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Eye Examination:Satisfying a Quality Care Measure in Diabetes

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EYE EXAMINATION: SATISFYING A QUALITY CARE MEASURE IN DIABETES

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Abstract

Purpose: Diabetic retinopathy (DR), a microvascular complication occurs in patients with poorly controlled diabetes mellitus (DM). A known risk of increased visual impairment associated with DM occurs in patients when the glycosylated hemoglobin level (HbA1c) increases over 7.0%. Therefore, an annual retinal assessment as a quality care measure in diabetes management is necessary. The conducted study aimed to evaluate the documentation of an annual eye exam in all patients with DM in a private family practice clinic and to investigate any possible association between HbA1c level.

Method: This quality improvement study included a retrospective medical record review in a cohort of patients with DM in a private Midwestern family practice clinic from June 1, 2017, through March 31, 2018. All adult patients, aged 18-90 years, meeting criteria for DM were included. The HbA1c for each patient with the presence or absence of a documented eye examination were recorded.

Results: All patients seen with DM had a documentation of HbA1c (n=129, 100%), average HbA1c results was 7.41%, SD = 1.78. Only 30% (n=39) had documented eye exam results.

Implications: An opportunity exists for lowering the HbA1c and documenting completed eye examinations in this family practice clinic. Consideration for a template for tracking HbA1c and eye exam results may fulfill the quality care measure requirements for DM. Lowering HbA1c reduces the risk for DR, and obtaining an annual eye exam allows early recognition and treatment for DR in patients with DM.

Key Words: diabetes, HbA1c testing, eye examination, diabetic retinopathy, quality improvement

Eye Examination: Satisfying A Quality Care Measure in Diabetes

Chronic and poorly controlled diabetes mellitus (DM) can result in diabetic retinopathy (DR, Pereira et al., 2017). By the year 2030, DR, is predicted to be the leading cause of blindness worldwide and is projected to affect nearly 200 million people (Benson et al., 2018). Visual impairment resulting from DR interferes with mobility, allowing for injury secondary to falls; contributes to deterioration in mental health, cognition, and therefore, employment and educational achievements (National Academies of Sciences, Engineering, and Medicine, 2017). Additionally, DR negatively impacts the quality of life (QoL) by limiting social interaction, independence, and the ability for self-care (Hendrick, Gibson & Kulshreshtha, 2015).

Patient and provider participation enhance the prevention of DR. Glycosylated hemoglobin (HbA1c), a serum marker which provides a numeric result for determining glycemic control over a period of three to six months, has been used for both diagnostic and management purposes in patients with DM. While a HbA1c of 6.5% or higher is indicative of a diagnosis of diabetes, during management, a lower HbA1c is associated with a lower likelihood of development of complications related to long-standing report patients with a HbA1c of 7.0% or higher are at an increased risk of DR associated visual impairment (Gale et al., 2017). In addition to the provider-patient team working together to achieve better glycemic control to prevent DR, recognition of and participation in preventive health maintenance is essential. Facilitating patient teaching and enhancing knowledge for improving health are necessary components in DM (Li et al., 2014).

Annual ophthalmic examinations allow for detection of early microvascular changes in vision (Nentwich & Ulbig, 2015). As such, the American Diabetes

Association (ADA, 2018) recommended a comprehensive annual eye examination with high-quality fundus photographs, capable of diagnosing DR in patients with DM. Hence, the healthcare provider may achieve better health outcomes for patients with DM by monitoring the HbA1c, identifying patients who are at significant risk for diabetes-associated complications and referring patients for an annual eye examination within the context of a Quality Improvement (QI) process. Ophthalmology referrals at the onset of DM is preferred to allow early detection and treatment of DR to retain optical capability (Evans, Michelessi & Virgili, 2014). Utilizing QI techniques, a practice can maintain standards of care for disease management (Peterson, Jaén & Phillips., 2013). The National Quality Forum (NQF) ambulatory metrics for the Healthcare Effectiveness Data and Information Set (HEDIS) accreditation recommended an annual retinal eye exam screening (NQF 0055) as a Quality Care Measure (QCM) and a HbA1c test (NQF 0057) in patients with DM (Golden et al., 2017).

The purpose of this study was to evaluate if the eye examination QCM was being met in the patients with DM. This QI project was conducted in an independent family practice in the Midwest. The HbA1c values and documentation of an annual eye examination for all patients with DM in the electronic medical record (EMR) were obtained. The study questions were: In a private family practice, among adults aged 18-90 years with DM,

1) what was the range of HbA1c level from June 1, 2017-March 31, 2018?

2) what was the rate of documented eye examinations from June 1, 2017-March 31, 2018?

3) what was the difference in the HbA1c values between the ages, races, and genders in the available data?

4) what was the difference in the rate of completed eye exams between the ages, races, and genders in the available data?

Review of the Literature

Publications from Medline, EBSCO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, UMSL library, Google Scholar, the Centers for Disease Control and Prevention (CDC) were reviewed using the search terms: diabetes, HbA1c, testing, eye examination and DR. Inclusion criteria were patients aged 18-90 years, clinical trials and studies in glucose control and ophthalmic manifestations. Exclusion criteria were studies published over six years and studies with other comorbidities. Out of the 58 studies obtained, 31 met the inclusion criteria for content and review.

Management of DM care includes a routine eye examination to diagnose DR before its progression to visual loss and to provide early and effective treatment. Reportedly, there are 285 million people worldwide living with DM, including 30 million people in the United States accounting for 9.4% of the population (Lee, Wong & Sabanayagam, 2015). In the United States, over one-third of patients with DM are diagnosed with DR, and seven of the 30 million patients with DM are living undetected and without the appropriate medical care and guidance (CDC, 2017).

Provider guidance in medication and lifestyle modification to facilitate lower glucose levels in poorly controlled DM results in lower HbA1c levels (ADA, 2018). Glycemic controls improved with post culturally appropriate education in 1,442 patients with DM in 14 trials (mean difference [MD]-0.4% with a 95% confidence interval [CI] -

0.5 to -0.2) and in 1,972 patients (MD -0.5% [95% CI -0.7 to -0.]) when HbA1c levels were checked at three- and six-months (Attridge, Creamer, Ramsden, Cannings, and Hawthorne, 2014). Thus, provider support with resources, and teaching patient to self-manage their DM will improve outcomes (Powers et al., 2017).

Moreover, the ADA (2018) recommended HbA1C below 7.0% to reduce risk of DR, urged providers to work with their patients in lowering HbA1c and obtain an annual eye examination. In patients with DM, a decrease in 1% of HbA1c, may result in a 40% reduction in DR (Ting, Cheung & Wong, 2016). Despite several treatment options, the 2011-2014 National Health and Nutrition Examination survey reported only 50% of patients with DM achieved a recommended HbA1c of less than 7.0%, possibly due to the cost and poor adherence to medications (Edelman & Polonsky, 2017).

Poor glycemic control with a longer duration of DM may increase the prevalence of DR; the incidences of DR increases with progression in age (Ding & Wong, 2012). Thus, DR cases are higher in patients who were diagnosed with DM later in life. Furthermore, the duration of having DM for five- to fifteen-years puts a patient at a higher risk for DR (Forga et al., 2016). Lima, Cavalieri, Lima, Nazario, and Lima (2016) conducted a three-year, case-control study utilizing the number of years of having DM, the presence or absence of DR, and glycemic control. The presence of DR in individuals with poor glycemic control was evident with 11-15 years of DM (Lima et al., 2016). In patients with DM greater than 15-years, the odds ratio (OR) increased to 9.01 (95% CI, 3.58–22.66) (Lima et al., 2016). Finally, in patients diagnosed with diabetic nephropathy, the chance for DR was highest (OR 3.32 and a 95 % CI 1.62–6.79) (Lima et al., 2016).

The impact of ethnicity and the relation to vision loss due to DM is a global epidemic afflicting all races, ages, and genders. Increased migration across the world, integration of multi-cultural foods and sedentary lifestyles attribute to DM at global levels (Das, 2016). Thomas and Ashcraft (2013) utilizing the Social Learning Theory and the Health Belief Model indicated that the adaptation of different cultural diets attributed to the rise of DM among South Asians who live in the United States. Asia accounts for over 60% (200 million) of the world's population for patients with DM (Thomas & Ashcraft, 2013). Indians and Malays had higher levels of HbA1c in comparison to Chinese at the same fasting plasma glucose (FPG) level, but an assessment of ethnicity-specific for a diagnostic threshold for DM in Asia still may differ from those born in the United States (Sabanayagam et al., 2015). By 2035, India and other parts of Asia are projected to have the highest prevalence in DM with close to 592 million people diagnosed (Kyari et al., 2014). There are increased occurrences of DM in African-American and Hispanic cultures; due to multifactorial reasons, DR is 46% more prevalent in African-Americans than in Caucasians (ADA, 2018).

Gender-related differences also occur, "diversities in biology, culture, lifestyle, environment, and socioeconomic status impact differences between males and females in predisposition, development, and clinical presentation" (Kautzky-Willer, Harreiter & Pacini, 2016, p.1). In a cross-sectional study of 17,702 men (44%) and women (56%) with DM, gender as the primary predictor variable, with indicators of HbA1c and dilated eye exams, the results showed women had the recommended dilated annual eye examinations in comparison to men (Williams, Bishu, Germain & Egede, 2017).

The ADA (2018) recommended management of patients with DM for optimum health outcomes. Combining a heuristic approach and a defined framework such as the Donabedian approach using the three categories, structure, process, and outcome measures to assess while evaluating the quality of health care rendered in a facility can improve patient outcomes (Moore, Lavoie, Bourgeois & Lapointe, 2015). Recognition of a HbA1c level of greater than 6.5% indicates a diagnosis of DM and providers are recommended to refer patients for an annual fundoscopic examination as there is an increased risk for DR or vision loss with a HbA1c over 7.0% (ADA, 2018). One of the QI methods in improving standards of care is the adaptation of the Johns Hopkins EBP conceptual model and the use of the "PET" approach (Dearholt & Dang, 2012). Adaptation of this model by posing questions (P), finding the evidence (E), and allowing incorporation of the most current research findings for treatment (T) for patient care ultimately enabling an optimum result. Patient and provider participation are both essential in management to reduce DR resulting from microvascular compromise (McCulloch, 2014). Hence, a provider's knowledge of the practice guidelines and patient preferences may enhance management of DM and microvascular comorbidities such as DR.

Limitations and gaps in the literature included addressing costs of eye examinations, socio-economic behavior, and cultural differences for ages and genders. The QCM measures and QI are newer concepts with insurance payors, and many publications did not address those topics. Conducting further studies to promote documentation for QCM measures, improving documentation of eye examinations, and implementing additional practice guidelines may contribute to knowledge regarding the care for those with DM.

Methodology

Design

An observational and descriptive design was utilized. A retrospective medical record review was conducted to obtain the data. This acquired data was the first Plan-Do-Study-Act (PDSA) cycle of the QI process (Donnelly & Kirk, 2015) for improving outcomes for the patients diagnosed with DM in a clinical setting.

Setting

This study was conducted in a privately-owned family practice clinic serving a large Midwestern metropolitan area with over three million residents. The clinic accepts over 20 private insurance plans, Medicare, Medicaid, and self-paying patients servicing over 9,000 patients of diverse ages, genders, races, and ethnicities. At this clinic, there were over 200 patients with DM aged over 18 years. The clinic utilizes a certified EMR to maintain patient records and uses electronic communication to obtain laboratory values and electronic facsimile for ophthalmology reports.

Sample

A data with a convenience sample of patients with DM who visited the clinic from the retrospective study period, June 1, 2017 through March 31, 2018 was obtained. Inclusion criteria were patients aged 18 through 90 years. Exclusion criteria were pregnant women and children under 18 years of age.

Procedures

A quality improvement team was formed and comprised of the office staff which included a medical physician, a registered nurse, two medical assistants, a biller, a receptionist, and the principal investigator. An initial meeting held revealed the difficulty in locating eye examination results in the EMR. Methods were reviewed which entailed tedious searching under filed documents. The staff and the provider's concerns were addressed to incorporate tactics to better serve the clinic in improved methods for obtaining results. Communication with an EMR consultant revealed options for obtaining patient lists and lab reports, however, the EMR lacked the capability of formulating a flowsheet for patients with DM. The staff and the provider were educated on the QCM of DM management and the significance of documentation available for QI.

Data Collection/Analysis

Demographic information collected included age, gender, and self-identified race and ethnicity. The primary outcome variable was the most recent HbA1c result, which was recorded both as a continuous variable, as well as categorical (as absent or present), and the presence or absence of completion of an eye examination within the designated time period. The deidentified collected data was stored with a password-protected computer. Descriptive and inferential statistics were analyzed using Microsoft Excel 2016, and Intellectus Statistics 2017, with counts or percentages for categorical variables with means and standard deviations for continuous variables. Summary statistics were calculated for each interval and ratio variable. Frequencies and percentages were calculated for each nominal variable. Where appropriate, the tests performed were: a control chart, *t*-test, Chi-Square, Pearson's Correlation and ANOVA. A p-value < 0.05 is considered statistically significant. Pivot tables were utilized for a visual representation of the data.

Approval Process

Approval for this study was obtained from the clinical site, Institutional Review Board (IRB) and the University of Missouri-St. Louis (UMSL) Graduate School.

Results

During the study period 129 patients (*N*=129) were identified to meet the inclusion criteria. Majority of the patients were male (*n*=93, 72%), with an average age of 53-year (*SD* = 13.29), the youngest patient being 22 years of age and the oldest being 88 years of age. Race analysis of the cohort showed majority self-identified as Asian (*n*=89, 69%), Caucasian (*n*=27, 20%), African-American (*n*=10, 7%), and Hispanic (*n*=3, 2%). One-hundred percent of patients seen with DM had a documentation of HbA1c. The assumptions of normality and homogeneity of variance were assessed. The mean HbA1c was 7.41%, (*SD* = 1.78) with a minimum HbA1c value of 4.90% and a maximum HbA1c value of 15.40% (See Appendix A).

A scatterplot for available HbA1c results was performed to find how many of the sample patients had a HbA1c result of below 7%. The HbA1c results indicated that (*n*=66, 51%) had HbA1c values of less than 7.0% and (*n*=63, 49%) were over the desired HbA1c range of 7.0% (See Appendix B).

Levels of HbA1c were evaluated for correlation between different age groups. A Pearson correlation requires that the relationship between each pair of variables is linear (Intellectus Statistics, 2017). A Pearson *r* correlation and Spearman's *rho* analysis conducted between age and HbA1c results were not statistically significant (critical values of 0.17, 0.23, and 0.29 for significance levels .05, .01, and .001 respectively). There were no significant correlations between any pairs of variables as there was no linear curvature that was available. Thus, there was no relationship between levels of HbA1c and age.

An independent sample *t*-test for genders for the mean of HbA1c results was not statistically significant, HbA1c among male (*M* 7.57, *SD*=1.93) and female (*M* 6.98 *SD*=1.21) patients (t=1.72 p=0.88). The assumptions of normality and homogeneity of variance were assessed. The independent *t*-test in patients with HbA1c results less than 7.0% was not statistically significant between males (*M* 6.31%, *SD*=0.46) and females (*M* 6.10%, *SD*=0.55), (t (64) = 1.55, p =0.12). Hence, there was no difference in average HbA1c levels between males and females.

An analysis of variance (ANOVA) determined that there were statistically significant differences in HbA1c results among the levels of race (F (3, 125) = 3.56, p = .016), with an 8% variance in the HbA1c results. The assumptions of univariate normality of residuals, homoscedasticity of residuals, and the lack of outliers were assessed. Post Hoc with paired *t*-tests were calculated between each pair of measurements to examine the differences among the variables. There were not enough Hispanic patient population to run the test statistically. For race/ethnicity, the mean of HbA1c results for Asian (M = 7.24, SD = 1.34) was significantly smaller than for African American (M = 9.03, SD = 3.33), p = .018 which was significantly larger than for Caucasian (M = 7.23, SD = 1.58), p = .037. No other significant effects were found. Hence, there was a statistically significant difference in HbA1c levels in the African-American population (p=0.018) when compared to the Asian and Caucasian populations.

The occurrence of completed eye examination documented in all groups was 39, with African American 40% (*n*=4), Caucasian 40% (*n*=11), Hispanics 0% (*n*=0) and the lowest in Asians 27% (*n*=24) (See Appendix D). In patients with HbA1c results of greater than 7.0%, 11 patients had their eye examination results in the chart (*n*=11). The most notable results were revealed in the Asian population (*n*=65, 73%) who did not have an available documented eye examination (See Appendix E).

An independent samples *t*-test was conducted to examine whether the mean age of those with eye exams was significantly different between those without available eye exams. The result of the independent samples *t*-test was significant, $t\ (127) = -2.57$, $p = .011$ The mean age of those with eye exams in ages *(M= 57.64, SD13.73)* was significantly higher than those without eye exams at (*M= 51.22, SD 12.69*).

A McNemar's Chi-Square test was performed to evaluate if the relationship between the availability of eye exam (*N*=129) and gender were equal. Eye examination results were not available for 70% of patients (*n*=90). Of the patients for whom eye examination results were available, there was no significant difference in gender (male *n*=25, female *n*=14, $\chi^2 = 0.191$, $df = 1$, $p = .662$). Among patients with HbA1c <7.0%, there were significantly fewer available eye examination results in both males ($\chi2(1) = 19.57$, $p < .001$), and females ($\chi2(1) = 5.40$, $p = .020$). The subset of female patients in this latter group is small. There were no differences in the number of eye exams obtained by gender.

Additionally, a Chi-square Test of Independence was conducted to examine whether the documented eye exams were independent in the Asian and Caucasian group; the Hispanics and the African Americans had fewer exams done, making the sample size too small for statistical analysis. The observed frequencies between the Asian and Caucasian groups were not statistically significantly different from the expected frequencies, $\chi 2$ (1) = 2.01, p = .156, suggesting the available results could be independent of one another.

Finally, a comparison was evaluated for time-lapse between the visit and the availability of results. Time-lapse results demonstrated that 22.48% (*n*=29) had no eye exam documentation in three months, 41.09% (*n*=53) did not have an eye exam in six months, 25.58% *(n*=33) had no documented eye exam in nine months, and 10.85% (*n*=14) had no documented eye examination in 12 months.

Discussion

This QI project reviewed questions for values of HbA1c results and documented vision consultations. Patients with a HbA1c greater than 7.0% are at risk of development of DR per ADA (2018), and although the recommendation is for annual screening, the perception may be that only these patients are at risk. The results of the study showed that although 51% (*n*=66) of the patients had a HbA1c of 7.0%, nearly 49% (*n*=63) had HbA1c of 7.0% and greater. The mean HbA1c was 7.41% (*SD* = 1.78). These results are suggestive of the missed opportunities in working with patients to reduce of HbA1c levels. Coaching and counseling for managing DM and glucose monitoring are indicated. Patients may benefit from frequent counseling in medication adherence, diet, and exercise from the provider in reducing HbA1c values.

In this study, while 100% of patients had a documented HbA1c within the study period, only 30% of the patients had a documented eye exam within the past year, despite an overall average HbA1c greater than 7.0%. While there was not a statistically significant difference in documented eye exam results between male and female patients, both groups were less likely to have results if they had a HbA1c less than 7.0%. In addition, only 17% of patients with a HbA1c less than 7.0% had eye exam results documented. It is possible that patients in this category did not feel compelled to have additional testing performed because of their perception that their DM was well-controlled. Alternatively, perhaps the provider did not definitively counsel patients as aggressively for routine care, including the importance of an eye exam.

Another component may have been staff members who were unaware of the QCM requirements for an annual eye examination. Educating both patients and staff is recommended for obtaining the required annual eye exam documentation. Improved methods of communication with patients, vision providers and facilities may allow for the acquisition of eye exam results. Teaching staff to remind patients at the time of visit may be beneficial.

Additionally, the lack of a standardized documentation form contributed to considerable time spent in locating documented eye examination results in the EMR. A standardized documentation form for DM practice guidelines to include items such as the most recent HbA1c levels and last annual eye examination may readily aid providers in identifying key indicators for routine DM health maintenance. In addition, patient education by the provider regarding the importance of a dilated fundoscopic examination and the comorbidity of DR could motivate the patient to complete an annual eye exam.

The availability of appointments to vision providers in a period of three- to six-months following a referral from the primary care provider may enhance patient adherence to complete an eye exam. A limitation identified in the study included those patients seen in the latter three months may not have had ample time to have the eye examination completed, thus leading to a lack of documentation to meet the annual requirement. Results demonstrate that 22.48% (*n*=29) had no eye exam documentation in three months, 41.09% (*n*=53) did not have an eye exam in six months, 25.58% (*n*=33) had no documented eye exam in nine months, and 10.85% (*n*=14) had no documented eye examination in 12 months. In consideration of missing documentation, patients may not have requested eye exam reports to be sent to the primary care provider for clinic documentation. Discussing the importance of sharing results between the ophthalmic provider and primary care provider with the patient may assist in obtaining documentation of a completed eye exam in the patient's medical record.

Considerable contributions to the low rate of completed eye examination are factors such as cost, transportation, work schedule, visual discomfort due to eye dilation, and the patient's limited understanding of the implication of DM. Cost of the exam was not necessarily a barrier, as most of the patients had insurance with medical coverage for DM, including a comprehensive annual eye examination with a screening for DR. However, a patient's fear of screening positive for DR due to poor control of HbA1c may be a consideration for not completing an eye examination. Finally, patients may not have requested an eye exam report to be sent to the primary care provider for clinic documentation.

While results of this study are not generalizable, a benefit of this project was the availability of a mixed racial and ethnic diversity in the patient population studied. Comparison in HbA1c values and eye exams provided valuable information regarding DM management and completion of eye examinations between age, race and gender.

This project also demonstrated the importance of medical record reviews in DM management such as HbA1c values and eye examination results as a part of ongoing QI for patients with DM. The use of cultural sensitivity and a variety of communication techniques tailored to individual patient situations, such as motivational interviewing may enhance health outcomes. Educational methods and motivational techniques tailored to the needs of the patient are recommended for future studies.

Conclusions

This QI project obtained available data for HbA1c ranges and documentation of an eye examination in a private family practice to meet QCM recommendations for HEDIS accreditation. Opportunities to improve documented eye exam results and lower HbA1c in the DM population were identified. Options for enhanced patient health education with electronic or telecommunication reminders could be considered in the management of DM. In addition, patient education using cultural sensitivity and a variety of communication techniques may assist patients with DM in managing their disease. Implementation of a standardized form for QCM measures in DM might help the provider facilitate recommended care. Furthermore, implementing a facsimile communication form between both primary care and ophthalmic providers might facilitate the communication of eye exam results. Ultimately, the goal is to assist patients with glycemic control and reduce the risk for co-morbid conditions such as DR.

With a quality improvement (QI) process, enhancement in care can result in improved education, communication, implementation strategies, advocacy, and support for stakeholders, such as the clinicians, patients, caregivers, and advocacy groups. A medical record review is essential to identify baseline values. Strategies to increase efficiency in management and improve the quality of care delivered is a result of QI.

Utilizing a PDSA method to test change can assist in implementing standards of care in small increments for disease management.

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Appendix A

Table 1

Demographics and HbA1c means for age group, gender and race/ethnicity

Variable	**Count**	**% of N=129**	**HbA1cMean**
Age Group			
21-30	2	0.02	7.35
31-40	18	0.14	7.48
41-50	40	0.31	7.56
51-60	34	0.26	7.54
61-70	20	0.16	7.25
71-80	11	0.09	6.82
81-90	4	0.03	6.85
Gender			
F	36	27.91	6.98
M	93	72.09	7.57
Race/Ethnicity			
Asian	89	68.99	7.24
African American	10	7.75	8.80
Hispanic	3	2.33	9.40
Caucasian	27	20.93	7.23

Note: HbA1c (min of 4.90%, max of 15.40%), results include new and existing patients

Appendix B

Table 2

Demographic for an eye exam for gender and race, and availability of eye exam results

Variable	***n***	***% of N=129***
Sex		
M	93	72.09
F	36	27.91
Race/Ethnicity		
Asian	89	68.99
African American	10	7.75
Caucasian	27	20.93
Hispanic	3	2.33
Eye Exam Results available		
N	90	69.77
Y	39	30.23

Note. Due to rounding errors, percentages may not equal 100%.

Appendix C

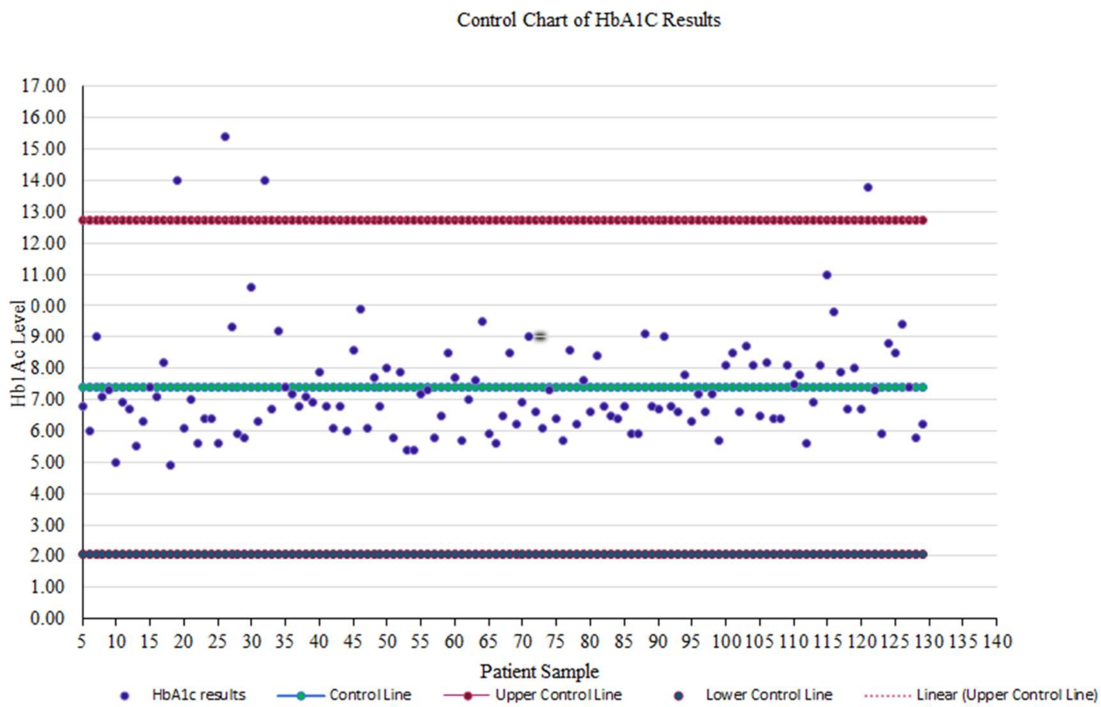

Figure 1. A control chart of HbA1c values comparing to the desired median of 7.0%

Appendix D

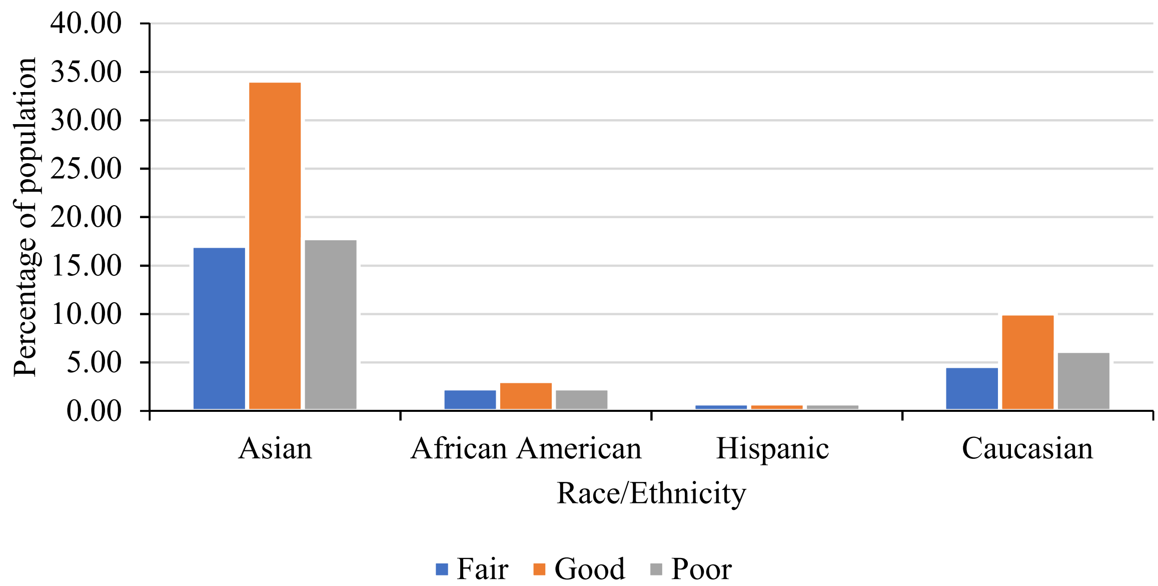

Figure 2. Level of control for available HbA1c results shown in percentage for race/ethnicity, good (<6.5%), Fair (6.5%-8%), Poor (>8%) (ADA, 2018)

Appendix E

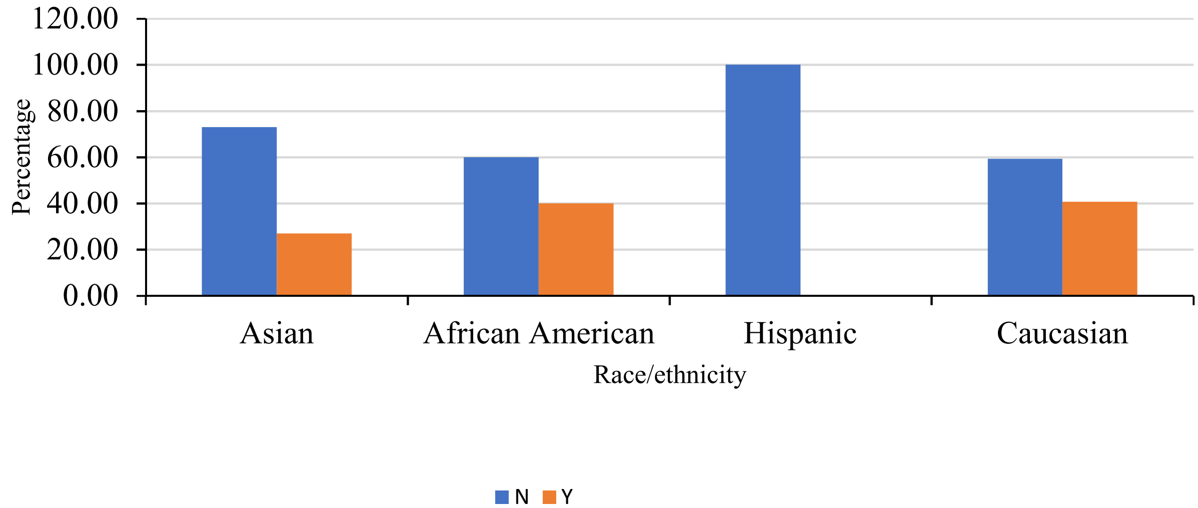

Figure 3. Percentage of available eye exam results by race/ethnicity.

N=result unavailable Y=available