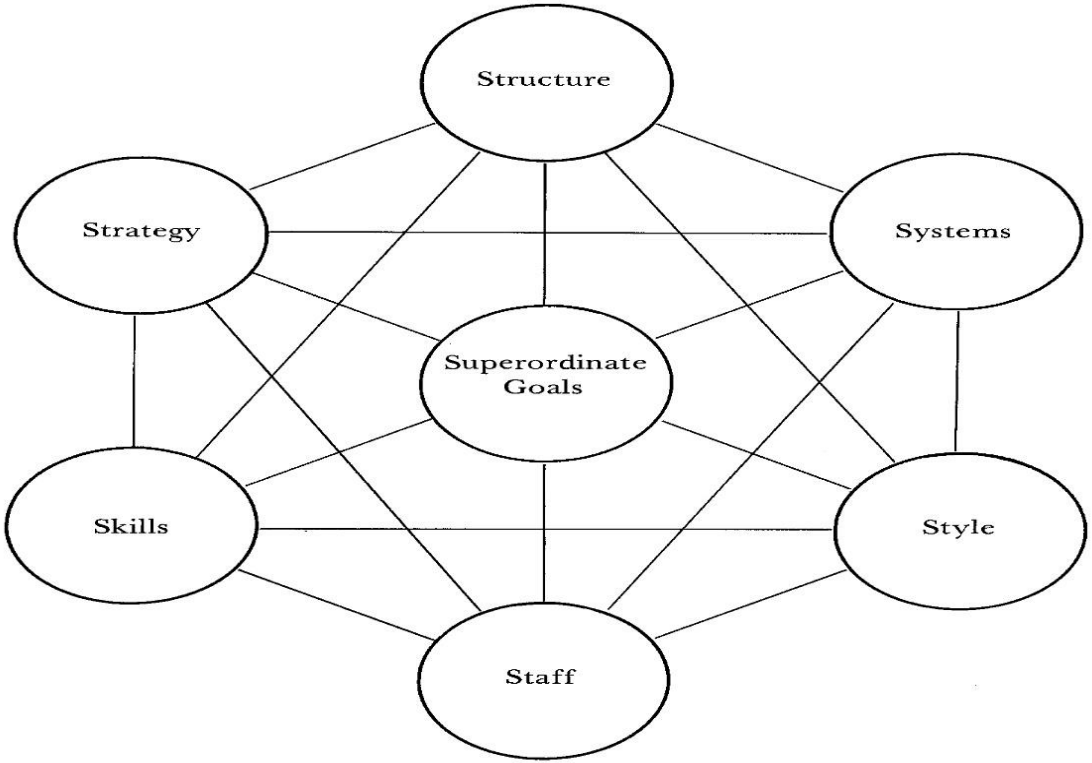
X = Primary care site

Model Guiding Phenomenon



(Wagner, 1998)

Organizational Assessment Framework
McKinsey 7S



(McKinsey & Company, 2008)

Organizational Assessment Findings (Table 1)

Safety Net Clinic

- 2500 patients served in 2021
- 48% of patients with household income below Federal Poverty Index
- 67% have no insurance
- 57% unemployed or underemployed

Integrated Healthcare

- Medical
- Vision
- Dental
- Spiritual
- Behavioral

More than fifty volunteers monthly

(ZZZZ, 2021)

SWOT Analysis

Strengths

- ***Flexible payment model for underinsured and uninsured***
- Integrated healthcare model with medical behavioral, spiritual, and dental services.
- Bilingual staff and volunteer interpreters
- ***Core group of key stakeholders and innovators***

Opportunities

- ***Leveraging community partnerships to increase funding support.***
- Purposeful engagement of surrounding Hispanic and refugee communities.
- ***Partnerships with local churches and community organizations.***
- Grant writing and fundraising activities

Weaknesses

- ***Limited operating budget limited as financial support is primarily through donations.***
- ***Large number of volunteer staff affecting workflow practices and standardization.***
- Interpretation services based on staff and volunteer availability.
- Independent organization lacking high level process structures.

Threats

- ***Loss of payor reimbursement***
- Severe weather impacting patient appointments
- Lack of stakeholder support and buy in
- Changes in reimbursement for teleretinal imaging.

Key Stakeholder Analysis (Table 2)

Clinical Practice Question

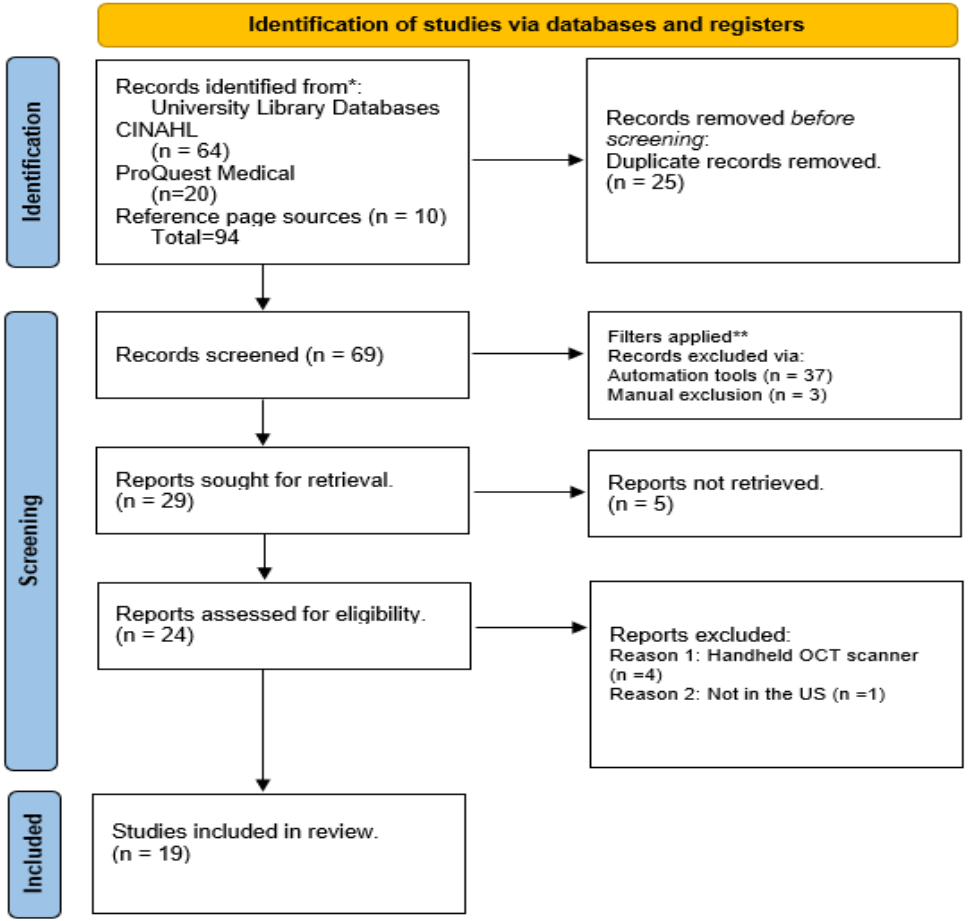
In patients over the age of 18 with type 1 or type 2 diabetes, will the implementation of a primary care optical coherence tomography (OCT) program result in increased adherence to annual DR screening recommendations?

Review Method

Integrative review

CINAHL and PubMed Medical

Prisma



(Page et al., 2020)

Literature Review Results (Table 3)

- Only 60% of adults over 18 with diagnosed diabetes had a recommended yearly screening for DR (CDC, 2022).
- “Early detection and treatment can prevent or delay blindness due to DR in 90% of people with diabetes” (CDC, 2022).
- Fundoscopic imaging is an evidence-based method to increase DR screening compliance (Hatef et al., 2017; Li et al., 2012).

Literature Review Results

- Screening strategies using OCT in combination with timely and appropriate referrals are an effective tool for the detection and diagnosis of diabetic retinopathy (Azrak, 2015; Faes et al., 2019).

- High pooled sensitivity and specificity for detection of DR (Faes et al. 2019; Gupta et al., 2017).

- Programs that use retinal photography are appropriate screening strategies with the provision of timely referral for a comprehensive eye exam when indicated (Walton et al., 2015).

Evidence for Project

- American Diabetes Association and American Academy of Ophthalmology ADA and AAO supported (ADA, 2022; AAO, 2019).
- OCT helps mitigate barriers to care access (Wandy et al., 2022).
- OCT has high sensitivity and specificity (Faes et al. 2019; Gupta et al., 2017).
- OCT has added a new perspective on understanding DR and technology is FDA approved (Manole & Shepard, 2022).

Summary of Literature Review

- OCT technology can increase compliance with annual diabetic eye exams among underserved, low-income patients in urban primary care setting (Hafef et al., 2017).
- OCT can be used to diagnose referable retinopathy (Azrak et al., 2015).
- OCT pooled sensitivity and specificity are promising for the assessment of retinal diseases (Faes et al., 2019).
- Nonmydriatic OCT has potential to be cost-effective screening modality for DR (Gupta et al., 2017).
- OCT fundoscopy provides accurate images for grading by an ophthalmologist (Joseph et al., 2023).
- Cost analysis indicates OCT is an alternative DR screening method with convenience and improved access (Li et al., 2012).
- Study suggest OCT telemedicine can improve DR screening rates in the primary care setting (Wandy et al., 2022).

PROJECT PLAN

Methods

Project Design: Quality Improvement

Setting: Urban Midwest primary care safety net clinic, Serving uninsured, underinsured patient population, primarily Spanish Speaking

Staff: Medical Staff, Physicians, volunteer optometrist

Participants:

- **Patients:** Adult (18+) patients with diagnosed type 1 or type 2 diabetes, convenience sample, cross-sectional

Purpose and Design

The purpose of this quality improvement project was to design, implement, and evaluate an OCT based DR screening program to increase adherence to American Diabetes Association retinopathy screening guidelines (ADA, 2022)

Streamlined access to Diabetic Retinopathy screening:

- Minimized patient barriers for screening
- Developed an efficient program workflow

Enhanced education and equipment use:

- Educated staff on OCT equipment usage
- Developed educational materials for staff
- Provided educational materials for patients

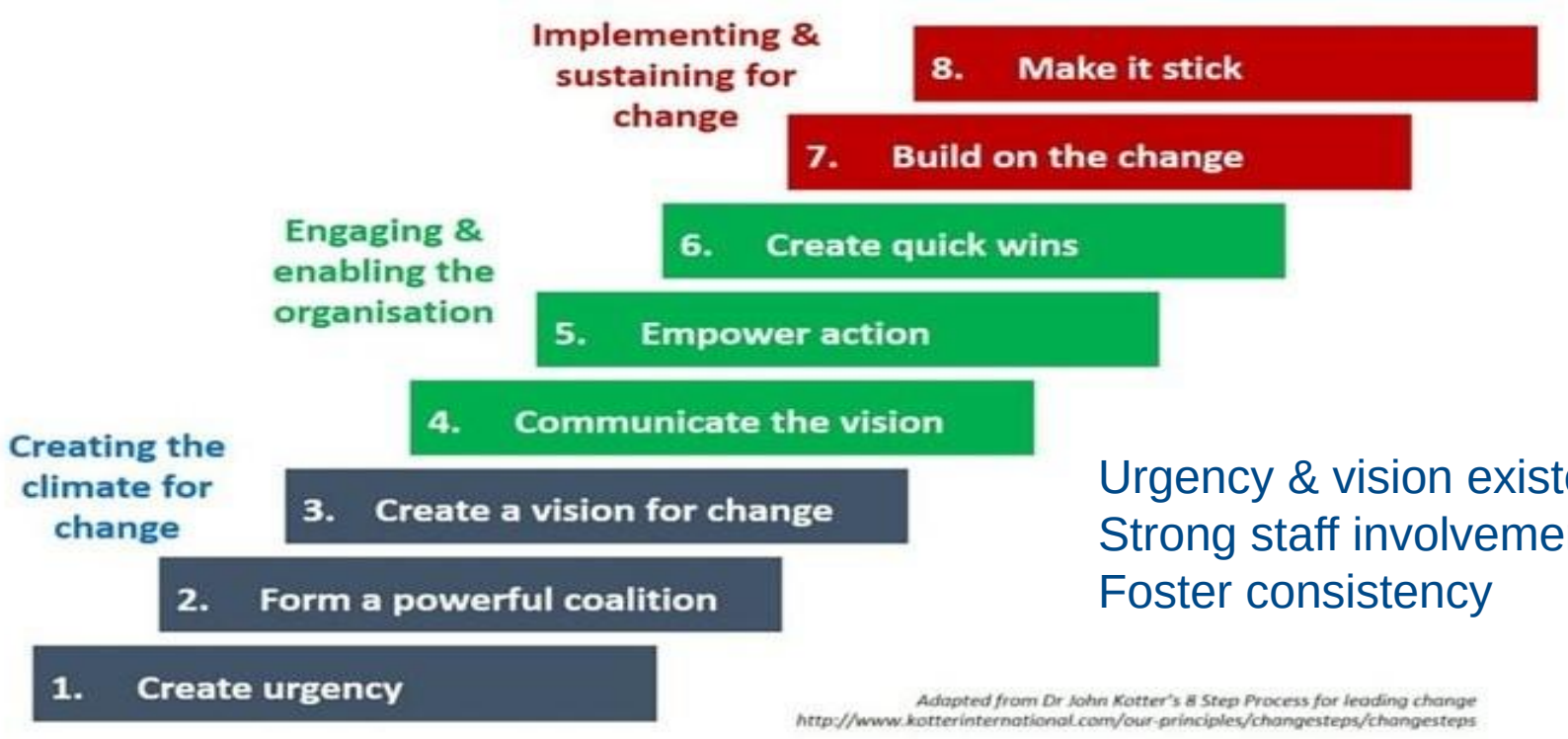
Improved patient management:

- Identified diabetic patients needing screening
- Encouraged in-office screening and refer as necessary

Project Timeline

Activity	December	January	February	March	April
Staff Education and informational meetings	X	X	X	X	X
Pre-implementation EHR data collection	X				
Intervention data collection	X	X	X	X	
Data collection ends				X	
Post-implementation data analysis				X	

Implementation Framework
Kotter's 8-Step Change Model



Urgency & vision existed.
Strong staff involvement.
Foster consistency

(EPM, 2018)

Strategies and Measures (EPM, 2018)

Topic	Concept	How Performed	Concept	When Performed	Who Measures
Creating the climate for change	"Create urgency Form a powerful coalition Create a vision for change"	EHR review for screening rates SWOT analysis Organizational assessment Stakeholder engagement Identify early adopters Literature review (LR)	Rogers' Diffusion of Innovation (Melnyk & Fineout-Overholt, 2019).	Pre implementation Pre implementation	Student Medical Staff Medical Director Optometrist
Engaging & enabling the organization	"Communicate the vision Empower action Create quick wins"	Discussed findings of LR Meetings with medical director Meeting with volunteer optometrist Updates during morning huddle Develop process workflow Workspace and room set-up Complete practice scans		Pre implementation Pre implementation	Student Medical Optometrist
Implementing & sustaining for change	"Build on the change Make it stick"	Medical staff feedback Champion training Process improvement Sustainability discussions Observe implementation and make necessary process changes	Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015). PDSA (AHRQ,2024)	Implementation	Student Medical Staff Optometrist

Outcomes and Measures

Topic	Concept	How Measured	Measures	Who Measures
Patient Outcomes	Improved DR screening compliance compared to pre-intervention	EHR audit	Post implementation	Student
	Referral to ophthalmology when medically appropriate	EHR audit	Post implementation	Student
	Increased patient knowledge and education			
System Outcomes	Addition of DR DX code to EHR	EHR audit	Intra and Post implementation	Student
	Proper Billing Code utilization when indicated	EHR audit	Post implementation Details still being finalized	Medical Director
	Improved patient DR screening compliance	EHR Statistical Analysis	Post implementation	Student
	Return of investment	EHR	Post Implementation	Medical Director
Policy Outcomes	New policy for procedure	Discussion	Post implementation	Student
	New training for appropriate staff	Discussion	Post implementation	Student

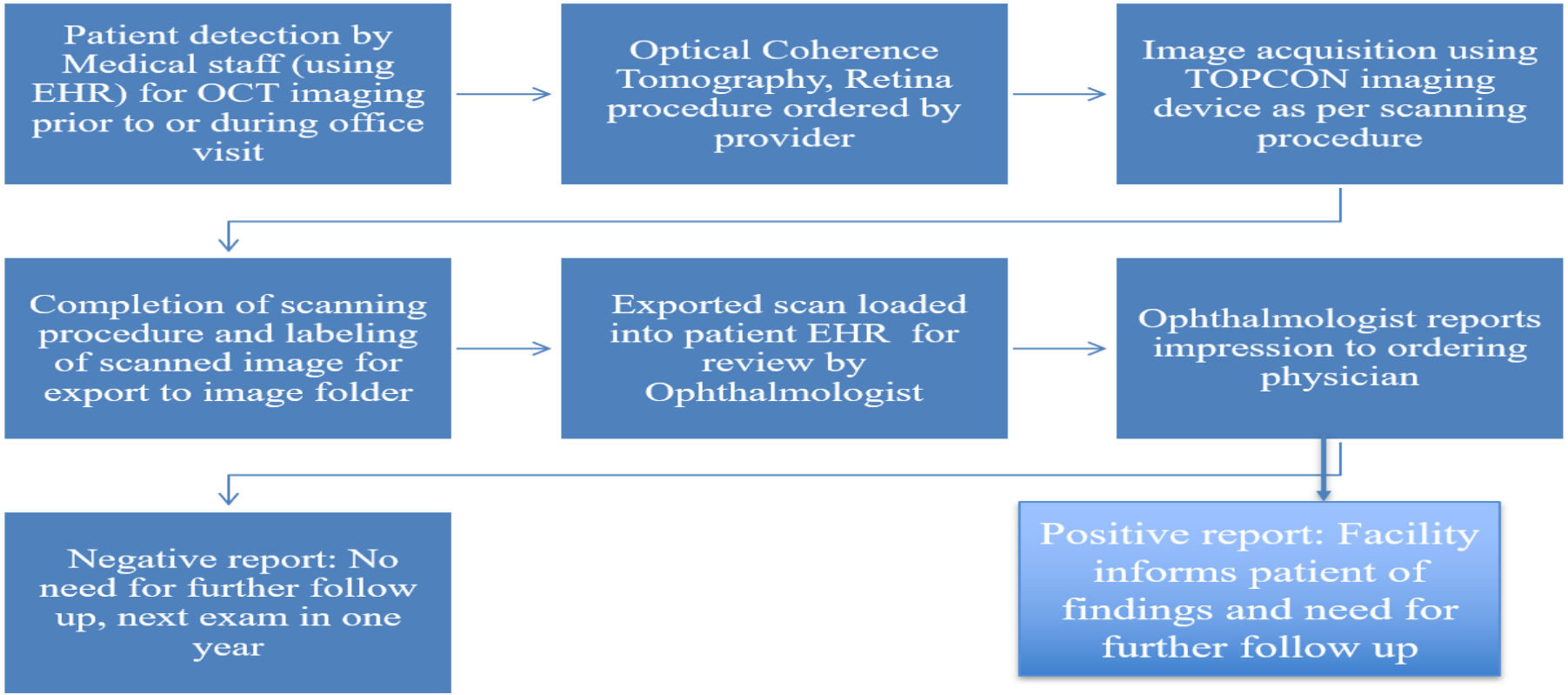
Ethical Considerations

- IRB determination completed by university review board (Figure 1).
- DNP student HIPAA compliant
- CITI Human Subjects Protection training
- Responsible Conduct of Research training
- De-identified data collected and stored on organization desktop
- Patient information protected via
  - Desktop located in a locked room
  - Password protected desktop
  - Encrypted USB flash drive used for data transfer (numerical data only)

Analysis

- SPSS version 29
- Descriptive statistics
- Independent samples Z-test to compare Pre and Post intervention proportion of patients who received DR screening exam
- Pre-intervention totals derived from previous year 12/1/2022-3/31/2023

Process Workflow



Criteria

Inclusion criteria

- Age 18+
- Diabetes type 1 or type 2

Exclusion criteria

- DR screening within the last 12 months

Results

Pre-implementation DR screening data (pre-OCT)

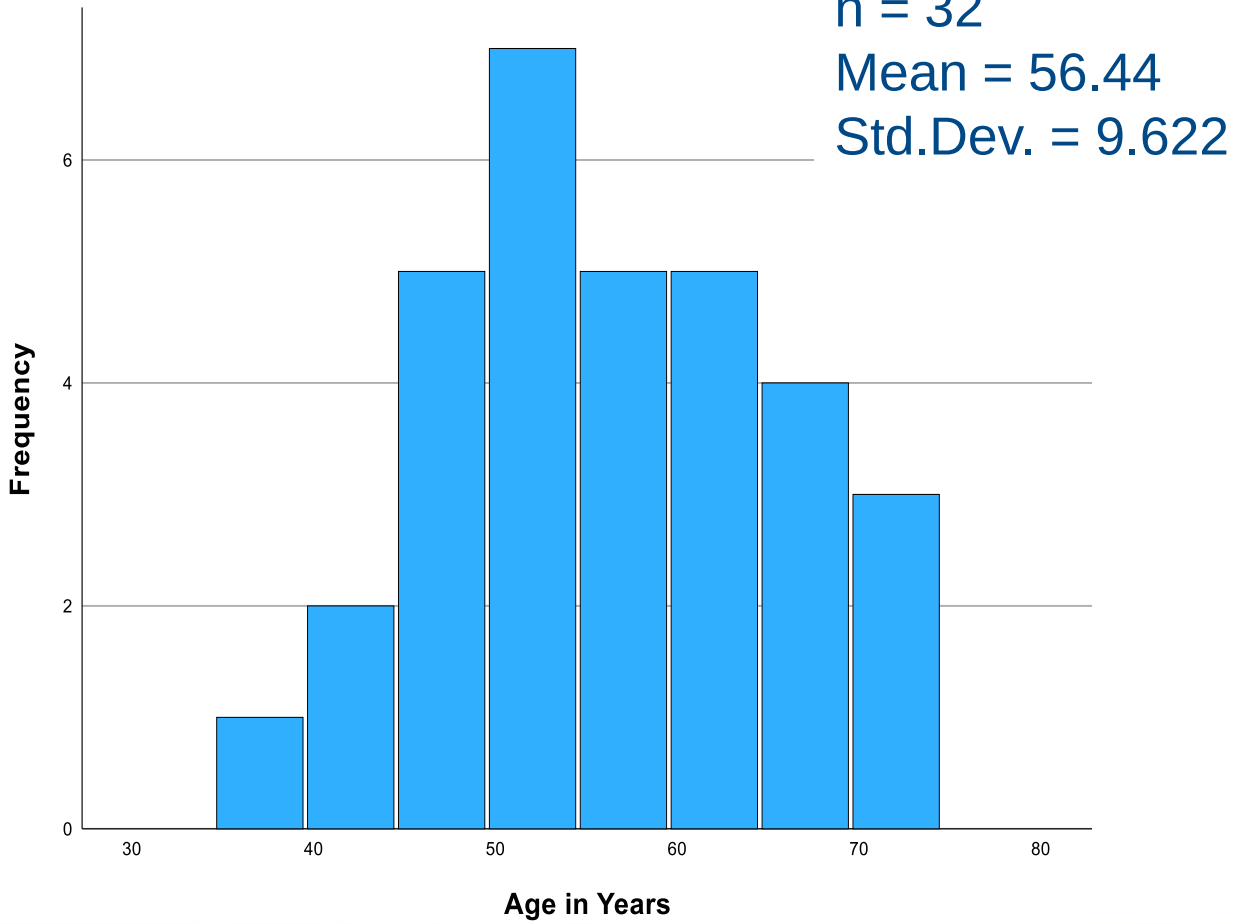
- December 1, 2022 to March 31, 2023
- Total sample size: n = 375
- Patients meeting inclusion criteria: n = 19
- Number of DR screening visits: n = 19

Post-implementation DR screening data (post-OCT)

- December 7, 2023 to March 5, 2024
- Total sample size: n = 375
- Patients meeting inclusion criteria: n = 33
- Patients excluded from study: n = 1
- Number of DR screening visits using OCT: n = 32

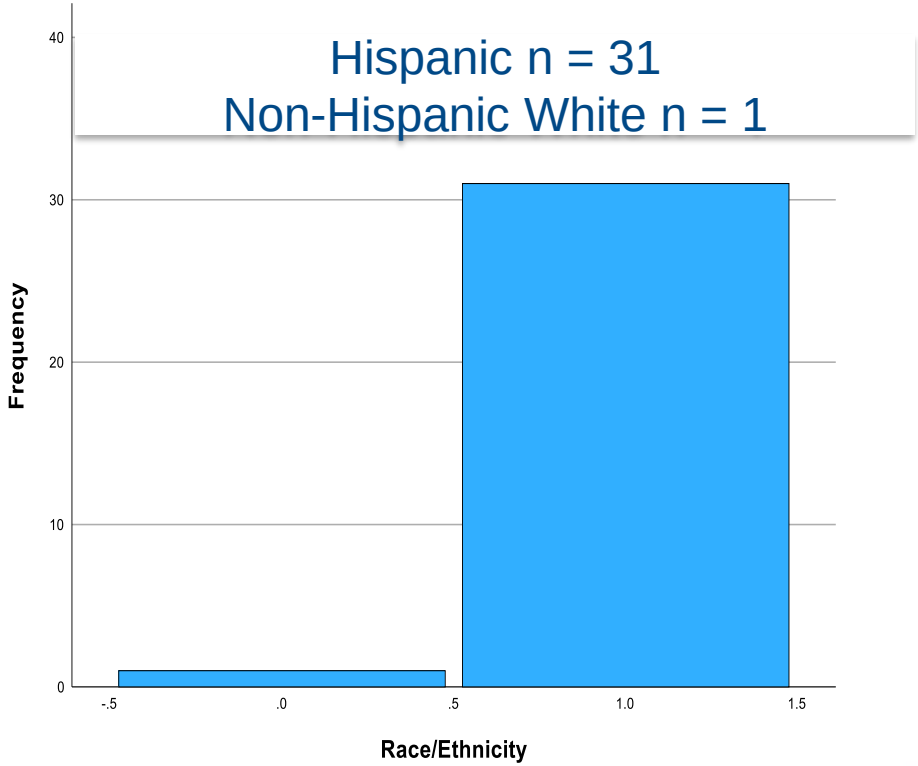
Results:

Participants

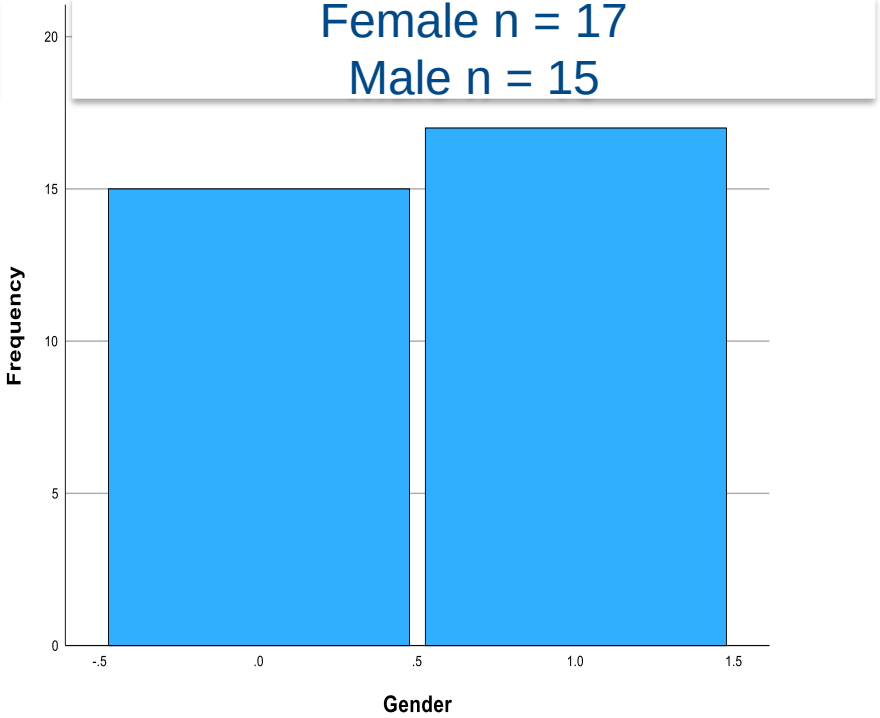


Results: Participants

Hispanic n = 31
Non-Hispanic White n = 1



Female n = 17
Male n = 15



Results: Statistical Analysis

Independent-Samples Proportions Confidence Intervals				
			90% Confidence Interval of the Difference	
		Difference in Proportions	Lower	Upper
	Wald	0.035	0.004	0.065

Independent-Samples Proportions Tests				
				Significance
		Difference in Proportions	Z	One-Sided p
	Wald	0.035	1.886	0.030

Results: Implementation Strategy (EPM, 2018)

Implementation Strategy	Result
“Create urgency”	Urgency existed Staff is eager, engaged, and motivated
“Form a powerful coalition”	Interprofessional coalition of medical staff, nursing staff, and volunteer optometrist to champion project
“Create a vision for change”	Vision existed within clinic staff Assessed current state of DR screening adherence Aligned project with organizational mission and values Enhanced process ownership
“Communicate the vision”	Literature findings shared with staff Medical staff and volunteer optometrist assisted in workflow development Process workflow and deliverables created EHR workflow developed and implemented

Results: Implementation Strategy (EPM, 2018)

Implementation Strategy	Result
“Empower action”	Addressed process change challenges Staff recognized the benefits of OCT technology for their patients Fostered interprofessional communication
“Create quick wins”	Staff involvement with process development Successful navigation of EHR data entry Practice scans for instructional purposes Statistically significant outcomes
“Build on the change”	PDSA-adapt and iterate Continued identification of workflow gaps Reaffirm goals of project
“Make it stick”	Foster consistency by tailoring approach Inclusion of volunteer staff Recognize the need to develop repository of resources and support Address program sustainability in staff meetings

Budget and Resources

Expenses for Implementation of Project	
Cost of technology (TOPCON OCT) - Donated	$29,950
Project Manager $55/hour 200 hours - Donated	$11,000
Clinical Educator $55/hour 2 hours	$110
Staff in-service time $25/hour 2 hours	$50
Site mentor meetings $75/hour 6 hours	$450
Supplies (Desktop station, Adjustable table)	$1200
Consultations (Stats, Ophthalmologist) $75/hour	$975
Total Expenses	$43,735
Income Revenue	
Fundus photography reimbursement: 32 @ $45.83 (Palmer, 2023) Yearly projection 120 @ $45.83	$1466 $5500
Cost Mitigation	
Cost of DR treatment (Larsen, 2023)	$2,000
Number of DR referred patients in 3 months (n = 1)	$2,000
Total Cost Mitigation	$2,000

Discussion

- Opportunity to refine patient engagement and increase patients served
- Opportunity to refine referral process when scans are abnormal
- Incorporate OCT into diabetic follow-up appointments
- Greater engagement of underserved population
- Promote sustainability

Limitations

- Length of data collection
- Sample size
- Homogeneity of sample
- Competing priorities

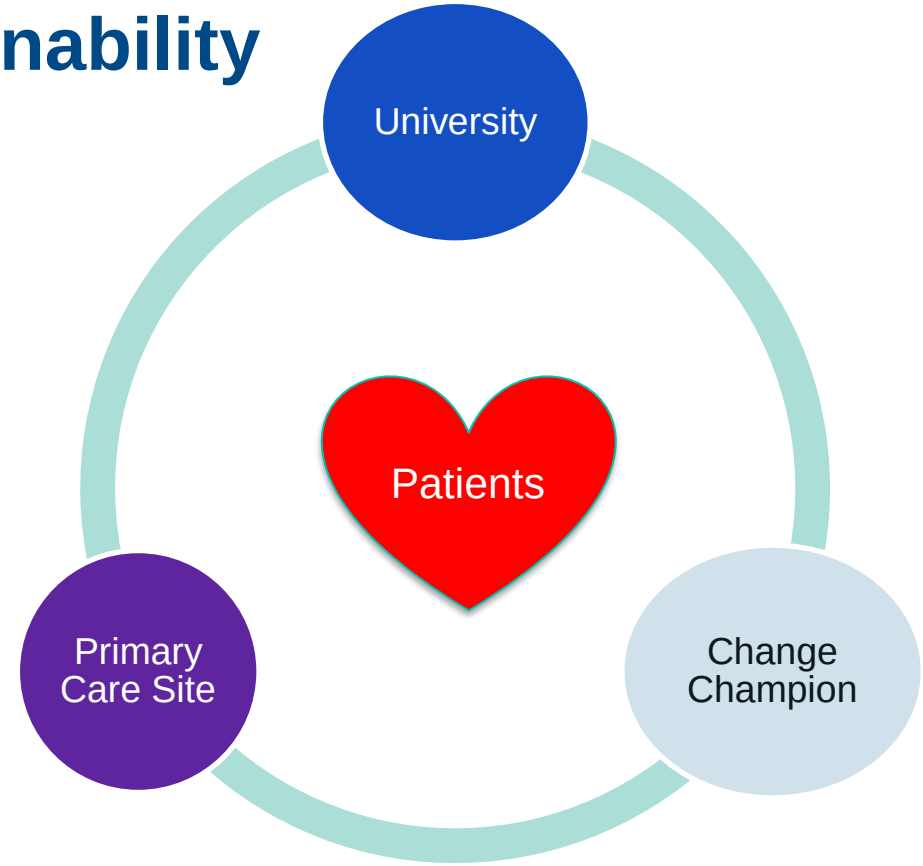
Implications for Practice

- Convenient-nonmydriatic strategy for DR screening
- Enhanced patient DR screening access
- Patient can be scanned in the clinic during visit
- EHR-retinal images as part of patient record
- Improved DR health literacy

Conclusions

- DR is the leading cause of blindness for adults in the US
- OCT programs can improve access and minimize barriers to DR screening
- OCT can also detect other forms of eye disease
- Project results are both clinically and statistically significant
- Patient education during intervention may improve health literacy
- Continued process refinement needed

Sphere of Sustainability



Sustainability Plan

University
- Maintenance of inter-organizational partnership-legacy project
- Systematic monitoring of intervention effectiveness
- Six month and one-year post-implementation follow up

Principle Investigator
- Create program document repository
- Schedule 3, 6, 12 month onsite follow up and process audit assistance
- Provide super user or champion training during onsite process audits

Site
- Continue patient education
- Identify super user or champion for training
- Maintenance of medical staff skills through training, supervision, and feedback
- Monitoring effectiveness of intervention
- PDSA to improve fit and compatibility of intervention within organizational workflow

(Hailemariam et al., 2019)

Dissemination

Organizational

Key stakeholders will receive a digital copy of:

- Manuscript
- Slide presentation
- Statistical analysis and findings

Scholarly

- Submission of manuscript to Scholarworks for public access
- Presentation of findings in DNP project defense

American Association of Colleges of Nursing (AACN) Reflection

DNP Essential	Result
I. Scientific Underpinnings for Practice	Integrated sciences to develop and evaluate advanced care delivery strategies using theories from nursing and other disciplines.
II: Organizational and Systems Leadership	Employed principles of organizational assessment, SWOT analysis, stakeholder analysis, and systems thinking to enhance practice delivery through design of Quality Improvement initiative
III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice	Developed PICO(T), integrated evidence to design screening program, program implementation, and statistical analysis to examine outcomes
IV: Information Systems/Technology	New technology integration (OCT), Data collection and storage, electronic medical record data extraction, statistical analysis packages.

(AACN, 2006)

American Association of Colleges of Nursing (AACN) Reflection

DNP Essential	Result
V: Health Care Policy for Advocacy	Advocated for the integration of screening recommendations at an institutional level. Practice change to increase access to screening for underserved and underinsured populations.
VI: Interprofessional Collaboration	Key stakeholders, physicians, medical staff, medical director, optometrist, graduate students, statistician, physician assistant.
VII: Clinical Prevention and Population Health	Program development to improve screening adherence and access to all patients by addressing barriers and facilitators.
VIII: Advanced Nursing Practice	Incorporated advanced clinical knowledge of chronic disease and illness and applied to the design of therapeutic interventions. Project and clinical immersion hours.

(AACN, 2006)

Questions?

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Handouts

- Organizational assessment-Table 1
- Stakeholder analysis-Table 2
- Literature review-Table 3
- IRB approval-Figure 1
- Process workflow-Figure 2

Appendix

Table 1: Organizational Assessment

ZZZZ Organizational Assessment with McKinsey 7-S model			
Concept	**Definition**	**Findings**	**Source of Information**
Structure	"The hierarchy of control exercised through delegated responsibility. The structure should be as simple as possible to help people understand who is accountable for specific results" (McKinsey & Company, 2008).	Leadership team: President Medical Director Dental Director Medical Coordinator Executive Assistant Board of Directors Spiritual Support Behavioral Health Community Liaison Volunteer Manager	Onsite observation and ZZZZ community facing website
Systems	"These are the activities, processes, and procedures that people engage in to do their work. It also includes software systems, which are increasingly automating activities, processes, and procedures" (McKinsey & Company, 2008).	Volunteer manger facilitates use of translators and accessory staff as needed on a daily/weekly/monthly basis. Organizational use of EHR to manage health documents.	Staff interviews as well as onsite observations
Style	"Also referred to as culture, this represents the way things are done and, particularly, the way the leadership team conducts itself in the	ZZZZ health maintains a hierarchy of leadership while also promoting shared governance. Servant leadership is also evident	Primarily Observation

Table 1: Organizational Assessment

	organization" (McKinsey & Company, 2008).	throughout the approach of the staff.	
Staff	"This includes the inherent talents of the organization's people, the number of staff and the diversity needed in each area to optimize organizational capability and capacity" (McKinsey & Company, 2008).	Staff consists of full-time employees as volunteers (see structure) each with an area of expertise and knowledge essential for the provision of service to the public.	Observation, Interview with volunteer coordinator
Skill	"Refers to the skills needed to deliver the cost transformation and management strategy. Having the right skills to deliver the strategy is vital and skills gaps can pose a risk to achieving cost competitiveness objectives" (McKinsey & Company, 2008).	Robust skill set is available. This is a direct result of the variety of volunteer positions and hours. In addition to the volunteers, the full time staff maintain current skills sets through various continuing education activities. The board of directors also offer experience and guidance as needed.	Interview with Medical director. Information gathered from website. Staff engagement.
Strategy	"Organizations need to compete in volatile, uncertain, complex and ambiguous environments. So, strategy needs to respond to this with agility" (McKinsey & Company, 2008).	Utilizes an integrative healthcare model approach to promoting community wellness. Community liaison whose purpose is to engage the community in the	Interview with community liaison

Table 1: Organizational Assessment

		pursuit of strategic partnerships.	
Superordinate goals	"These encapsulate the organization's purpose or its societal mandate. The organization's purpose tends to remain a fundamental constant over time and this purpose shapes the organization's values" (McKinsey & Company, 2008).	Faith based organization that primarily serves the uninsured, underinsured, and refugee community through a two-pronged approach of mission and vision; 1. serve the community with compassionate, safe, equitable, accessible healthcare that demonstrates our Christian mission. 2. A collaborative community where accessible healthcare promotes wellness for all (ZZZZ, 2021).	Discussion with ZZZZ president and review of the organizational website.

Table 2: Stakeholder Analysis

Key stakeholders	Rationale
Patients	Patients are the end user and consumer of DR program and OCT technology. Early detection will help improve outcomes.
Medical director **Staff Physicians** **Advanced practice providers** **Ophthalmologist/Optometrist**	Direct patient engagement and care providers. Provide information regarding the importance of baseline and continued vision screening. Program champions and innovators that influence patients and early adopters. Provide effective handoffs to other team members.
Quality manager	Provide oversight to quality measures and assure that measures have clearly identified mechanisms of tracking and reporting. Maintain reporting capabilities of organization to key community supporters and stakeholders.
Nurses **Medical assistants**	Will have a strong understanding of program definitions, workflow, processes, and equipment utilization. Assist with any referrals to related services. Connect patients to necessary community resources for follow up.

Table 2: Stakeholder Analysis

Volunteer coordinator **Volunteers**	Assist in communicating program implementation timeline to volunteers and informing them of training materials and access. Volunteers must be knowledgeable in program benefits and delivery of care/services to patients.
Interpreters	Assist in translation of key process or steps in patient screening. Provide support to clinic staff in the event there is a language barrier.
Community **Clinic supporters** **Board members**	Community involvement can lead to improved community awareness of implementation benefits. Clinic supporters will realize program benefits and continue to support clinic initiatives for population health. Board members provide etic perspective and can serve to inform further program development and iterative enhancements.

Table 3: Literature Review

Author (Year) Purpose	Design (N)	Inclusion Criteria	Intervention vs Comparison	Results		Conclusion
Azrak et al., (2015)	Observational, cross-sectional study-to determine the validity of a diagnostic test.	Patients diagnosed with DM		The results of this paper show that by using all the components of OCT, a diagnostic test with type A evidence is obtained that can be used to diagnose referable retinopathy		This. Study contributes a diagnostic test for referable diabetic retinopathy based on the three components of OCT, with type A evidence, to confirm or rule out the disease
(Faes et al., 2019)	Systematic Review/Meta analysis			We found a pooled sensitivity of 0.90 (95% confidence intervals (CIs): 0.82–0.95) and a pooled specificity of 0.97 (95% CI: 0.89–0.99). Corresponding positive and negative likelihood ratios were 32.3 (95% CI: 7.4–141.6) and 0.10 (95% CI: 0.06–0.20), respectively.		Findings from preliminary and heterogeneous studies provide promising characteristics of test performance for OCTA assessing vascular parameters associated with chorio-retinal diseases.
Gupta et al. 2017	Retrospective Cohort			sensitivity reduces the risk of missing the presence of DR (false negatives) and specificity reduces over-diagnosis (false positives). Among the gradable images, the overall sensitivity was 98%, and the specificity was 100% for DR within one grade of dilated retinal examination. A retrospective review was conducted of the records of 244 patients with diabetes to determine sensitivity and specificity of nonmydriatic		Telemedicine for diabetic retinal disease, properly validated and deployed, has the potential to become a cost-effective modality for diabetic retinal disease screening

Table 3: Literature Review

				stereoscopic retinal imaging in detecting DR		
Hafef et al. (2017)	Cross-sectional			After adjustment for age, gender, HgBA1C, disease severity, using resource utilization band score as a proxy, and medication possession ratio; telemedicine technology significantly increased the compliance (odds ratio: 4.98, P < 0.001). The completion rate for annual diabetic eye examinations in our population increased from 47.9% in 2010 to 78.1% in 2012		We found that the establishment of telemedicine technology was an effective and efficient way to increase the completion rate of annual diabetic eye examinations among underserved, low-income patients in an urban primary care setting. Digital retinal imaging with the application of telemedicine technology shows promising results for screening and detection of DR in the primary care setting without requiring an ophthalmologist or retina specialist on site
(Joseph et al., 2023)	Prospective			For moderate or worse DR, the sensitivity and specificity for grading by grader-1 with respect to the gold standard was 66.9% and 91.0% respectively and the same for the ophthalmologist was 83.6% and 80.3% respectively. For referable DMO, grader-1 and grader-2 had a sensitivity of 74.6% and 85.6% respectively and a specificity of 83.7% and 79.8% respectively		Our results demonstrate satisfactory level of accuracy for the fundus image grading performed by a trained non-ophthalmologist which was comparable with the grading by an ophthalmologist
Li et al., (2012)	Controlled trial			Among the 611 patients' digital retinal images screened in the first year of this program and for whom data are available, 166 (27.2%) cases of diabetic retinopathy were identified. Seventy-five (12.3%)		Our cost analysis indicates that telemedicine-based diabetic retinopathy screening cost less ($49.95 vs $77.80) than conventional retinal examination and the telemedicine-based digital retinal imaging examination has the potential to provide an

Table 3: Literature Review

				patients screened positive with clinically significant disease and were referred for further ophthalmological evaluation and treatment.		alternative method with greater convenience and access for the remote and indigent populations
Manole et al, (2020)				The National Eye Institute expects the number of Americans with DR to reach more than 10 million by 2030 and 14.6 million.by.2050. In the United States, DR causes approximately 80% of instances of legal blindness in people aged 20 to 74.		
Wandy et al., (2022)	Longitudinal			The 8-month pilot program began in late October 2017 with the placement of two tabletop TopCon IRIS cameras. The aim of this retrospective descriptive study was to examine whether a telemedicine platform can be used as a cost-effective way to increase diabetic retinopathy screening rates in the primary care setting.The-3-practices.showed increased diabetic retinopathy screening rates of 1%, 6%, and 24%, respectively. Aggregate data from the pilot period showed that of the 1213 patients who were screened, approximately 17.1% (n=207) were diagnosed with diabetic retinopathy and an additional 17.7% (n=215) were suspected of having some		This retrospective descriptive study suggests a telemedicine platform can be used to improve diabetic retinopathy screening rates in the primary care setting

Table 3: Literature Review

				other form of pathology. Of note, 10.1% (n=123) were also identified as being "IRIS saves," defined as having pathology identified that was severe enough to be considered an imminent threat to their vision		

Figure 1: IRB Approval

GRAND VALLEY STATE UNIVERSITY

Date: November 30, 2023

To: Dianne Slager
From: Office of Research Compliance & Integrity
Project Title: Increasing Adherence to Diabetic Retinopathy Screening: PrEYEmary Care Based Optical Coherence Tomography
Project Number: 24-124-H
Submission Type: IRB Research Determination Submission

Action: Not Research
Effective Date: November 30, 2023
Review Type: Administrative Review

Thank you for your submission of materials for your planned scholarly activity. It has been determined that this project does not meet the definition of research* according to current federal regulations. The project, therefore, does not require further review and approval by the IRB.

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as *"research"* in materials to participants, sponsors or in dissemination of findings. While performing this project, you are expected to adhere to GVSU's code of conduct and any discipline-specific code of ethics.

A summary of the reviewed project and determination is as follows:

The purpose of this project is to increase retinal screening adherence rates in adult diabetic patients through implementing a primary care-based diabetic retinopathy screening program. Project activities are systematic in nature but are not designed to be generalizable beyond the participating healthcare center. As such, this project does not meet the federal definition of research and further IRB review/approval is not required.

This determination letter is limited to IRB review. It is your responsibility to ensure all necessary institutional permissions are obtained prior to beginning this project. This includes, but is not limited to, ensuring all contracts have been executed, any necessary Data Sharing Agreements and Material Transfer Agreements have been signed, and any other outstanding items are completed.

If you have any questions, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. Please include the project title and project number in all correspondence with our office.

*Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).