

TITLE PAGE

Title: The Correlation Between Food Insecurity and Type 2 Diabetes Management at a Federally Qualified Health Center

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ABSTRACT

Type 2 diabetes is a complex, chronic disease that impacts over 34 million Americans. Effective long-term management through medications and lifestyle modifications can be complicated by social determinants of health. Food insecurity is correlated with poor diabetes management and is more prevalent in populations of low socioeconomic backgrounds. The Wesley Community and Health Centers (“Wesley”) is an FQHC that serves many diabetic patients but has not conducted any systematic food insecurity screenings before this year. In response to the COVID-19 pandemic, Wesley implemented a clinic-wide social determinants of health screening of their patients, including a validated 2-item food insecurity screening tool, the Hunger VitalSign™. This project was a retrospective chart review of diabetic patients at Wesley who were screened for food insecurity to determine if there are any correlations between food insecurity status, measured by the Hunger VitalSign™ responses, and glycemic control, measured by A1c levels. Correlation was analyzed by linear regression. The results demonstrated that this population had a similar prevalence of food insecurity as the population of Arizona. The linear regression analysis did not demonstrate any correlations between food insecurity status and A1c in this population, primarily because the final sample size did not reach sufficient statistical power. However, the results cannot rule out the possibility of any correlations, therefore further research is recommended to better characterize the true levels and impacts of food insecurity at Wesley.

Word Count: 232

**The Correlation Between Food Insecurity and Type 2 Diabetes Management
at a Federally Qualified Health Center**

INTRODUCTION

Use of Hemoglobin A1c to measure glycemic control in type 2 diabetes

Type 2 diabetes mellitus is a complex, chronic disease that impacts over 34 million Americans.¹ The primary mechanism of pathogenesis is the development of insulin resistance in a patient's cells, in which a cell's ability to take up glucose from the blood via insulin signaling is impaired. Excess levels of glucose in the blood lead to cell and vascular damage. Therefore, one of the most important measures of effective diabetes management is blood glucose. Previously, blood glucose monitors were only able to provide single data point measures of a patient's blood glucose levels, a snapshot in time. However, blood glucose levels naturally fluctuate throughout the day in a healthy individual, and it can fluctuate even more so in a diabetic individual. Therefore, the Hemoglobin A1c test was developed to provide a more complete picture of a person's blood glucose levels measuring the average blood glucose over a 3-month period.² According to the American Diabetes Association³, there is a strong correlation between high A1c levels and the subsequent development of diabetes. The current diagnostic cut-off point for diabetes is an A1c \geq 6.5%. Therefore, A1c levels will be used in this study as a measure of how effectively each study participant is managing their diabetes.

Definition of food insecurity and its relationship with type 2 diabetes

Many factors contribute to the development of type 2 diabetes, including diet choices, level of exercise, and genetics. While there are pharmaceutical treatments available for the management of diabetes, long-term, effective management depends heavily on patient's self-management through lifestyle modifications in addition to treatments from their medical provider.⁴ A review by Nam, et. al⁵ of 1454 articles found that diabetes management is affected by patient adherence,

attitudes, beliefs, knowledge, culture, literacy, financial resources, co-morbidities, and social support, and these can become barriers in successful management if not addressed properly. The authors concluded that further research to identify specific barriers for certain patient populations and to design interventions with these barriers in mind is needed.

One barrier that has been correlated with type 2 diabetes is food insecurity.^{6,7} The United States Department of Agriculture's Economic Research Service defines four levels of food security – high food security, marginal food security, low food security, and very low food security.⁸ High food security and marginal food security both fall under “food secure,” while low food security and very low food security fall under “food insecure.” Combining the definitions of low food security and very low food security yields the definition of food insecurity – a situation in which one experiences reduced quality, variety, or desirability of diet and potentially disrupted eating patterns and reduced food intake.⁸ Food insecurity tends to occur in the setting of limited financial resources.⁶ Therefore, when someone is food insecure, they may substitute nutritionally-rich foods with less expensive, but nutritionally-poor foods. They may also face difficulties in obtaining foods that are both affordable and compatible with a diabetic diet.⁶ Thus, screening for food insecurity helps identify a significant risk factor in developing and managing type 2 diabetes that should not be neglected.

Gaps of knowledge in Federally Qualified Health Center populations

While barriers to diabetes self-management can be generalized into large categories, every subpopulation of diabetic patients still grapples with challenges unique to their particular situations. Although there have been studies on the particular difficulties that diabetic patients of

low socioeconomic background face, few studies were found that specifically focused on diabetic patients at Federally Qualified Health Centers (“FQHCs”), community-based health centers that primarily serve patients in underserved areas. A search using the following key word strings – “federally qualified health center food security”, “fqhc food security”, “federally qualified health center diabetes food security”, and “fqhc diabetes food security” – in PubMed performed on March 24, 2020 yielded a total of 5 unique results. A similar search in Scopus yielded 56 results, and a similar search in Google Scholar yielded 190 results, but not every result was relevant to the research question. Therefore, more research is needed on how food insecurity specifically affects diabetics in the FQHC patient population.

The Wesley Community and Health Center (“Wesley”) is one of the FQHCs serving the city of Phoenix, Arizona. Wesley’s patient population includes many diabetics, and recent initiatives have been implemented to improve health outcomes and self-management for these patients. In response to the COVID-19 pandemic, Wesley recently began administering a social risk assessment tool, the Protocol for Responding to and Assessing Patients’ Assets, Risks, and Experiences (“PRAPARE®”)⁹ to all of its patients for the first time. However, the PRAPARE® is not specifically validated to screen for food insecurity. Therefore, the 2-item Hunger VitalSign™ screening tool¹⁰ was added on to the PRAPARE® to specifically screen for food insecurity. The purpose of this study is to perform a retrospective chart review of Wesley patients with type 2 diabetes who completed the food insecurity screening questions. We hypothesized that patients who identified as being food insecure (an affirmative answer to at least one question in the screening tool) will be more likely to have poor glycemic control (evidenced by >7.0% HbA1c on their most recent blood test). The results of this study can be

used to determine if food insecurity is a significant risk factor for poorly managed diabetes, to evaluate existing diabetes interventions at Wesley for quality improvement, and to design future diabetes interventions that directly address food insecurity alongside glycemic control.

METHODOLOGY

IRB Review

After consultation with our institutional IRB specialist, we determined that an IRB was not necessary. A Determination of Human Research (DHR) application was sufficient for this study. The DHR application was approved on February 5, 2021.

Study Design & Setting

This was a retrospective chart review of patients with type 2 diabetes who were screened for food insecurity using the Hunger Vital Sign™ screening tool at the Wesley Community and Health Centers in Phoenix, Arizona. The Wesley Health Centers are free-standing, independent FQHCs with their own medical and administrative staff and in-house electronic health record. Their principal patient population is the medically under- or uninsured, and members of lower socioeconomic backgrounds. There is a sizeable Spanish-speaking patient population and diabetic population. These characteristics fit the study objectives well. In addition, the principal investigator had pre-existing clinical relationships and EHR access credentials at Wesley that will be in effect for the duration of the study. Therefore, access to data and working relationships with Wesley staff were considered adequate and beneficial for the study.

Source of Patient Records

This study analyzed a deidentified dataset from the Wesley's social determinants of health screening tool. The data points that Wesley provided included screening respondents' demographic information (age, sex, racial/ethnic identity), Type 2 diabetes diagnosis status (active diagnosis or not), answers to the Hunger Vital Sign™ screening questions, and most recent A1c measurement. Each respondent's data was assigned a randomly generated identification number to prevent data mixing. Inclusion criteria for data analysis were that the respondent was at least 18 years old, they have a documented type 2 diabetes diagnosis, they have a documented A1c measurement between 5/1/2020 – 11/30/2021, and their answers to the Hunger Vital Sign™ screening questions were recorded between 5/1/2020 – 11/30/2021. Charts were excluded if they did not meet the inclusion criteria. Diabetes diagnosis was determined based on ICD-10 documentation codes. Wesley staff securely transmitted the dataset to the principal investigator after the screening period ended. The principal investigator transferred the deidentified data to a spreadsheet held securely within the University of Arizona's Box servers. Deidentified data will be stored for up to 7 years post-study and then destroyed according to standard protocols at the end of the holding period.

The Hunger Vital Sign™ Screening Tool

The Hunger Vital Sign™ is a validated 2-item questionnaire developed to screen for food insecurity.¹⁰ It was developed by administering the USDA 18-item Household Food Security Survey (HFSS) to a sample of 30,098 low-income US families with young children of which 23% were food insecure. The 2 questions in the Hunger Vital Sign™ screening tool are the same as questions 1 and 2 in the HFSS (see Appendix I). These 2 questions received the most frequent affirmative answers from food insecure households, with a sensitivity of 97% and a specificity of

83% for food insecurity. The Hunger Vital Sign™ screening tool was also validated later on for use in youth and adolescents in 2015 and in adults in 2017.^{11,12} These studies indicate the Hunger Vital Sign™ screening tool is a rapid and effective screening tool for food insecurity. It has been made available for use by the authors without fee or license requirements.

The Hunger Vital Sign™ screening tool was incorporated into the PRAPARE® screening which Wesley began administering to all patients as part of their intake and patient outreach process beginning in May 2020. The screening questions were made available in English and Spanish. Because of some technological limitations in Wesley's electronic medical record system, the response options in Wesley's version of the Hunger Vital Sign™ only included "Yes" and "No", as opposed to the original survey's "Never True", "Sometimes True", "Often True" options (see Appendix II). However, since the original validation studies for the Hunger Vital Sign™ aggregated all affirmative responses ("Sometimes True" and "Often True") into a single positive food insecurity screening result, we determined that this change in Wesley's response options would not significantly impact the final results.⁹ Based on each patient's response to Question 1 (Q1) and Question 2 (Q2) of the Hunger Vital Sign™, their results were interpreted as either positive for food insecurity (answered Yes to either Q1 or Q2) or negative for food insecurity (answered No to both Q1 and Q2). The patient's A1c level was then correlated to their food insecurity screening result.

Statistical Analysis

The primary outcome of this power and sample size analysis was the mean difference in A1c between patients without and with food insecurity. Using data from the literature, 506 (253 in

each group) would be needed to detect a mean difference that is 25% of the standard deviation at 80% statistical power. If the mean difference increased to 30% of the standard deviation, 352 patients (176 in each group) would be needed to achieve 80% statistical power.

Patient demographic and baseline clinical characteristics were reported as medians for continuous variables and frequencies, and as percentages for categorical variables. The Mann-Whitney Test and Independent sample t-test were used to compare continuous variables while Chi-squared/Fisher's Exact Test was used to compare categorical variables. All p-values were 2-sided and $p < 0.05$ was considered statistically significant.

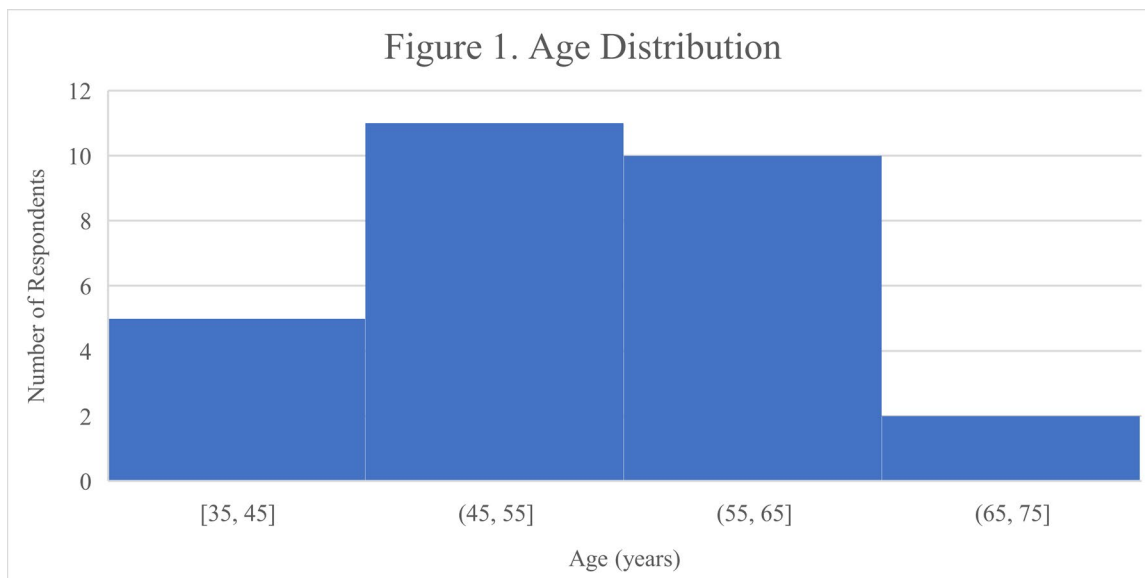
RESULTS

One-hundred seventy-seven patients responded to the Hunger Vital Sign™ questions during the chart review period. Out of these, 119 patients were excluded for not having a documented type 2 diabetes diagnosis. Out of these, an additional 29 patients were excluded for not having a documented A1c measurement. This left 29 patients' data which met the inclusion criteria for analysis. Of these, one patient's response to question 1 was invalid, so their data was excluded from analysis. A total of 28 patients were included in the final analysis.

Demographics

Table 1 shows the breakdown of respondents by sex, ethnicity, and race. Figure 1 shows the age breakdown.

Table 1. Demographic Data		
Sex	Count	% of Total
Male	9	32%
Female	19	68%
Ethnicity	Count	% of Total
Hispanic or Latino	24	86%
Not Hispanic or Latino	2	7%
Declined to Specify	2	7%
Race	Count	% of Total
White	3	11%
Black or African American	0	0%
Other Race	2	7%
Unreported/Refused to Report	7	25%
Declined to Specify	16	57%
Total	28	



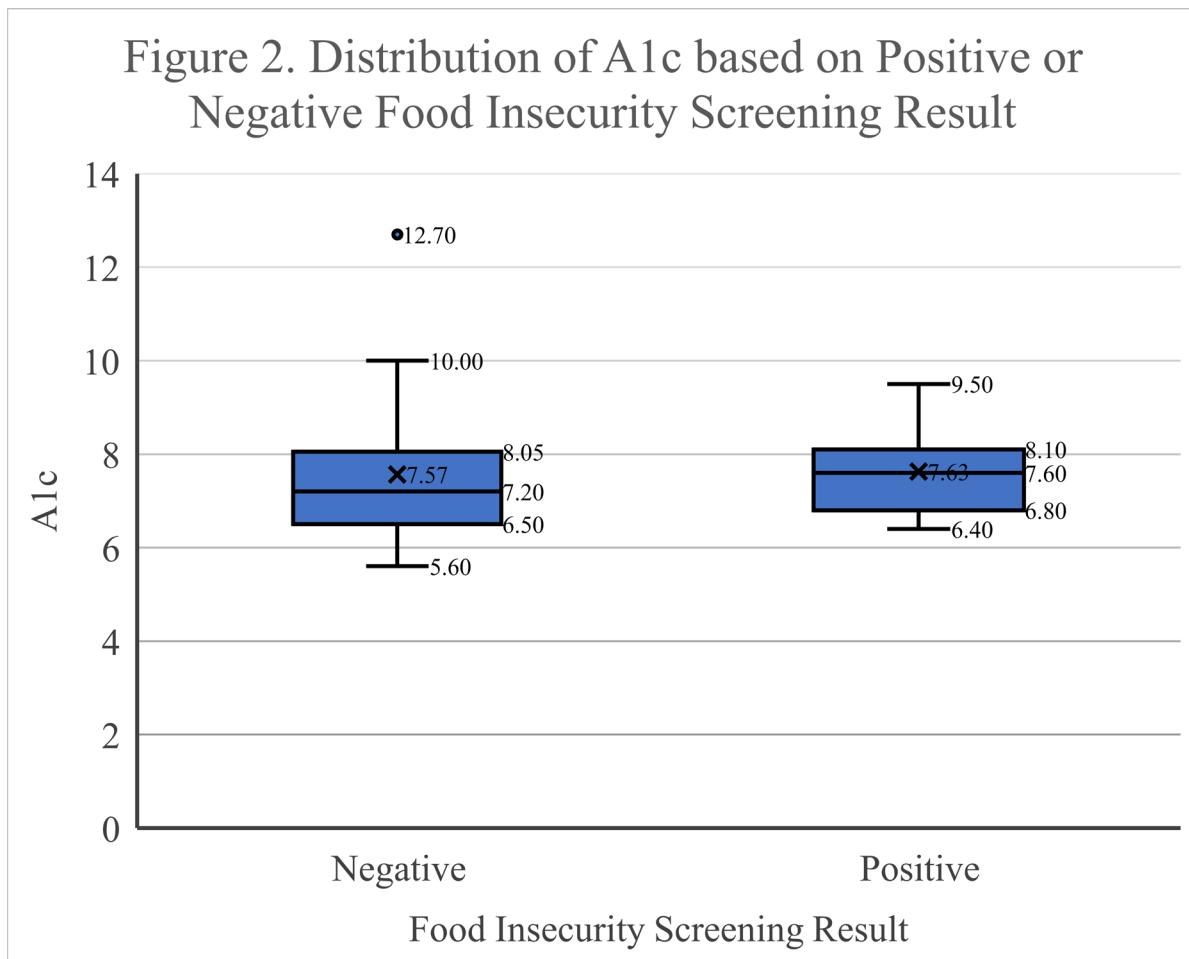
Responses to the Hunger Vital Sign™ compared to A1c

Table 2 summarizes the responses to the Hunger Vital Sign™ questions.

Table 2. Responses to the
Hunger Vital Sign™
Questions

	Q1	Q2
Yes	5	7
No	23	21

Figure 2 illustrates the distribution of A1c levels categorized based on food insecurity screening results.



The results of statistical analysis are in Table 3.

Table 3. Statistical Associations between Food Insecurity Screening and A1c, and Baseline Demographics				
	Total	No	Yes	p-value
	N=28	N=21	N=7	
A1c				0.44
median (IQR)	7.25 (6.75-8.05)	7.2 (6.7-8)	7.6 (6.8-8.1)	
mean	7.58 (1.50)	7.57 (1.66)	7.63 (1.00)	
Sex				1
F	19 (68%)	14 (67%)	5 (71%)	
M	9 (32%)	7 (33%)	2 (29%)	
Ethnicity				0.71
Declined to Specify	2 (7%)	2 (10%)	0 (0%)	
Hispanic or Latino	24 (86%)	18 (86%)	6 (86%)	
Not Hispanic or Latino	2 (7%)	1 (5%)	1 (14%)	
Race				0.22
Declined to Specify	16 (57%)	10 (48%)	6 (86%)	
Other Race	2 (7%)	2 (10%)	0 (0%)	
Unreported/Refused to Report	7 (25%)	7 (33%)	0 (0%)	
White	3 (11%)	2 (10%)	1 (14%)	
Age	54.07 (8.84)	54.90 (8.52)	51.57 (10.00)	0.4

Data are presented as mean (SD) or median (IQR) for continuous measures, and n (%) for categorical measures.

DISCUSSION

The Prevalence of Food Insecurity in the Wesley Community & Health Centers

In our study, according to Table 2, we found that the prevalence of food insecurity among the 28 patients who were analyzed was 25%. This was more than twice the national prevalence of food insecurity in 2022 (10.2%)¹³. However, it was consistent with the prevalence of food insecurity in Arizona (25.4% before COVID-19, 32.5% since COVID-19)¹⁴. Although our sample size was

small, the fact that we were able to capture similar levels of food insecurity as the rest of the state implies that the Wesley patient population is no exception to the challenges of food insecurity. Therefore, routinely screening for food insecurity and partnering with community resources to address food insecurity should not be neglected.

The Correlation between Food Insecurity and Glycemic Control

According to Figure 2 and Table 3, we found no association between food insecurity and glycemic control measured using A1c values among this population ($p = 0.44$). There was no statistical difference in the mean and median A1c levels between patients who answered No (mean 7.57, median 7.2) versus those who answered Yes (mean 7.63, median 7.6) to either screening question on the Hunger Vital Sign™ tool. There were also no associations found between sex ($p = 1$), race ($p = 0.22$), and ethnicity ($p = 0.71$) regarding the food security response. Given that we were not able to obtain a large enough sample for a sufficiently powered study, these results were not surprising.

Confounding factors & Limitations of this study

We recognize that this study was severely underpowered due to a variety of unexpected factors. The COVID-19 pandemic presented a significant challenge during the data collection process for both the Wesley clinical staff and the principal investigator. It is likely that the pandemic reduced the number of patient visits at the Wesley clinic, and disrupted the usual workflow, making it difficult to collect sufficient data. In addition, there were difficulties with recording responses to the screening tool in the electronic medical record. Finally, it is very common among FQHC patient populations to have difficulty following up, which may have contributed to the lack of

A1c measurements for many screened patients, even though they were diagnosed with type 2 diabetes.

Another factor that contributed to low power may have been the decision to incorporate the Hunger Vital Sign™ screening questions into the PRAPARE® screening that Wesley implemented. Before the pandemic, the principal investigator planned to administer the Hunger Vital Sign™ personally with paper forms during patient intake, or to personally supervise the administration of the Hunger Vital Sign™ on-site. After the pandemic disrupted normal clinic operations, we decided to incorporate the Hunger Vital Sign™ into the PRAPARE® screening order to reduce the number of screening tools that needed to be administered per visit. We also believed that increasing the number of questions by 2 questions would not have a significant impact on the willingness of patients to respond to the questionnaire, especially since the Hunger Vital Sign™ questions expanded upon one of the PRAPARE® questions about not being able to obtain one's living necessities such as food. However, it is possible that because of the order in which the Hunger Vital Sign™ questions were asked in relation to the rest of the PRAPARE® questions, in conjunction with the challenges mentioned previously, that this decision may ultimately have had greater negative impact than anticipated on our ability to successfully gather sufficient data. There were also likely inconsistencies in the way the Hunger Vital Sign™ and the PRAPARE® were administered among diabetic patients, which reduced the usable sample size. For example, there were 784 unique responses to the PRAPARE® but only 177 unique responses to the Hunger Vital Sign™ within the same chart review period. The PRAPARE® received 82 responses that food was something difficult to obtain when needed, but the Hunger Vital Sign™ questions were only asked in follow-up two of these times, and these two instances

were both for the same individual. These inconsistencies likely resulted from logistical challenges with administering the screening to every patient due to the pandemic, and from technical limitations of the clinic electronic medical record. In future studies, improving the logistics of administering the survey instrument may correct these inconsistencies.

In this study, we did not collect data about patients' socioeconomic status or their current diabetes management regimen. National and local statistics do find an inverse correlation between socioeconomic status and food insecurity.^{12,13} Therefore socioeconomic status may be a confounding factor in our results. Since the Hunger VitalSign™ answers and the respondent's corresponding A1c measurement were not dated, we were unable to determine when the A1c was measured in relation to when they were screened for food insecurity. It was also difficult to determine at what stage of the respondents' diabetes management plan the screening took place, and whether they were currently taking medications for glycemic control. These were also likely confounders in the correlation between food security status and glycemic control. Further investigation that takes these factors into account would help to better characterize the relationship between food insecurity and glycemic control.

CONCLUSIONS

In this retrospective chart review of food insecurity and type 2 diabetes in an FQHC during the COVID-19 pandemic, we found food insecurity was present at a level consistent with the prevalence of food insecurity in Arizona. We did not find any statistical correlation between food insecurity and poor glycemic control. However, under the circumstances which led to a severely underpowered study, these results do rule out any correlation between food insecurity and

poor glycemic control. Therefore, repeating this study with a larger sample size while also controlling for socioeconomic status and diabetes management would likely yield a more statistically significant description of any correlations between food insecurity and poor glycemic control in this population. The results of the study can still be used to inform clinical practices at the Wesley in regards to general food insecurity screening and in regards to providing tailored diabetes management strategies and resources for patients who are negatively impacted by food insecurity.

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Appendix I

The Hunger Vital Sign™ Screening Tool⁹

Food Security

The following statements have been made by people about their food situation. For each statement, please circle whether the statement was never true, sometimes true or often true for *your household in the last 12 months*.

1. “We worried whether our food would run out before we got money to buy more.”

Never True

Sometimes True

Often True

2. “The food that we bought just didn’t last, and we didn’t have money to get more.”

Never True

Sometimes True

Often True

Seguridad Alimentaria:

Gente ha hecho las declaraciones siguientes sobre su estado de comida. Con cada declaración, por favor encierre en un círculo si la declaración nunca era verdad, a veces era verdad, o muchas veces era verdad en *su hogar en los últimos 12 meses*.

1. “Estábamos preocupados que se iba acabar la comida antes de que tengamos dinero para comprar más.”

Nunca era verdad

A veces era verdad

Muchas veces era verdad

2. “La comida que compramos no era suficiente, y no teníamos dinero para comprar más.”

Nunca era verdad

A veces era verdad

Muchas veces era verdad

Appendix II

Screenshot of Wesley Social Determinants of Health Screening in EHR (Taken 7/27/2020; yellow highlighting added for emphasis)

Subjective:

Chief Complaint(s):

SDOH SCREENING TEST, COVID 19 Nurse Visit Template, Outreach Nurse Visits- SDOH.

HPI:

F/u

Telephone contact initiated with patient for evaluation of social determinants of health, and mental/physical health status.

Hi, my name is _____. I am calling from Wesley Health Center. We are reaching out to all of our patients during the coronavirus pandemic to check on how they are doing, and to see if there is any way we can help. Do you have a couple of minutes to talk to me?.

In the last 12 months, have you worried whether your food would run out before you got money to buy more? ____, The food that you bought just didn't last, and you didn't have money to get more ____. Have you... Felt safe in your home? ____, Felt down, depressed, or hopeless? ____, Had problems getting childcare that make it difficult for you to work? ____. Are you... Currently working? ____, Worried you may not have stable housing now or in the future? ____, Worried you may have water/gas/electricity/etc shut off to your home? ____, Worried about your ability to pay your other bills? ____. Would you... Like/need refills on any medications? ____, Like/need to schedule a telemedicine visit with a provider? __.

This patient was evaluated by WHC clinical staff, including temperature, symptoms, and possible exposure to COVID-19.

The patient was recommended to schedule a telemedicine visit with a WHC MD/NP: YES/NO.