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Increasing Provider Awareness of Patient Health Literacy Needs for Dental Screenings Among Patients With Diabetes in a Rural Health Clinic

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INCREASING PROVIDER AWARENESS OF PATIENT HEALTH LITERACY NEEDS FOR DENTAL SCREENINGS AMONG PATIENTS WITH DIABETES IN A RURAL HEALTH CLINIC

by

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Abstract

The purpose of this project was to increase provider awareness of health literacy needs for recommended dental screenings among patients with diabetes in a rural clinic setting. Over 35% of adults in the United States are considered to have low literacy levels (Agency for Healthcare Research and Quality, 2015). Low health literacy levels have an impact on patient outcomes due to decrease compliance with recommended treatment plans and preventive health screenings. Patients with diabetes have a trifold increase of developing oral infections such as periodontal disease, fungal infections, and xerostomia (Kudiyirickal & Pappachan, 2015). Healthcare providers acknowledging a patient's health literacy level can provide appropriate educational material concerning recommended health screenings for diabetes including an annual dental exam and cleaning (Agency for Healthcare Research and Quality, 2015; Hummel, Phillips, Holt, & Hayes, 2015). This was a descriptive statistical quality improvement project conducted on a non-profit rural health clinic offering medical and dental services. Retrospective chart reviews concluded that patient's health literacy and diabetic referrals to dental are not being conducted. Clinical staff was educated on health literacy assessments and patients with diabetes were administered the Short Assessment of Health Literacy-English/Spanish. A stamp was place on the patient face sheet to prompt the provider of the patient's health literacy level and the need for a referral to dental. The intervention did increase provider awareness of patients' health literacy and affected the interaction between the provider and patient. This project has increased referrals for dental screenings among patients with diabetes.

Keywords: Health Literacy, Rural Health, Dental Screenings, Preventive health services

Provider Awareness of Patient Health Literacy

The American Diabetes Association (2015) estimates that about 14% of the population in Texas is considered diabetic and over 37% are considered prediabetes causing an estimated expense of over 23 billion dollars yearly due to comorbidities of diabetes. In 2016, 25% of the clinic's adult patients were diagnosed with diabetes. During the microsystem assessment, it was found that diabetic patients with uncontrolled hemoglobin A1C levels had common trends such as inconsistent referrals, noncompliance to appointments, and confusion about medication regime.

Diabetic patients have a trifold increase of developing oral infections such as periodontal disease, fungal infections, and xerostomia (Kudiyirickal & Pappachan, 2015). Due to this increased risk, the American Diabetes Association (2017) recommends health care providers monitor if their patients are being seen regularly by a dentist. Talpur, Shams, & Punjabi (2015) conducted a study measuring if patients with diabetes understood the importance of proper oral hygiene. They found that over 30% of diabetic patients are not aware of the effect that diabetes has on their teeth (Talpur et al., 2015, p. 489). They concluded that health care providers need to provide awareness and education to patients about how diabetes can affect their oral health (Talpur et al., 2015).

Health care providers have a duty to provide their patients with resources to help them comprehend and improve their health (Coleman & Fromer, 2015). Health literacy addresses the learning needs of the patients and serves as guidance for providing appropriate educational materials. Currently, the clinic is not taking into consideration the patient's health literacy or providing education materials to their diabetic patients about oral health complications and the importance of dental screenings. The lack of referrals and dialogue from the providers hinders

the patient from understanding the connection between diabetes and dental complications (Inge & Garcia, 2016).

Statement of the Problem

One of the key components of improving the functionality of the clinic was to understand how the clinic operated and identify gaps in care. The need for health literacy to be incorporated into the clinical visit was noted during the microsystem assessment. Clinic staff was not assessing the health literacy level of the patients. This affected the interaction between the patient and provider. Upon conducting staff surveys, it was found that over 66.7% felt that they do not provide sufficient audio and/or visual aids to help patients comprehend their disease process (Agency for Healthcare Research and Quality, 2016).

Health care providers are referring for ophthalmology and podiatry routinely. Results from the needs assessment indicated that health care providers are not referring patients with diabetes for dental screenings. It was also noted, that there is no health education being provided to patients with diabetes about oral health complications and the importance of dental screenings. Per the American Diabetes Association (2017), healthcare providers should refer diabetic patients for a dental screening of periodontal disease on an annual basis. Staff training needed to include how to assess their patient's health literacy level and provide education accordingly. This, in combination with providing patients an understanding of dental complications and how it impacts their overall health can increase referrals to dental and preventing periodontal disease (Inge & Garcia, 2016).

Background and Significance

A study conducted by the U.S. Department of Education found that over 35% of adults have low health literacy levels contributing to an inability to comprehend their healthcare

provider (Agency for Healthcare Research and Quality, 2015). Some of the governing agencies that have established guidelines regarding health literacy include the Institute of Medicine, The Joint Commission, and Healthy People 2020 (Agency for Healthcare Research and Quality, 2015; The Joint Commission, 2017). Their recommendations have led to health literacy implementation in all areas of health care. Low health literacy levels can have a negative impact on patient outcomes because of decrease compliance with recommended treatment plans and preventive health screenings.

In the United States, 47 % of adults over the age of 18 will have periodontal disease (Centers for Disease Control and Prevention, 2017). Healthcare providers need to understand the patient's health literacy level so they may provide appropriate educational material regarding recommended health screenings for diabetes including an annual dental exam and cleaning (Agency for Healthcare Research and Quality, 2015; Hummel et al., 2015). Current research has established recommendations for providers to refer patients with diabetes for annual dental screening and incorporate oral health education as part of their assessment (Centers for Disease Control and Prevention, 2017; Hummel et al., 2015; Safety Net Medical Home Initiative, n.d.). Providing appropriate educational materials per the patient's health literacy levels has been shown to improve outcomes and prevent dental complications.

Assessment

One of the key components of improving the functionality of the clinic setting is understanding how it is currently functioning and identity any gaps in the care being provided. To be able to do that, a needs assessment was performed. The focus of the needs assessment was to help determine what barriers were seen in the clinical setting and how they were affecting patient outcomes. Gaps in the clinic were identified after the Doctor of Nursing Practice student

understood what is the purpose of the clinic, current patient population and the clinical staff (Nelson, Bataldan, Godfrey, & Lazar, 2011).

The project took place at a non-profit family clinic located in a rural area south of San Antonio, Texas. The clinic is owned and managed by a non-profit Catholic organization. The health care providers (physician, physician assistant, and nurse practitioner) are contracted by another local agency to provide care at the clinic. The physician works at the clinic one day of the week for only four hours. The nurse practitioner and physician assistant work Monday through Friday 8 a.m. to 5 p.m. and are expected to see an average of 16 to 18 patients daily. They have the support of three front desk staff, two medical assistants, one licensed vocational nurse, one laboratory personal, and the clinic director who is a registered nurse.

Most the patients seen at this clinic do not have health insurance, are underinsured, or are on a Medicaid/Medicare program. The main source of funding for this clinic is provided through donations, grants, Medicaid, Medicare and a small percentage of patients have private insurance. The clinic saw a total of 2,451 unduplicated patients from July 2015 to June 2016. Demographics of patients seen during this period are elaborated on Figure 1. Out of the patients seen during this period a total of 603 had a diagnosis of diabetes and 497 had a diagnosis of hypertension. Out of that number, a total of 762 adults were Medicare patients. A patient's ethnicity, race, household composition and gender are tracked in the electronic medical record. However, a patient's primary language and education are not always tracked and frequently left blank on registration forms. There was no documentation of a patient's health literacy level in the electronic medical record.

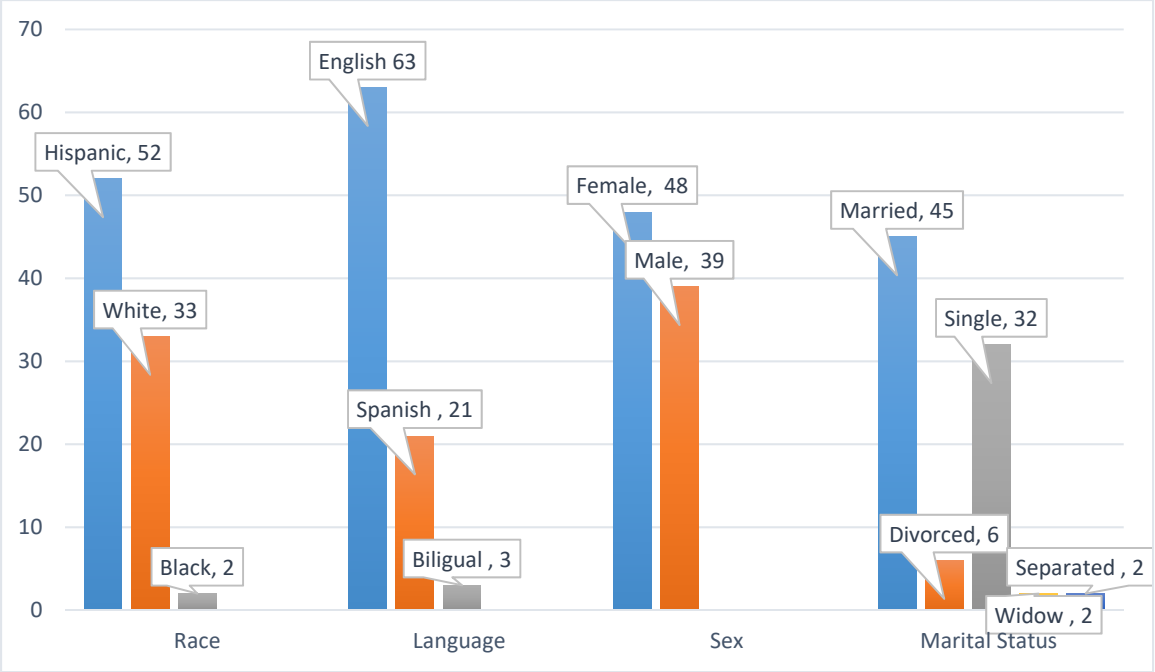

Figure 1. Demographics. This illustrates the demographic information of patients with diabetes who were seen in the clinic prior to the project intervention.

One of the clinic problems is the lack of accessible educational materials in the exam rooms. This is partly due to a lack of funding available for educational materials. Clinic staff must resort to patient education materials that are provided free of charge from outside vendors and/or pharmaceutical companies.

The Agency for Healthcare Research and Quality (n. d.) has established benchmarks to be used as guidance. Upon reviewing how the state of Texas is doing compared to the standard benchmark, it became apparent that this state is far behind in reaching the goal (Agency for Healthcare Research and Quality, n. d.). When conducting the microsystem assessment, it became evident that the clinic has a gap in health literacy and is not following clinical practice guidelines or recommended benchmarks. This clinic does not have receive any funding to purchase patient educational materials. However, staff knows the importance of giving patients appropriate educational materials.

Healthy People 2020's indicator on "Oral Health-7 Children, adolescents, and adults who visited the dentist in the past year (age-adjusted, percent,2+ years)" had dropped from 44 % in 2007 to 42 % in 2012 not close to the goal of 49 % by 2020 (Healthy People 2020, 2017). In Texas, approximately 51 % of diabetic patients had a visit to the dentist in the last year (Centers for Disease Control and Prevention, 2016). However, it was noted upon the review of medical records that patients were not being referred for a dental exam. Healthcare providers validated the lack of focus that is currently being place in doing dental referrals.

Another concern besides the lack of dental referrals is the cost of dental screenings since insurances such as Medicare; do not cover routine dental screenings. The clinic has an onsite dental department that provides dental screenings with cost for services based on a patient's income level. This allows for patients to have access to care independent of insurance coverage and at a low cost. It was noted during the assessment that no communication is done between medical and dental staff. Neither department knows which patients are or are not being seen at their respective side of the clinic. Patients are not made aware of dental clinical programs available to help reduce their out of pocket expense.

Organization's Readiness for Change

Assessing the clinics readiness to change was needed prior to implementing the project. Once gaps in care were identified then an assessment of the clinical staff readiness to change was completed. This helped identify clinical staff reasons for resistance and concerns staff may have. Many organizations are under the assumption that if a process is not broken then why does it need to be fixed. Schein has identified characteristics of change that are commonly found in organizations (Nelson et al., 2011). They are unfreezing (thinking that something will go wrong and affect the organization's values), cognitive restructuring (helps staff adapt to change due to

previous mistakes seen), and refreezing (staff have accepted the change) creating equilibrium in the organization (Nelson et al., 2011).

One of the ways this clinic's readiness to change was assessed was by utilizing the Clinical Microsystem Assessment Tool to find out if workarounds were being conducted (Dartmouth College, 2015; Nelson et al., 2011). The staff was asked how they felt about the current care they are providing patients and if there needed to be any improvements. The clinic staff felt that some of the patients' concerns are not being addressed and verbalized understanding of how a change in their process can help improve patient outcomes.

Another survey used on the staff was the Health Literacy Assessment Questions developed by the Agency for Healthcare Research and Quality as part of their Health literacy Universal Precautions toolkit (Agency for Healthcare Research and Quality, 2016). Most of the staff felt that they were not provding their patients with the appropriate educational material. Over 55.6 % of clinic staff reported not having health literacy education, 22 % reported that their practice is not screening for health literacy, and 22 % reported that the practice could do better. When clinic staff was asked if they understand how to implement changes to help improve their daily performance, 44.4 % did not know the answer and/or felt that this question did not apply to them. It become apparanet during the health literacy assessment, that more resources regarding health literacy need to be provided to clinic staff and patients.

Project Identification

Understanding the health literacy of patients can help improve their outcomes, compliance with treatment, and help them understand their disease process as well as complications that can arise (DeWalt et al., 2010). Patients with diabetes are at an increased risk for periodontal disease, xerostomia, and/or other infections that can predispose them to oral

complications of diabetes (American Dental Association, 2017). Empowering healthcare providers and patients with this information can help increase dental referrals and improve compliance.

Purpose

The purpose of this project is to increase provider awareness of health literacy needs for recommended dental screenings among patients with diabetes in a rural clinic setting.

Objectives and Anticipated Outcomes

Objective 1: Increase provider awareness of health literacy in patients with diabetes. This can help impact the interaction with the patient and how the information is presented.

Objective 2: By August 2017, 100% of the patients with diabetes presenting to the clinic will be screened for health literacy. Assessing the patient's health literacy provides a baseline on what educational material would be appropriate for the patient.

Objective 3: By August 2017, there will be at least a 50% increase in number of patients with diabetes that are given appropriate dental education materials based on health literacy levels. This helps provide patients with diabetes appropriate educational material that they can understand.

Objective 4: By August 2017, there will be at least a 50% increase in the number of provider referrals to dental. This aligns with current standards of the American Diabetes Association (American Diabetes Association, 2017).

Summary and Strength of the Evidence

A randomized control studies found that patients who received educational material based on their health literacy had an increase of knowledge compared to those that did not receive any educational material (Agency for Healthcare Research and Quality, 2016; Koonce et al., 2015). While their study was conducted on parents of children with diabetes it did showcase the importance of increasing a patient's awareness. Understanding the health literacy of patients can help improve their outcomes, compliance with treatment, and help them understand their disease process as well as complications that can arise (Al Sayah, Majumdar, Egede, & Johnson, 2015; DeWalt et al., 2010). Implementing a screening tool for health literacy can be conveniently done in a health care setting (DeWalt et al., 2010; Faruqi, Lloyd, Ahmad, Yeong, & Harris, 2015; Lee, Stucky, Lee, Rozier, & Bender, 2010). Research shows the evidence and the importance of incorporating health literacy as part of the provider's assessment.

Improving oral health has been associated with a reduction of diabetic complications (Haber et al., 2015; Hummel et al., 2015; Sohn & Rowe, 2015). There is sufficient evidence indicating the risks that poor oral health has on diabetics and the current oversight of providers by not incorporating oral health into routine medical visits. Preventive measures in oral health are less costly than treatment for periodontal disease for patients (Haber et al., 2015; Hummel et al., 2015). Patients need to be educated on the correlation between diabetes and periodontal disease (Kudiyirickal & Pappachan, 2015; Sohn & Rowe, 2015).

Methods

This was a descriptive statistical quality improvement project conducted on a non-profit rural health clinic offering medical and dental services. A total of 100 electronic medical records were reviewed before the intervention to determine if providers were screening for health

literacy and dental screenings. After the intervention, patients' charts were reviewed to determine if awarness of health literacy increased dental referrals among patients with diabetes. The populations of focus for this intervention were patients with diabetes who were over the age of 18 who are seen in the clinic. The interventions implemented were the self-report survey on health literacy given to patients with diabetes upon arrival to the clinic by the front desk staff, a stamp was placed on the patient face sheet by the nursing staff, pre-printed patient dental educational materials were given by the providers, dental referral form were done by the providers and given to the patients by the nursing staff, dental referrals were tracked by dental front desk staff, and follow up phone calls were made to patients who did not make a dental appointment or missed their appointment by clinic staff.

Project Intervention

The project was implemented into a 12-week time frame. The interventions allowed the staff to feel comfortable with assessing the patient's health literacy level and understanding how the referral process can be improved. During the first week, staff was given an in-service on health literacy and shown an educational video on the importance of health literacy. Staff was given an opportunity to ask questions and project implementation was discussed. The medical assistants were trained on how to screen patients with diabetes using the Short Assessment of Health Literacy-English/Spanish to measure their health literacy level and how to properly score them (Lee et al., 2010). Front desk staff was also given a copy of the screening tool to give to patients upon their arrival to the clinic. Short Assessment of Health Literacy-English/Spanish was administered to patients with diabetes over the age of 18 who were being seen for a follow up visit.

Education on how to use the stamp was given to the medical assistants and providers. A stamp (Figure 2) was given to the medical assistants to place on the patient face sheet. Educational materials were placed in each exam room. Providers were provided education about the dental patient education materials and how to give them to the patients after assessing their health literacy level. A dental referral form was implemented to be able to track the process. Dental referrals were monitored as per American Diabetes Association standards of care (American Diabetes Association, 2017). After the patients were seen they were given a paper referral to dental and told how and where to make appointments. Dental referrals were tracked by the dental department front desk staff. Follow up calls were made to patients who did not make an appointment or missed the appointments.

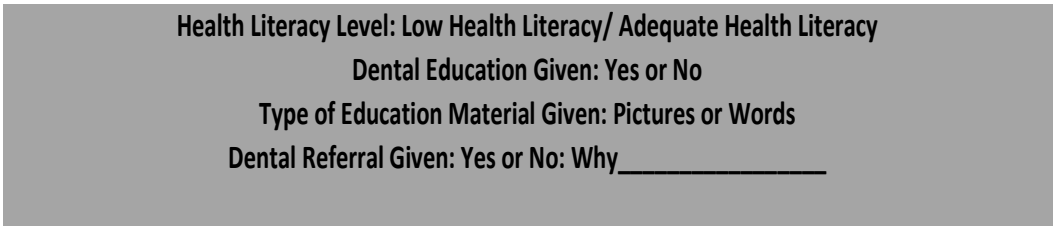

Figure 2. Project Stamp. This illustrates the project stamp used during project implementation.

Organizational Barriers and/or Facilitators

It is important to understand what some of the things that might hinder this project and/or help with the interventions provided (White et al., 2015). It became apparent early on that certain factors could not be changed and modifications would need to be done. One such example is the use of the EMR to help with the implementation process, but upon speaking with the clinic's information technology department that was ruled out due to the regulations required prior to any implementation. It was concluded that the project would work best in paper. Another barrier noted was the clinic's current lack of patient educational materials in the exam room, and the lack of the staff time to provide education.

Facilitators for this project are the clinical staff including both front and back office personal. The clinic director is very engaged in the daily activities occurring in the clinic and working on improving clinical processes. The dental clinic, located within the clinic makes it easily accessible for patients. There are no ethical considerations for this project. The only concern is this project only focused on patients with diabetes instead of applying this intervention to all patients that are seen in the clinic.

Results

Objective 1: As a result of the intervention, providers reported their awareness of health literacy did increase. Overall, providers felt knowing the patients' health literacy level before the office visit changed the way they educated their patients.

Objective 2: Although the goal of 100% was not met there was an upward trend of people with diabetes being screened for health literacy. Figure 3 outlines the demographics of patients with diabetes. Clinical staff realized that is something that can be easy implemented with all patients. Table 2 displays health literacy levels.

Objective 3: Although the goal was not met there was an upward trend of 42% of patients with diabetes receiving appropriate education materials based on their health literacy level. Figure 4 displays the results of the number of patients with diabetes that received educational material, results of health literacy levels, referrals that were completed, and the date of the last dental exam. Table 3 displays the patients with diabetes documented education level. Patients with diabetes reported understanding the material that was given to them and recognized how diabetes impacts their oral health.

Objective 4: Although the goal was not met there was an upward trend 31% of patients with diabetes referred for their dental screening. A total of 14 patients with diabetes were

referred to dental. Follow up calls were made but only six responded (only one made an appointment but had to cancel due to a new job and the other six reported not being able to afford a dental visit). The other eight patients were left voicemails or did not answer.

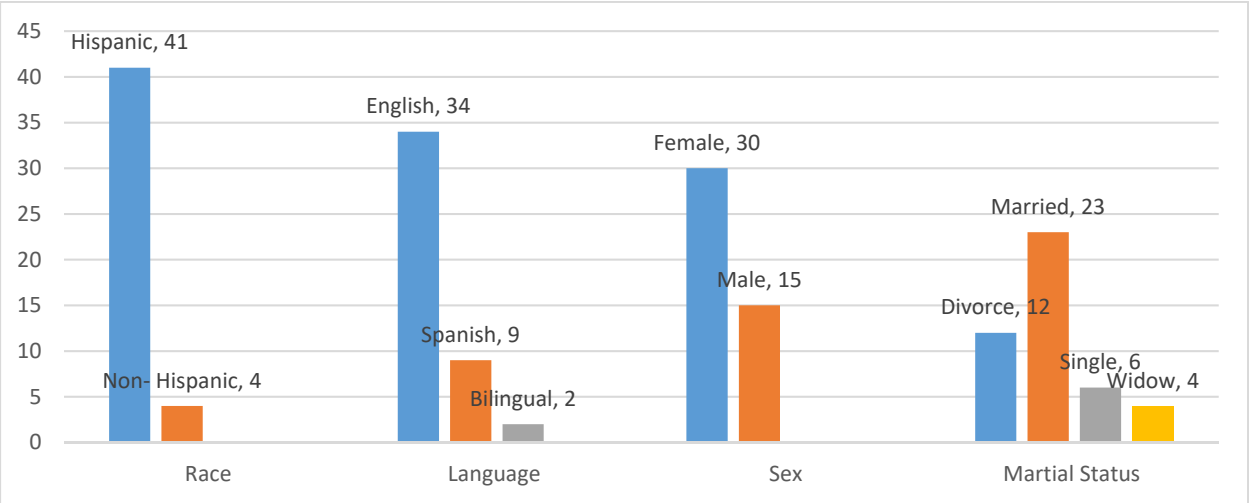

Figure 3. Patient Demographics. This illustrates the demographic information of patient with diabetes seen during the project.

Table 1

Health Literacy Levels

HL Level

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Low	11	24.4	24.4	24.4
	Adequate	34	75.6	75.6	100.0
	Total	45	100.0	100.0	

Note. The numbers represented in the table are the health literacy level of patients with diabetes.

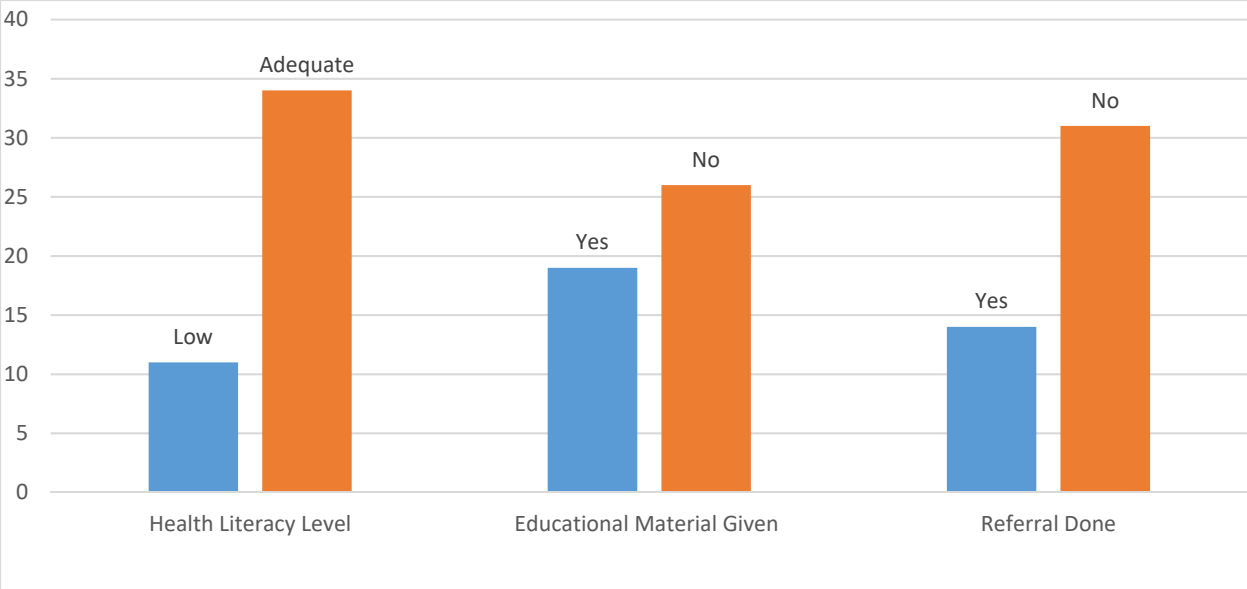

Figure 4. Results. This illustrates the results of the project based on a total of 45 patients with diabetes. Displayed are the results of the health literacy assessment, if educational material was given and if a dental referral was done.

Discussion

Clincal staff identified the importance of knowing the health literacy level of a patient. They repeated information and asked questions to ensure a patient understood their plan of care. One of the strength of the project has been the recongition of the clinical staff on the importance of incorporting appropriate educational materials to patients. One of the difficulties noted by clinical staff is the extra time that is needed when conducting a health literacy assessment. Clinical staff tended to not conduct health literacy assessements or offer dental referrals on days when they had a higher influx of patients.

Table 2

Educational Level

Valid	Frequency	Percent	Valid Percent
6th grade	1	2.2	2.2
7th grade	4	8.9	8.9
8th grade	1	2.2	2.2
9th grade	3	6.7	6.7
10th grade	3	6.7	6.7
High school grad	12	26.7	26.7
GED	1	2.2	2.2
Some college	5	11.1	11.1
Associates degree	3	6.7	6.7
Education not documented	12	26.6	26.6
Total	45	100	100

Note. The numbers illustrate the educational level of the patients with diabetes.

Table 3

Correlation Results

			Health Literacy Level	Dental Education given	Dental Referral Given
Kendall's tau_b	Health Literacy Level	Correlation Coefficient	1.000	-.172	-.211
		Sig. (2-tailed)	.	.253	.151
		N	45	45	45
	Dental Education given	Correlation Coefficient	-.172	1.000	.545**
		Sig. (2-tailed)	.253	.	.000
		N	45	45	45
	Dental Referral Given	Correlation Coefficient	-.211	.545**	1.000
		Sig. (2-tailed)	.151	.000	.
		N	45	45	45
Spearman's rho	Health Literacy Level	Correlation Coefficient	1.000	-.172	-.217
		Sig. (2-tailed)	.	.258	.153
		N	45	45	45
	Dental Education given	Correlation Coefficient	-.172	1.000	.559**
		Sig. (2-tailed)	.258	.	.000
		N	45	45	45
	Dental Referral Given	Correlation Coefficient	-.217	.559**	1.000
		Sig. (2-tailed)	.153	.000	.
		N	45	45	45

Note. There was a significant positive relationship between health literacy level , dental education given and dental referral given, $r = .559$, ***$p < .001$.

**. Correlation is significant at the 0.01 level (2-tailed).

Limitations

Limitations noted during the project implementation included not being able to use the electronic medical record to document health literacy assessment results. Patients are at an increased risk of being screened multiple times without a system in place of tracking who was

already screened. Front desk staff left the clinic and an additional licensed vocational nurse was hired during the implementation period causing potential patients to be missed during the screening process. Lack of participation from certain front desk staff, who did not fully understand the need for the project, caused potential patients to be missed as well.

If a patient did not leave with a dental appointment they were required to come back to in person to fill out new patient forms prior to receiving an appointment. Another limitation noted was the inability of patients to afford the cost of a dental visit. Patients reported that funding was the main reason that they did not attend or make an appointment for dental.

Recommendations

The Joint Commission has made health literacy assessment mandatory in hospitals yet that does not apply in the clinical setting (Agency for Healthcare Research and Quality, 2015; The Joint Commission, 2017). Health literacy assessment should be implemented in the clinic setting to help reduce the cost of uncontrolled chronic conditions. Providers need to be educated on what health literacy is and how it can impact their practice. This project would benefit if is expanded to all patients with chronic conditions (e.g. hypertension, hyperlipidemia, and chronic obstructive pulmonary disease). While this project only focused on dental screenings, it would have to be adjusted based on the guidelines of the specific diagnosis.

Implications for Practice

Governing agencies that have established guidelines regarding health literacy are The Joint Commission, Healthy People 2020, and the Institute of Medicine (Agency for Healthcare Research and Quality, 2015; The Joint Commission, 2017). The standards created by these agencies were to help health care professionals provide effective care to patients based on their learning needs to help reduce confusion (Agency for Healthcare Research and Quality, 2016;

The Joint Commission, 2017). Providers found that knowing a patient's health literacy level did positively affect their interaction with the patient. Health literacy is an essential component to not only improve patient outcomes and compliance but it also allows patients to take ownership of their health (Agency for Healthcare Research and Quality, 2015). It is the responsibility of every healthcare provider to understand health literacy.

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Appendix A

Telephone Follow up Survey

General Patient Information

In general, how did you feel about recent medical visit?

☐ Outstanding ☐ Good ☐ Poor

How would you rate your visit?

☐ Outstanding ☐ Good ☐ Adequate

☐ Needs improvement ☐ Poor ☐ N/A

How often have you visited this clinic within the past year?

☐ First Visit ☐ 2-5 Visits ☐ More than 6

Scheduling Your Dental Appointment

Did you schedule your dental appointment at this clinic or with your private dentist?

☐ Clinic ☐ Private Dentist ☐ Have not made appointment: Reason?

_____

Did you schedule your dental appointment the day of your medical visit, by phone or did you drop in?

☐ Day of Medical visit ☐ By phone ☐ Dropped in

If you scheduled an appointment, was your appointment date later than you expected?

☐ Yes | ☐ No

Additional Feedback

_____

_____

_____

Thank you for taking the time to fill out our survey and participating in this project. Your input is greatly appreciated.

Appendix B

Family Health Care

Patient Information for Referrals

Primary Medical Care

This referral order serves as medical request for this patient to receive appropriate dental treatment.

Date of referral:

Referring clinician

Patient name:

Contact information:

Date of birth:

MRN:

High risk for tooth decay due to family history [Y/N]:

Insurance status:

Reason for referral:

Pertinent medical information (problem list, medication list, allergy list):

Impression for patient to tolerate dental treatment:

Dentistry (please return to referral coordinator after dental visit)

Date patient was seen:

Reason for referral:

Dentist:

Appendix C

UNIVERSITY OF THE INCARNATE WORD

May 11 2017

PI: Ms. Diana Solis

Protocol title: Increasing Provider Awareness of Patient Health Literacy Needs for Dental Screenings Among Patients with Diabetes in a Rural Health Clinic

Diana:

Your request to conduct the study titled "Increasing Provider Awareness of Patient Health Literacy Needs for Dental Screenings Among Patients with Diabetes in a Rural Health Clinic" was approved by Exempt review on 05/11/2017. Your IRB approval number is 17-05-009.

Please keep in mind these additional IRB requirements:

- This approval will expire **one year** from 05/11/2017.
- Request for continuing review must be completed for projects extending past one year. Use the **IRB Continuing Review Request form**.
- Changes in protocol procedures must be approved by the IRB prior to implementation except when necessary to eliminate apparent immediate hazards to the subjects. Use the **IRB Amendment Request form**.
- Any unanticipated problems involving risks to subjects or others must be reported immediately.

Approved protocols are filed by their number. Please refer to this number when communicating about this protocol.

Approval may be suspended or terminated if there is evidence of a) noncompliance with federal regulations or university policy or b) any aberration from the current, approved protocol.

Congratulations and best wishes for successful completion of your research. If you need any assistance, please contact the UIW IRB representative for your college/school or the Office of Research Development.

Sincerely,

Ana Wandless-Hagendorf, PhD, CPRA

Ana Wandless-Hagendorf, PhD, CPRA

Research Officer, Office of Research Development

University of the Incarnate Word

(210) 805-3036

wandless@uiwtx.edu

Cc: Research <research@uhs-sa.com>

Subject: RE: 17-285N Solis, NR, UHS Review Completed

Protocol Number: HSC20170285N
Title: Increasing Provider Awareness of Patient Health Literacy Needs for Dental Screenings Among Patients with Diabetes in a Rural Health Clinic

The issue of this QI project was discussed with the UHS Research Director, Deidre Winnier, PhD.

As discussed with Diana Solis this morning. Due to the fact no activities will take place at any UHS facility and it will not impact UHS PRN employee Diana Solis work hours, UHS review and approval is not required.

If you have any questions, please do not hesitate to contact the UHS Research Office.
Thank you,

June 2, 2017

To: Diana M. Solis (Dianamsolis2@uhs-sa.com)
UTHSCSA

cc: Diana Beckmann-Mendez (beckmann@uiwtx.edu)

From: Institutional Review Board

Subject: **No IRB Approval is Required; Project is Not Regulated Research**

Protocol Number: HSC20170285N
Title: Increasing Provider Awareness of Patient Health Literacy Needs for Dental Screenings Among Patients with Diabetes in a Rural Health Clinic

Dear Principal Investigator,

It was determined that your project does not require IRB approval because it is:

***Not regulated research* as defined by DHHS regulations at 45 CFR 46 and FDA regulations at 21 CFR 56.**
The proposed activity is not funded by DHHS as research; AND is not a systematic investigation to test a hypothesis and permit conclusions to be drawn; AND is not designed to develop or contribute to generalizable knowledge; AND the purpose is not to investigate the safety or effectiveness of a drug, medical device or biologic.

If the goals and/or activities of the project ***change*** during the course of the project, or if new activities are proposed that would constitute human subjects research, please re-contact the OIRB so that we may determine whether or not the revised plan involves human subject research activities.

Project/study sites: University Health System La Mision Family Health Care

Sincerely,

Juanita Ching

Digitally signed by Juanita Ching
DN: cn=Juanita Ching, o=UTHSCSA, ou=OCR, email=chingu@uthscsa.edu, c=US
Reason: I am the author of this document
Date: 2017.06.02 13:16:23 -05'00'

Research Compliance Coordinator
Research Protection Programs

Appendix D

The 18 items of *SAHL-E*, ordered according to item difficulty (keys and distracters are listed in the same random order as in the field interview)

Stem	Key or Distracter		
1. kidney	__urine	__fever	__don't know
2. occupation	__work	__education	__don't know
3. medication	__instrument	__treatment	__don't know
4. nutrition	__healthy	__soda	__don't know
5. miscarriage	__loss	__marriage	__don't know
6. infection	__plant	__virus	__don't know
7. alcoholism	__addiction	__recreation	__don't know
8. pregnancy	__birth	__childhood	__don't know
9. seizure	__dizzy	__calm	__don't know
10. dose	__sleep	__amount	__don't know
11. hormones	__growth	__harmony	__don't know
12. abnormal	__different	__similar	__don't know
13. directed	__instruction	__decision	__don't know
14. nerves	__bored	__anxiety	__don't know
15. constipation	__blocked	__loose	__don't know
16. diagnosis	__evaluation	__recovery	__don't know
17. hemorrhoids	__veins	__heart	__don't know
18. syphilis	__contraception	__condom	__don't know

Appendix E

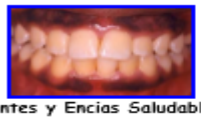
SAHL-S keys

Correct answers are bolded and highlighted in yellow

Stem	Key or Distractor		
empleo	__trabajo	__educación	__no se
convulsiones	__mareado	__tranquilo	__no se
infección	__mata	__virus	__no se
medicamento	__instrumento	__tratamiento	__no se
alcoholismo	__adicción	__recreo	__no se
riñón	__orina	__fiebre	__no se
dosis	__dormir	__cantidad	__no se
aborto espontáneo	__pérdida	matrimonio	__no se
estreñimiento	__bloqueado	__suelto	__no se
embarazo	__parto	__niñez	__no se
nervios	__aburrido	__ansiedad	__no se
nutrición	__saluable	__gaseosa	__no se
indicado	__instrucción	__decisión	__no se
hormonas	__crecimiento	__harmonia	__no se
abnormal	__diferente	__similar	__no se
diagnóstico	__evaluación	__recuperación	__no se
hemorroides	__venas	__corazón	__no se
sífilis	__anticonceptivo	__condón	__no se

Appendix F

El Salud Oral affecta su Salud General!


Dientes y Encias Saludables


Caries


Enfermedad de las Encias

Caries Dentales

- Cuando come comidas azucaradas, **bacteria** en la boca convierte la azucar a **acido**. El **acido hace huecos** en los **dientes** y hace **caries**. Caries pueden resultar en infecciones **graves**.
- Es mas probable que caries se formen si come comidas azucaradas mas a menudo.

Enfermedad de las Encias

- **Encias que sangran** son uno de los primeros signos de enfermedad de las encias.
- Si no se trata, la enfermedad de las encias puede causar que sus dientes se aflojen. Mas a menudo, estos dientes se tienen que sacar.

Prevenir Caries y Enfermedad de las Encias

- Solamente come bocados sin azucar entre comidas.
- **Evite** bebidas con azucar entre comidas, como jugos y soda. Tome agua y leche.

- Limpie entre sus dientes con hilo o palillo **dental todos los dias**.
- Vea a un dentista **dos veces al ano** para limpiezas y chekeos.

Caries y Medicamentos

- Muchos **medicamentos** hacen **secar la boca,** lo cual puede resultar en mas **caries**.
- Medicamentos que secan la boca incluyen esos para la depresion, alta presion de la sangre, el dolor, alergias y problemas del corazon.
- Si toma medicamentos que secan la boca, **tenga mucho cuidado al prevenir las caries**.

- Pregunte a su dentista o doctor acerca de enjuages y gel con fluoruro para protejer sus dientes.
- **Cepille** sus dientes **dos veces al dia** usando un **pastel dental con fluoruro.**

Su Boca y Salud General

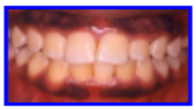
- Si esta **embarazada,** y no se trata la enfermedad de las encias, quizas pueda tener un parto prematuro.

- Usted puede pasar caries a sus hijos. Cuide sus dientes para ayudar que sus hijos tengan dientes sanos.
- Si tiene **diabetes,** el reisgo de tener una enfermedad de las encias es alto para usted. El control de su azucar puede ser mas dificil por la enfermedad de las encias.
- Una persona con enfermedad de las encias puede estar en reisgo mas alto para una enfermedad del **corazon.**
- Para prevenir **cancer oral,** evite o limite alcol y tobacco

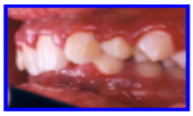
Developed by AB Douglass, MD, JM Douglass, BDS DDS, HJ Silk, MD
A product of the STFM Group on Oral Health www.stfm.org

Appendix G

Oral Health affects your Overall Health!


Healthy Teeth and Gums


Cavities


Gum Disease

Dental Cavities

- When you eat **sugary** foods, **bacteria** in the mouth turn the sugar into **acid**. The **acid eats holes** in **teeth** and makes **cavities**. Cavities can lead to serious **infections**.
- The more often you eat sugary foods the more likely cavities will form.

Gum Disease

- **Bleeding gums** are one of the first signs of gum disease.
- If not treated, gum disease can cause teeth to become loose. These teeth often have to be taken out.

Preventing Cavities and Gum Disease

- Eat only **sugar free** snacks between meals.
- **Avoid** sugar containing drinks between meals such as juices and soda. Drink water and milk.

- Clean between your teeth **every day** with **floss** or toothpicks.
- See a dentist **twice a year** for cleanings and check ups.

Cavities and Medications

- Many **medications** make your **mouth dry** which can lead to more **cavities**.
- Medications causing dry mouth include those for depression, high blood pressure, pain, allergies and heart problems.
- If you take medications that cause dry mouth be **very careful to prevent cavities**.

- Ask your dentist or physician about fluoride containing mouthrinses and gels to protect your teeth.
- **Brush** your teeth **twice a day** with a **fluoride** toothpaste.

Your Mouth and Overall Health

- If you are **pregnant**, untreated gum disease may cause you to deliver your baby too early.
- You can pass cavities on to your children. Take care of your teeth to help your children have healthy teeth.
- If you have **diabetes** you are at high risk for gum disease. Gum disease may make it more difficult to control your blood sugar.
- A person with gum disease may be at greater risk for **heart disease**.
- To help prevent **oral cancer** avoid or limit tobacco and alcohol.

Developed by AB Douglass, MD, JM Douglass, BDS DDS, HJ Silk, MD
A product of the STFM Group on Oral Health www.stfm.org

Appendix H

Patient FACTS

Oral Health and Diabetes

Patient FACTS

Oral Health and Diabetes

Appendix I


Patient FACTS

La salud bucal y la diabetes

ACP

Patient FACTS

La salud bucal y la diabetes