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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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A Process Improvement Project to Increase Diabetic Retinopathy Screening Rates as

Evidenced by Formal Documentation

Michelle Renae Campbell

University of Kentucky

December 1, 2017

Sharon E. Lock, PhD, APRN, FNAP, FAANP - Committee Chair

Julie Ossege, PhD, APRN, FNAP – Committee Member

Angela Rayhill, APRN – Clinical Mentor

Dedication

This manuscript is dedicated to my children, to my parents, and to my husband. Thank you to my precious children, Makenna and Corbin Osbourne, for your sacrifice of countless hours of playing, family, and snuggling time with me in order to watch me succeed. I hope that, through this 3-year journey, you have learned that hard work and sacrifice are often the key ingredients in the recipe for success and a brighter future. Thank you to my mom and dad, Dennis and Wanda Layman, for without your words of encouragement and your willingness to be there for my children when I couldn't be, I never would have made it through this program. And, thank you to my husband, John Justin Campbell, for supporting me, believing in me, keeping me grounded, and encouraging me to keep taking steps forward toward success. I am so blessed to have had all of you behind me every step of the way and will never forget your role in my success.

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Abstract

Purpose: To evaluate the effects of a referral process on diabetic retinopathy screening rates among patients with Type 2 diabetes and formal documentation completion rates of these screenings within a primary care setting.

Methods: A referral process for patient referral to an ophthalmologist for annual diabetic retinopathy screening was instituted for a 4-week period within a Norton Community Medical Associates (NCMA) primary care location for Type 2 diabetes patients. Charts of 30 patients pre-intervention were compared with the charts of 30 patients seen during the intervention phase of the study to evaluate the effects of the referral intervention. Demographic data, including age, race, gender, and type of insurance, along with clinical data, including most recent Hgb A1C level, were collected for data analysis comparison.

Results: There was no statistically significant difference between the demographic and clinical data collected from the pre- and post-intervention groups. Additionally, the difference in referral rates and formal documentation rates for the two groups was not statistically significant (p>0.05).

Conclusion: A process improvement project using a brief referral intervention in a primary care setting showed no effect. Further study into this type of intervention to increase diabetic retinopathy screening rates in Type 2 diabetes patients and formal documentation completion rates of these screenings may be more beneficial if performed over a longer study period with evaluation of barriers preventing success at set time points during the study.

Keywords: Type 2 diabetes, diabetic retinopathy, dilated fundus examination, referral, intervention, ophthalmology, documentation

A Process Improvement Project to Increase Diabetic Retinopathy Screening Rates as Evidenced by Formal Documentation

Background

Approximately 4.2 million Americans greater than age 65 years are affected by diabetic retinopathy, a disease in which elevated blood glucose causes damage to the tiny blood vessels in the retina of the eye (Weiss et al., 2015). Without effective healthcare interventions, the number of people affected by diabetic retinopathy is expected to increase to three times that amount by 2050 (Zangalli et al., 2016). It is also estimated that, in 2004, more than \$500 million was spent on direct and indirect healthcare costs related to blindness caused by diabetic retinopathy and its complications (Weiss et al., 2015). As the primary cause of new-onset blindness among Americans aged 20 to 74 years (Weiss et al., 2015), this expected increase in the number of cases of diabetic retinopathy will create a substantial and costly healthcare burden (Zangalli et al., 2016).

Because diabetic retinopathy is asymptomatic in its early stages (Sheppler, Lambert, Gardiner, Becker, & Mansberger, 2014) and because early detection of retinopathic changes by annual dilated fundus examination is essential in the prevention of serious eye complications and blindness (Walker, Schechter, Caban, & Basch, 2008), the American Diabetes Association recommends that all individuals with Type 2 diabetes have a comprehensive dilated eye examination soon after diagnosis (American Diabetes Association [ADA], 2013). Additionally, according to the American Optometric Association's "Evidence-based Clinical Practice Guideline: Eye Care of the Patient with Diabetes Mellitus," individuals with diabetes should receive dilated eye examinations at least yearly and more frequently if they have changes in vision or have diabetic retinopathy that is severe or progressing (American Optometric

Association [AOA], 2014). However, compliance rates in obtaining annual dilated fundus examinations remain low, with fewer than half of people with diabetes obtaining this annual screening and with 50% of those that comply being screened too late for optimal treatment (Weiss et al., 2015).

The issue further intensifies when considering that primary care providers are held at a higher accountability for their patients receiving yearly screenings such as diabetic retinopathy examinations. With yearly dilated fundus examinations now being part of one of the HEDIS measurements, primary care providers risk changes in reimbursement when their diabetic patients do not successfully complete this exam and/or when they cannot provide formal, written documentation showing that their patients have had this service performed (Centers for Medicare and Medicaid Services [CMS], 2015).

With the severity of the issue increasing in numbers and in costs, the question becomes, "What are the most efficient healthcare interventions for promoting yearly diabetic eye exam compliance in patients with Type 2 diabetes mellitus, and what is the best method of tracking overall compliance rates?"

According to literature sources, interventions that contain an educational component that emphasizes the importance of annual dilated fundus examinations along with a personal component that helps patients overcome perceived barriers in getting the examinations may be the most effective in improving yearly examination compliance (Brunisholz et al., 2014; Sheppler et al., 2014; Walker et al., 2008; Weiss et al., 2015; & Zangalli et al., 2016). The purpose of this paper is to evaluate the effects of a referral process on diabetic retinopathy screening rates and formal documentation completion rates of these screenings among patients with Type 2 diabetes in a primary care setting.

Literature Review

A literature search was conducted to identify articles with interventions that focused on the improvement of annual dilated fundus examination rates among people with diabetes. The search terms were diabetes OR diabetic in the title AND intervention OR education in the title or abstract AND eye OR fundus OR retinal OR vision in the title or abstract. The database used in the search was PubMed.

Inclusion criteria for articles were: published between 2006 and 2016, written in English, full-text available, peer-reviewed, and focused on human species. Exclusion criteria were: studies that were not solely diabetes-focused, studies that concentrated only on Type 1 diabetes, and studies that did not involve an intervention that explored annual dilated fundus examination rates. A total of 103 articles were retrieved using the inclusion criteria. Five of these 103 articles were chosen overall for this literature review once the exclusion criteria were applied.

Three of the reviewed studies were randomized controlled trials with one of these three having a fairly large sample size of n=1,920. The overall levels of evidence among the studies included four Level B studies as defined by the American Association of Critical-Care Nurses (AACN) and one Level C study as defined by AACN (Melnyk & Fineout-Overholt, 2011). A Level A meta-analysis of multiple controlled trials (Melnyk & Fineout-Overholt, 2011) that specifically targeted interventions that improved annual dilated fundus compliance rates was not found in the literature search.

All five of the reviewed literature studies suggest that interventions that contain an educational component that emphasizes the importance of annual dilated fundus examinations along with a personal component that helps patients overcome perceived barriers in getting the examinations may be the most effective in improving annual dilated fundus examination

compliance (Brunisholz et al., 2014, Sheppler et al., 2014, Walker et al., 2008, Weiss et al., 2015, and Zangalli et al., 2016). One of the five reviewed studies suggested a possible improvement in dilated fundus examination adherence with these two components present based on survey results (Sheppler et al., 2014). Additionally, four of the five studies reviewed suggested an improvement in dilated fundus examination compliance rates in the intervention group versus the control group when both of these components were present. Interventions in these four studies included a behavioral activation intervention versus supportive therapy, an education- and telephone-based intervention versus standard care, a telephone intervention versus standard care (Brunisholz et al., 2014, Walker et al., 2008, Weiss et al., 2015, and Zangalli et al., 2016).

Purpose

The overall purpose of this process improvement project was focused on increasing diabetic retinopathy screening rates among patients diagnosed with Type 2 diabetes by implementing a referral process in a primary care setting. More specifically, this project focused on the following objectives:

- a. Increase the number of referrals to ophthalmology for diabetic retinopathy screenings in Type 2 diabetes patients.
- b. Increase the number of diabetic retinopathy screenings that were formally documented in the patient's electronic medical record.

Methods

Design

This study was a process improvement project to improve diabetic retinopathy screening rates and formal documentation rates among patients with Type 2 diabetes. The results from this

study will serve as a pilot study for the feasibility and initial effects of the intervention. The study was conducted in four phases as follows:

Phase 1: Prior to implementation of the intervention, a retrospective chart review was performed to evaluate current practice for referrals to ophthalmology for diabetic retinopathy screening and formal documentation of completion of these exams within the patient population of the primary care practice that was utilized for the project.

Phase 2: The principal investigator (PI) educated the providers and supporting medical staff participating in the study about the process for referring Type 2 diabetes patients for diabetic retinopathy eye exams.

Phase 3: After receiving education, the providers and office staff were instructed to follow the referral process for all patients that met the inclusion criteria. This phase was conducted over a 4-week period.

Phase 4: A second chart review was conducted after the 4-week period to evaluate the number of patients that were properly referred for a diabetic retinopathy eye exam and the number of cases in which formal documentation of these screenings was received back from the ophthalmologist's office.

Study Population

Provider Group: All of the providers within the designated Norton Community Medical Associates (NCMA) practice were invited to participate in the study. Only patient charts from participating providers who signed informed consent forms were audited after the educational intervention. Inclusion criteria for providers were licensed healthcare providers (physicians, nurse practitioners, or physician assistants) employed by Norton Healthcare (NHC).

Chart Review Group: Inclusion criteria for Phase 1 and 4 were medical records of patients with a diagnosis of Type 2 diabetes (ICD-10 codes of E11-E11.9) whose ages were between 18-70 years old. Exclusion criteria were medical records of patients whose age was outside of the specified age range of 18-70 years, those who did not have a current diagnosis of Type 2 diabetes, patients with Type 1 diabetes, and pregnant women.

Permission to Conduct Study

Permission to conduct the study was granted from the University of Kentucky (UK) Institutional Review Board (IRB) and from the Norton Healthcare Office of Research Administration (NHORA). As data collection from patient records was retrospective and deidentified, a waiver of informed consent was granted. All prescribing medical providers were consented at a routine in-office staff meeting where they were given an informed consent form and asked to participate in the study. Supporting medical staff members were also educated at this time on their roles in the successfulness of the intervention.

Procedures

Phase 1: Needs Assessment. In order to conduct a needs assessment, a retrospective chart review of 30 patient medical records was completed to assess the designated NCMA office's current diabetic retinopathy screening rates and the rates of formal documentation within their Type 2 diabetes patients' medical records. The medical records were randomly selected from Type 2 patients seen in the practice for all appointment types between January 1, 2016 and December 31, 2016 that fit the inclusion and exclusion criteria previously discussed as characteristics of the chart review group. Charts for review were randomized by the IT Department at Norton Healthcare and sent to the primary investigator in an Excel spreadsheet with medical record numbers listed. The primary investigator assessed the medical records

through the EPIC electronic medical record (EMR). This was done in a private room with no other individuals present. Information including the number of referrals for dilated fundus screening performed, the number of diabetic retinopathy screenings reported and/or documented, and the number of patients in which formal documentation of screening was present in the EMR was obtained. Additionally, information on the patients' age, race, gender, pregnancy status, type of insurance, and most recent Hgb A1C level was collected for data analysis comparison.

Phase 2: Educational Intervention and Referral Process. To begin the intervention phase, the PI met with the NCMA providers and supporting medical staff to introduce the referral process and to answer questions regarding the implementation process. Education included the need for a referral protocol, the target patient population for the study, where to enter ophthalmology referrals into EPIC, and the process for making the patients' ophthalmology appointments and faxing the patient documentation form at patient check-out.

The referral process for patients that met the inclusion criteria was as follows. When patients came in for any appointment type and had a diagnosis of Type 2 diabetes in their electronic medical record, the primary care provider was to interview the patient and review the EMR to determine if the patient had completed their annual diabetic retinopathy screening by dilated fundus exam within the past 12 months. This discussion between the patient and the provider was to occur as part of the patient's health maintenance assessment as per usual practice.

If the patient stated that they had not had their annual screening, the primary care provider was instructed to enter a referral into the system to a local ophthalmologist of patient and/or provider choice. If the patient refused a referral, the provider was to enter a note in the referral section to document the refusal. Any education that the provider felt compelled to share

with the patient about the importance of the diabetic retinopathy exam should have taken place at this time as well.

At check-out, the patient's paperwork should have reflected the referral, alerting office staff members that they needed to aid the patient in scheduling their ophthalmology appointment. This assistance in scheduling the appointment for the patient was designed as part of the intervention as a personal component to help overcome any patient-perceived barriers to the screening, for this was a key factor in increasing screening rates as seen in the review of the literature.

When making the appointment, the formal documentation form designed for this study was to be faxed to the referred ophthalmologist with instructions to fax it back upon completion of the diabetic retinopathy eye exam (see Appendix 1). If check-out paperwork stated the patient's refusal for a referral, office staff was instructed to provide the formal documentation form to the patient for when or if they made their own ophthalmology appointment. Once the form was completed and faxed back to the NCMA office from the ophthalmology office showing completion of the diabetic retinopathy eye exam, NCMA office staff was educated to scan it into the system as a permanent part of the patient's medical record.

Phase 3: Implementation Phase. The implementation phase of the study lasted for 4 weeks. During this phase, consenting providers conducted visits with their normal patient population and were to use the referral process on all Type 2 diabetes patients that met the inclusion criteria. Providers and staff were to follow all of the steps of the referral process described in Phase 2 during this time. The PI had no contact with patients during this phase, and contact with consenting providers was limited to providers contacting the PI with questions they had regarding the referral process.

Phase 4: Chart Review after 4-week Implementation Phase. The PI conducted a second chart review of the patient medical records from participating providers after the 4-week implementation phase. This chart review was performed on Type 2 diabetes patients that were seen during the implementation phase that fit the inclusion and exclusion criteria previously discussed as characteristics of the chart review group. Thirty charts were randomly selected by the IT Department at Norton Healthcare using the inclusion and exclusion criteria, and medical record numbers were sent to the PI within an Excel spreadsheet. Charts were reviewed 4 weeks after completion of the implementation phase as to allow time for completion of the scheduled ophthalmology exams and attainment of the formal documentation forms from ophthalmology to the primary care office. This chart review was conducted in a private room with no other individuals present.

The 30 randomized charts of Type 2 diabetes patients seen for all appointment types during the implementation phase were reviewed for information including the number of referrals for dilated fundus screening performed, the number of diabetic retinopathy screenings reported and/or documented, the number of patients in which a referral was indicated at the time of their appointment, and the number of patients in which formal documentation of screening was received back from ophthalmology. Additionally, information on the patients' age, race, gender, pregnancy status, type of insurance, and most recent Hgb A1C level was collected for data analysis comparison to pre-intervention data.

Data Analysis

Descriptive statistics, including means, standard deviations, and frequencies, were used to summarize the data for the pre- and post-intervention groups. Bivariate statistics, including the two-sample t-test and chi-square test of association, were used to compare demographic

characteristics between the two groups at each time. All data analysis was conducted using SPSS Version 22. An alpha level of 0.05 was used to determine statistical significance.

Results

Within the NCMA, Mount Washington location, all 6 providers consented to participate in the study. Patient medical records that fit the inclusion and exclusion criteria previously discussed as characteristics of the chart review group were randomly selected by the IT Department at Norton Healthcare to fulfill the PI's request of a pre-intervention group and a post-intervention group of 30 patients each. All 60 patient medical records that were reviewed met the inclusion and exclusion requirements.

Bivariate statistics showed no statistically significant difference between the demographic and clinical data collected from the pre- and post-intervention groups (see Table 1). A two-sample t-test comparing age and most recent Hgb A1C and a chi-squared test of association comparing gender, race, and type of insurance payor showed that there was no statistically significant difference between the groups with a p-value >0.05 in all categories.

The pre-intervention group had a mean age of 57.8 years and a mean last Hgb A1C of 7.1. The group consisted of 40% males and 60% females with 96.7% being Caucasian. The post-intervention had a mean age of 55.6 years and a mean last Hgb A1C of 7.7. The group consisted of 36.7% males and 63.3% females with 93.3% being Caucasian.

After performing a chi-square test of association and obtaining a p-value >0.05, it was determined that the difference in referral rates and formal documentation rates for the two groups was not statistically significant (see Table 2). The pre-intervention indication of screening rate could not be assessed since the needs assessment chart review consisted of a review of all Type 2 diabetes patient visits in the specified 12-month time period, and the diabetic retinopathy

screening is an every 12-month intervention. However, the post-intervention indication for screening rate could be assessed, and despite an indication for referral during the intervention phase of 66.7%, the referral rate for the pre- and post-intervention groups was unchanged at 3.3%. Additionally, the formal documentation rate was less for the post-intervention group at 13.3% compared to the pre-intervention rate of 26.7%.

Discussion

The brief referral intervention used in this process improvement project within a single primary care setting showed no effect. The two main objectives of the study were not met, as referral rates for diabetic retinopathy screenings did not increase nor did formal documentation completion rates of these screenings.

The decrease in the formal documentation rates in the post-intervention group versus the pre-intervention group could likely be explained by the fact that the pre-intervention group's rate was evaluated over a 12-month period, whereas the post-intervention group was only evaluated over a 1 to 2-month period, depending on when the post-intervention patients had their follow-up appointment within the intervention phase. An evaluation of the post-intervention group over a longer period of time to allow for more time for completion of diabetic retinopathy screenings likely would have increased this percentage. This decrease might also be explained by an issue with the form designed for this study not being properly routed to the ophthalmology office. An evaluation of the check-out and referral procedures after the patient was referred was not assessed but may have been useful.

The unchanged referral rate pre-intervention versus post-intervention might be explained by the type of appointment the patient had scheduled, by time constraints inherent in providers' busy schedules, and/or by expected and unexpected barriers that are often seen with change

processes. This could have been the case, for instance, if a Type 2 diabetes patient was being seen for a respiratory issue where the patient's Type 2 diabetes was not the focus of the appointment. In this case, the illness might have taken precedence over any thought or emphasis on the diabetic retinopathy screening exam or even any diabetes treatment at all. Additionally, it might have been the case that the provider seeing the patient for the appointment simply forgot to refer, chose not to refer based on their personal knowledge of the patient, or ran out of time to refer for various reasons.

Limitations

The biggest limitation in this study was time. The intervention phase of the study was only 4 weeks long, and the post-intervention chart review was only performed on charts up to 4 weeks after completion of the intervention phase. An intervention phase limited to such a small time window might have made it difficult for providers to remember to enact the change into their normal work routine, which could explain the limited number of referrals made to ophthalmology during the study. Additionally, a post-intervention chart review lasting only 4 weeks after completion of the intervention phase may have been an inadequate time frame for patients to have their ophthalmology screenings performed, documentation of the screenings to be returned from ophthalmology, and/or documentation uploaded into the patients' electronic medical records once returned. This could explain the decrease in formal documentation rates in comparison to the pre-intervention group.

Another limitation of the study was an inability, mostly limited by time constraints, to evaluate how closely the referral intervention process was followed. The PI did not have any interaction with the providers or the staff during the intervention phase. As such, the providers were not reminded to put in referrals for diabetic retinopathy screenings, and the staff was not

reminded to fax the form designed for this study to the ophthalmologist office once a referral was made. Additionally, the forms that were faxed to ophthalmology were not kept for further review to evaluate if the process was correctly followed, and interviews about the process were not performed for adherence or barrier to adherence evaluation. All of these factors could have contributed to a lower than expected referral rate and formal documentation rate.

Additional limitations of this study included a small sample size and homogenous demographics. Because this was a pilot study, only one primary care office seeing mostly Caucasian patients was studied, and only 60 charts in total were reviewed between the preintervention and post-intervention groups. Related to these specific study limitations, the study findings do not allow for application to the general population, but they do hold significance for the particular primary care office studied.

Implications for Clinical Practice

Literature sources suggest that interventions that contain an educational component that emphasizes the importance of annual dilated fundus examinations along with a personal component that helps patients overcome perceived barriers in getting the examinations may be the most effective in improving annual dilated fundus examination compliance (Sheppler et al., 2014, Walker et al., 2008, Weiss et al., 2015, and Zangalli et al., 2016). Patients in the literature studies were up to 2.5 times more likely to get their dilated retinopathy screenings when these two components were present (Walker et al., 2008, Weiss et al., 2015, and Zangalli et al., 2016). Nevertheless, this short-term pilot study in a primary care office showed no effect when an intervention that contained these components was implemented. However, future studies that include modifications to how this pilot study was implemented and evaluated may be beneficial in order to determine the true value of the type of intervention used in this study.

Further study performed over a longer study period with evaluation of barriers preventing success at set time points during the study might be especially useful. Evaluation of referral compliance when Type 2 diabetes patients are being seen specifically for diabetes follow-up appointments instead of all appointment types may also uncover unexpected barriers to referral. Additionally, a pre-designed educational handout, rather than varied verbal education, that providers could give patients that they refer to ophthalmology might better fit the necessary educational component uncovered in the literature review to increase screening compliance and formal documentation rates. Furthermore, an evaluation over an extended study period of all of the individuals that explicitly receive referrals during the intervention period versus just evaluating a random sample may give more insight into the effectiveness of the referral process on the receipt of formal documentation. And, allowing for a longer amount of time to assess compliance in patients from the intervention group completing their annual dilated fundus examination after they receive their referral may offer more insight into the true effect of the referral intervention on formal documentation rates.

Conclusion

Annual dilated fundus examinations are the standard of care in the prevention of and complications from diabetic retinopathy in patients with Type 2 diabetes (Walker, Schechter, Caban, & Basch, 2008). Literature sources suggest that interventions that focus on education related to diabetic retinopathy exam importance and that help patients overcome barriers to exams may be the most successful at increasing compliance rates (Brunisholz et al., 2014; Sheppler et al., 2014; Walker et al., 2008; Weiss et al., 2015; & Zangalli et al., 2016). A brief referral intervention in a primary care setting that utilized these components showed no effect in compliance or formal documentation evidencing compliance, but study limitations may have

skewed the true capability of the intervention's effect. Further study over a longer time period with modifications made to this study's intervention is suggested to evaluate the potential effect of referral on dilated fundus exam compliance and formal documentation rates.

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	Pre-intervention (n=30)	Post-intervention (n=30)	р
Age, Mean (SD)	57.8 (9.3)	55.6 (11.3)	0.07
Last Hgb A1C, Mean (SD)	7.1 (1.4)	7.7 (1.9)	0.35
Gender Male Female	40% 60%	36.7% 63.3%	0.79
Race White African American Asian Other	96.7% 3.3% 0% 0%	93.3% 0% 3.3% 3.3%	0.39
Payor Type Private Insurance Medicaid/Medicare	63.3% 36.7%	46.7% 53.3%	0.19

Table 1. Demographic and Clinical Data Summary (N=60)

	Pre-intervention (n=30)	Post-intervention (n=30)	р
Referral Written	3.3%	3.3%	1
Patient-reported Exam	43.3%	33.3%	0.43
Formal Documentation	26.7%	13.3%	0.20
Referral Indicated	Unable to assess	66.7%	N/A

Table 2. Frequency of Study Indicators (N=60)

Appendix

Appendix 1: Diabetic Retinopathy Screening Form

DIABETES EYE EXAM REFERRAL AND COMMUNICATION FORM

PLEASE FAX THIS COMPLETED FORM TO THE REFERRING PRIMARY CARE PROVIDER UPON COMPLETION OF THE PATIENT VISIT

To: Optometrist/Ophthalmologist
Name:
Address:
Phone:
Fax:
Referral Information:
from Norton Community Medical Associates
Mt. Washington location has referred the following patient to you for a dilated retinal examination for evaluation of diabetic retinopathy:
Patient Name: DOB:
Insurance: Date/time of scheduled exam:
EYE EXAM REPORT:
Retinal Examination Findings: No diabetic retinopathy Retinal abnormalities detected as follows: Non-proliferative changes noted in: Right (Grade) N/A Mild Moderate Severe Clinically significant diabetic macular edema? Yes No Left (Grade) N/A Mild Moderate Severe Severe Clinically significant diabetic macular edema? Yes No Proliferative changes noted in: Right (Grade) N/A Active Regressed/Stable Left (Grade) N/A M/A Active Regressed/Stable Left (Grade)
Other:
Recommended follow-up: 6 months 12 months Other: Additional Comments/Treatment Plan:
Date: Date:

Adapted from the Massachusetts Health Promotion Clearinghouse, "Diabetes Eye Exam Referral and Communication Form," 2017