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VALIDATION OF A TYPE 2 DIABETES RISK STRATIFICATION TOOL IN A LOW INCOME HISPANIC PATIENT POPULATION

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A pilot study was undertaken to evaluate the appropriateness of a previously published diabetes risk stratification tool in a diabetic population. The tool was applied to a sample of 500 prediabetic and diabetic adults receiving primary care services at a Federally Qualified Health Center (FQHC) in Cameron County, Texas. The study population was largely Hispanic and underserved. The National Health and Nutrition Examination Survey (NHANES) 2015-2016 data set was used as a comparison group. The risk assessment tool was applied to separately to the prediabetic and diabetic subset of both study groups. The tool stratified the patients into three risk categories: green (low risk), yellow (moderate risk) and red (high risk). The tool was applied to both the weighted and unweighted NHANES data; however, unweighted NHANES data was used for most of the comparisons as this was a pilot study. After applying the tool, among the prediabetic clinic patients, 20% were categorized into the red zone, while 1% of the prediabetic comparison group was placed in this zone. For diabetic clinic patients, 56% fell into the red zone, with 42% of the comparison group in this zone. These differences were significant. The utility of the tool was limited by the degree of missing data points, particularly among the clinic patients. The tool uses the values of the Patient Health Questionnaire 9 (PHQ9) in the risk stratification process. At least

64% of the PHQ9 scores were missing in clinic patients. The average PHQ9 score was computed and assigned to those clinic patients with missing PHQ9 scores. Applying the tool to this simulated data reduced the percentage of prediabetic clinic patients in the red zone to 16% and the percentage of diabetic patients in this zone to 44%. After this simulation, the distribution of the risk zones of the diabetic patients was no longer significantly different from the comparison group. This study demonstrates the importance of assessing for missing data in applying a risk stratification tool.

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BACKGROUND AND PUBLIC HEALTH SIGNIFICANCE

Diabetes is a growing health problem in the United States. It is estimated that, as of 2015, 9.4% of the U. S. population has diabetes. It is projected that the prevalence will increase 54% by 2030 (Rowley, Benzoid, Arilcan, & Byrne, 2017). The estimated total economic burden of diabetes was $245 billion in 2012 (American Diabetes Association, 2013). By 2030, the cost of diabetes in the U. S. is estimated to be $622.3 billion in 2015 dollars. (Rowley, 2017). Furthermore, it has been estimated that hospital inpatient care, nursing home stays, home health services and prescription medications to treat complications of diabetes account for nearly 75% of all health care expenditures attributed to diabetes. (Herman, 2013)

The prevalence of diabetes is unevenly distributed, and is highest in non-Hispanic black and Hispanic populations compared to whites. (Centers for Disease Control, 2017). A cohort of Mexican-Americans in Cameron County in south Texas, on the Texas-Mexico border, shows a 27.6% prevalence of diabetes, with an average Hemoglobin A1c of 7.8%. This cohort resides in one of the two poorest counties in the U. S. In addition, only 34% of this population has health insurance. (Fisher-Hoch, Vatcheva, Rahbar & McCormick, 2015). Previous work with this population found an average A1c of 9.4% in those with diabetes. (Fisher-Hoch, Rentfro, Salinas, Perez, Brown, Reninger, et al, 2010). Thus, this is a population with higher rates of uncontrolled diabetes than the U. S. average. Additionally, this population lacks the resources to cope with the financial burden imposed by diabetes.

The growing prevalence and economic burden of diabetes suggest that the U. S. primary care system has been ineffective in preventing or controlling diabetes and its

associated adverse health effects. The Patient Centered Medical Home (PCMH) is a care model characterized by comprehensive primary care, quality improvement, care management, and enhanced access. These components of care are provided in a patient-centered environment. Specifically, the PCMH model is intended to focus on early management of health problems while reducing unnecessary specialty and inpatient care (Patient Centered Primary Care Collaborative) thereby improving health outcomes and controlling cost.

Many safety net clinics are adopting the PCMH model under the umbrella of Federally Qualified Health Centers (FQHC), as this model is generally thought to be ideal for providing high quality care for chronic diseases to underserved communities. Evidence demonstrating the effectiveness of the this model is mixed. For example, one systematic review of 19 comparative studies found the PCMH had small to moderate positive effects on delivery of primary care services. There was a reduction in emergency department visits, but not in hospital admissions. No evidence of overall cost savings was found. (Jackson, Powers, Chatterjee, Bettger, Kemper, et al., 2013)

Effectiveness of PCMH when considering diabetes alone is also not yet clearly established. Ackroyd and Wexler (2014) reviewed results from major demonstration projects. While there were overall improvements in measures such as A1c and LDL cholesterol, those improvements tended to be small. Furthermore, some programs demonstrated cost savings with others seeing increased costs or net cost neutrality. Another study examined the association between the PCMH characteristics and quality of diabetes care in 15 safety net clinics across five states. The results found inconsistent care quality. There was a positive

association between the care management component of the PCMH and quality of diabetes care. This finding lead the authors suggest that PCMHs may need to intensify focus on the care management component of this care delivery model. (Gunter, Nocon, Gao, Casalino & Chin, 2017)

Patient centered care for diabetic patients has shown to be cost effective for those with Hemoglobin A1c > 8.5%. A randomized trial of 506 patients with type 2 diabetes in the Netherlands stratified patients into three groups based on A1c: 7% or less; 7.0-8.5%; and >8.5%. All of the patient were then enrolled in a patient-centered care program that included detailed diabetes passports in which the results of guideline-based care was recorded. The patients also attended multiple education sessions. The group with the highest A1c (>8.5%) demonstrated higher A1c reductions and a higher incremental cost effectiveness ratio per QUALY than for patients stratified into the other two groups. (Slingerland, Herman, Redekop, Dijkstra, Jukema, et al., 2013). In fact, this patient centered care was not cost effective for the baseline group (A1c <7%). The lack of cost effectiveness for the baseline group suggests that identifying groups of patients who will not benefit from use of additional resources is important in providing high value care to a population as a whole.

Risk stratification methods are being explored as potential tools to help the PCMH identify patients who benefit most from the additional services provided by the coordinated care component of the PCMH model. A retrospective study which evaluated six non-disease specific risk stratification models found that, while one model outperformed the others, all models evaluated were able to predict hospitalizations, emergency department visits, 30 day

readmissions, and highest cost patients. (Haas, Takahashi, Shah, Strobel, Bernard, et al., 2013).

The Patient Centered Medical Home Assessment (PCMH-A) is a tool designed to help PCMHs identify opportunities for improvement. The PCMH-A measures eight domains: empanelment; continuous team-based healing relationships; patient centered interactions; engaged leadership; quality improvement strategy; enhanced access; care coordination; and organized, evidence-based care. Transformation activities in each of these domains have been shown to improve overall PCMH-A scores. (Daniel, Wagner, Coleman, Schaefer, Austin, et al., 2013). It sees reasonable to surmise that improvement of PCMH-A scores in several of these domains could be achieved by the development of an effective risk stratification strategy. This represents an additional reason for studying risk assessment models.

The number of predictive models for management of diabetes and its complications has been growing rapidly. Cishoz, Johansen & Hejlesen (2016) reviewed the studies published and found that extensive effort has been put into building models. However there is a noticeable paucity of studies examining the impact of these models. Therefore, the usability, clinical and economic impact of risk stratification models is largely unknown.

Risk stratification for diabetic patients is not clearly defined, and there is no universally accepted method. One Danish study of diabetic patients in an endocrinology practice stratified 589 patients into 3 levels. Level 1 was the lowest risk group, with levels 2 and 3 representing successively higher risk groups. While the main purpose of this study was to compare the risk stratification by endocrinologists to a risk stratification using objective

criteria, only 4% of the patients in the study were stratified to the lowest risk group. Stratification criteria included blood pressure, A1c, total, HDL and LDL cholesterol, retinopathy, nephropathy and neuropathy. (Munch, Arreskov, Sperling, Overgaard, Knop, et al., 2016) It is not clear that the risk stratification process used in this study would be applicable in the primary care setting.

The Joint Asia Diabetes Evaluation (JADE) Program is a web-based program that categorizes patients into 4 risk levels based on results from a comprehensive annual assessment. It also suggests care protocols and offers clinical decision and self-management support based on the computed risk level. A study done to validate the risk stratification process of the program reported a stratification distribution as follows: level 1, 6%; level 2, 19.5%; level 3, 54.9%; level 4,15.1%. The sample size was 7534 patients, and levels 1 through 4 represent successively higher risk categories. This tool uses several calculated risk scores as part of the stratification criteria (Chan, So, Ko, Tong, Yang, et al. 2009). Therefore, it may be too complex for use in a busy primary care practice.

The Moorehouse Healthcare Comprehensive Family Health Center serves a poor, disadvantaged population. They report developing a risk stratification process based on number of chronic conditions combined with the number of behavioral health conditions to stratify patients into 3 global risk groups. High risk patients were then offered enrollment in a chronic disease management program. The intervention included one physician visit, four home visits with a community health worker (CHW) and behavioral health assessments. Three hundred and forty seven patients out 3,360 were in the high risk group. Hypertension was the most common condition. Next were hyperlipidemia, obesity, and type 2 diabetes.

More than half the high risk group also had depression. The study did not report outcomes, and was not specific to diabetes. However it illustrates the importance of using a simple risk stratification tool that uses exclusively internal data readily available to clinic staff. (Xu, Livingston-Williams, Gaglioti, McAlister, & Rust, 2018). Because our population of interest is also underserved, we also sought a fairly simple risk assessment tool.

One promising risk stratification tool was developed as part of the multi-center Beacon Community Program for use of health information technology. This tool was developed at the Cincinnati, Ohio Beacon community with the intent of helping the affiliated PCMHs increase compliance with the National Quality Forum endorsed "D5" measure (Christopher, Trudnak, Hemenway, Bolton, Tobias, et at., 2015). The "D5" refers to five goals for patients with type 2. These include Hemoglobin A1c <8%, blood pressure < 140/90, LDL cholesterol <100mg/dL, 1 aspirin per day as appropriate, and self-reported nonsmoking status. (Curnow, Knight, Harris, & Linscott, 2012)

The risk stratification tool developed by the Cincinnati Beacon Community accounts for all the "D5" measures except aspirin use. It also accounts for depression via the Patient Health Questionnaire, depression module (PHQ-9) score. It was developed in conjunction with clinicians who were the intended users, and was incorporated into the EHR of several clinics that were part of the Cincinnati Beacon Community It is appealing because it would be fairly quick to complete, which is important in a busy practice. All components would be easily obtained from the information available locally to an individual clinic. This tool also contains questions designed to assess some care management issues, such as "Did you address the patient's readiness to change? If so, what stage is the patient?" and "Did you

assist the patient with coordination of other care services during their visit? If so, what did you coordinate?". Inclusion of such questions suggest this tool may help improve incorporating care management with diabetes quality measures, as suggested by Gunter et al. 2017. Once a patient is assigned a risk level, these questions direct the clinician to consider what additional resources might be needed for that patient. This could help the PCMH in proper resource allocation.

One FQHC operating under the PCMH model is known as *Su Clinica*, located in the Rio Grande Valley area of Texas, on the Texas-Mexico border. This clinic serves a low income, largely Hispanic population with a panel of approximately 45,000 active patients over four clinic sites. The management of *Su Clinica* is interested in evaluating risk stratification methods in order to help effectively guide the allocation of resources for chronic disease management. Given that this is a population with a high prevalence of uncontrolled diabetes, it makes sense to evaluate risk stratification methods for diabetes. We have chosen the Cincinnati Beacon Community diabetes risk stratification tool. This tool was chosen because it can be completed quickly using information readily available to the clinic from clinic records. The tool also contains questions matched to each risk level to help direct patients assigned a given risk level to the appropriate resources.

This study will use the tool to stratify the clinic's diabetic patients into the three risk categories. Since this is a population a higher rate of uncontrolled diabetes, we recognize the possibility that a majority of patients could be stratified to the highest risk level, potentially minimizing the usefulness of the tool. Therefore, we will also use the tool to stratify a subset

of the NHANES cohort as a comparison group. We are using this strategy as we are unaware of any studies published evaluating the use of this tool in the clinical setting.

This study represents a first step in the process of adopting a risk stratification strategy. Additional work will be needed to evaluate if the resource allocation suggested by the tool would lead to improved diabetes outcomes.

Study Objective

The overall goal of this study is to conduct a pilot assessment of the appropriateness of a diabetes risk stratification tool in a population of adults receiving primary care services at one of the four locations of *Su Clinica,* who have had at least two visits, with at least one visit between May 31, 2017 and May 31, 2018 and who were over the age of 25 years old as of May 31, 2017. The tool will be applied to a sample of 500 patients. The risk stratification tool will also be applied to the National Health and Nutrition Examination Survey (NHANES) data set from 2015-2016 as a comparison group. The risk stratification tool to be used is presented in Appendix A**.**

Research Objectives

1. To identify a sample of 500 patients meeting the above criteria who have a diagnosis of diabetes or prediabetes.
2. To stratify these patients into 3 risk groups using the Diabetes Risk Stratification Tool developed by the Cincinnati Beacon Community.
3. To perform the same risk stratification using the NHANES 2015-2016 data set.
4. To compare the risk stratification results from the *Su Clincia* patient sample to the risk stratification results from the NHANES data set.

5. To identify possible confounders (such as age in five-year increments and insurance type) in the clinic sample of patients

METHODS

Study Design

This is a cross sectional study

Study Setting

The study setting is a Federally Qualified Health Center (FQHC) know as *Su Clinica*, located in the Rio Grande Valley area of Texas, on the Texas-Mexico border. *Su Clinica* has four clinic locations in the cities of Brownsville, Harlingen, Raymondville and Santa Rosa. These clinics combined have a panel of approximately 45,000 active patients. As a Patient Centered Medical Home (PCHM), the clinic management is evaluating strategies to most effectively allocate resources to maximize patient and population health outcomes. Towards this end, it is theorized that stratifying patients with chronic diseases by risk for complications will identify which patients will benefit most from more intensive resource allocation.

Study Subjects

The study population is all non-pregnant adult individuals older than 25 years of age who have received primary care services at one of the four *Su Clinica* locations. The study sample is a randomly selected sample of 500 patients meeting the inclusion criteria listed below.

Inclusion and Exclusion Criteria

Inclusion criteria

1. Who have had at least two visits at one of the four *Su Clinica* sites with at least one visit between May 31, 2017 and May 31, 2018.

2. Are over age 25 years as of May 31, 2017.

3. Have a diagnosis of Type 2 Diabetes Mellitus (as indicated by ICD 10 code (E11.XX) OR a diagnosis of prediabetes as indicated by ICD 10 code R.73.XX) as of May 31, 2017.

Exclusion criteria

1. Patients who otherwise meet the inclusion criteria but have died between May 31, 2017 and May 31, 2018.

2. Patients who were pregnant at any time between May 31, 2017 and May 31, 2018.

Sample Size Calculation and/or Study Power

Because this is a pilot study to assess the possible utility of a risk assessment tool, no statistical power calculations are necessary.

Data Collection

This study used data already collected by *Su Clinica* and contained in the clinic's Electronic Health Record (EHR). The clinic IT staff provided the research team a de-identified data set with patients assigned to pre-determined age groups in five year increments. Data points were include sex, race/ethnicity, hemoglobin A1c, statin medication use, low density lipoprotein (LDL), Patient Health Questionnaire, depression module (PHQ-9) score, systolic and diastolic blood pressure and tobacco use. Insurance type was also collected. Patients were assigned to 5-year age groups.

Data points intended to help evaluate the appropriateness of the risk stratification was also collected. These included height, weight, urine microalbumin, glomerular filtration rate (GFR), and documentation of eye examination in the past year. No identifiable protected health information was collected or accessible to the research team, therefore informed consent was not needed.

The same data were extracted from the NHANES 2015-2016 data set. These data were downloaded as a Statistical Analysis System (SAS) file.

Data Handling and Record Keeping

The data for the *Su Clinica* population was accessed at the Harlingen location via the EHR. Only the relevant data points collected and listed above were stored in an Excel file and made available to the research team. The data for the comparison group will be from publicly available NHANES data which will be accessed as a SAS file.

No human subjects were identifiable, either directly or indirectly.

Data Analysis

Data analysis was conducted using Stata version 15.1 (College Station, TX). Data obtained in SAS format was converted to Stata format prior to analysis. For both the clinic and NHANES data, each clinical characteristic contributing to the overall risk score (A1c, SBP, DPB, LDL, statin present or absent, PHQ9, and tobacco use) was assigned the appropriate value using the criteria given in the risk stratification tool. These scores were summed and the individual was placed into the appropriate risk category of green, yellow, or red.

The NHANES population was subdivided into the categories of not diabetic, prediabetic and diabetic based on A1c. Those with A1c $\leq$ 5.6 were categorized as not diabetic. Those with A1c 5.7- 6.4 were categorized as prediabetic. Those with A1c $\geq$ 6.5 were categorized as diabetic. Those with missing A1c were categorized as unknown. We then applied the weighting necessary to extrapolate these categories to the entire US population.

Descriptive statistics for both the clinic and unweighted NHANES data were tabulated and compared using chi 2 test. The remainder of the analysis using NAHNES data was performed on the unweighted data and further limited to those categorized as prediabetic or diabetic as the comparison group. The clinic patients were subdivided into prediabetes and diabetes based on ICD 10 code. Both groups were kept separated into prediabetes and diabetes. The risk categorization process was used to assign the risk zone of green, yellow or red.

For both the clinic and the unweighted NHANES data, the mean and standard deviation of the clinical characteristics of the continuous variables (A1c, SBP, DBP, LDL, PHQ9) for each risk level were computed. These were then compared using t test. This comparison was done for both the prediabetic and diabetic groups.

Next, the percentage of missing values of continues variables (A1c, SBP, DBP, LDL, PHQ9) was calculated. This was done for each risk level, in both the prediabetic and diabetic groups. Missing values for both the clinic and unweighted NHANES data was assessed.

The odds ratio for insurance presence vs red zone (highest risk) was computed for the clinic population. The odds ratio was computed separately for the prediabetic and diabetic patient groups.

A post-hoc analysis intended to simulate the risk stratification without missing values was performed. For the clinic data only, the average PHQ9 score was computed and this value was substituted for any missing PHQ9 values in the clinic sample to create a simulation. This simulated clinic sample was then re-stratified into simulated risk categories

RESULTS

Using the A1c to categorize the NHANES data into diabetes and prediabetes and then extrapolating to the entire US population suggests that 25% of the US population has either prediabetes or diabetes. Nearly 7% have diabetes and almost 19% have prediabetes. Applying this risk stratification tool to the diabetic population, 21% of those individuals would fall into the green zone, 42% into the yellow zone and 31% into the red zone. For prediabetes, 65% fall into the green zone, 34% in the yellow zone and 1% in the red zone. These distribution differences are statistically significant ($p<0.001$). (Table 1) The distribution is depicted graphically in Figure 1.

When the unweighted NHANES respondents were categorized as prediabetic or diabetic based on A1c values, there were 1482 respondents who are prediabetic and 691 who are diabetic, with a combined total of 2173. This is the comparison group used for the clinic sample of 500 for the rest of the analysis.

Comparing the clinic population to the subset of the unweighted NHANES of prediabetic and diabetic respondents reveals some striking demographic differences. The clinic population is largely female and overwhelmingly Hispanic. Relative to the NHANES data set, the clinic has a larger percentage of patients in the middle age groups, and a much higher percentage of uninsured (44.4% vs 14.2%). The difference between the two groups in all demographic characteristics assessed are significant at the $p<0.001$ level. (Table 2)

The overall risk stratification distribution of clinic prediabetic and diabetic population is shown in Table 3. Seventeen percent of the prediabetic patients and 10% of the diabetic patients fall into the green zone. The yellow zone contains the bulk of the prediabetic patients, with 63% of them falling here along with 34% of diabetic patients. The majority of diabetic patients fall into the red zone, which contains 56% of diabetic, as well as 20% of prediabetic patients. These differences are significant at the $p<0.001$ level. Figure 2 displays a graphic depiction of the distribution.

When the risk stratification results of the prediabetic clinic patients is compared to the unweighted NHANES prediabetic respondents, there is a difference in distribution between the two populations. For the clinic patients, 17% fall into the green zone, whereas 65% of the NHANES respondents fall into the green zone. The yellow zone contains 63% of the clinic patients and 34% of NHANES respondents. Twenty percent of the clinic patients and 1% of NHANES respondents are assigned to the red zone. All of these differences are significant at the $p<0.001$ level. (Table 4)

Comparing the risk stratification of the diabetic clinic patients with the unweighted NHANES diabetic respondents, 10% of clinic patients and 18% of the NHANES respondents

are categorized in the green zone. In the yellow zone are 34% of the clinic patients and 40% of the NHANES respondents. The red zone contains 56% of the clinic patients and 42% of the NHANES respondents. These differences are significant at the $p<0.001$ level. (Table 5)

For the values of A1c, blood pressure (both SBP and DBP), LDL and PHQ9, we compared the mean of these values for both the clinic and unweighted NHANES respondents within each risk zone in the prediabetic and diabetic categories. In the prediabetic category, there was no significant difference in any of these values between the clinic patients and unweighted NHANES respondents in the green zone. In the prediabetic category, there was a significant difference in the mean value for A1c and SBP between the clinic patients and unweighted NHANES respondents for the yellow zone. In the red zone, the mean values for SBP, DBP and PHQ9 were significantly different between the clinic patients and the unweighted NHANES respondents. These results are shown in Table 6.

In the diabetic category, the mean values for A1c and LDL were significantly different between the clinic patients and unweighted NHANES respondents in the green zone. In the yellow zone, there was a significant difference in the mean value for A1c and SBP between the clinic patients and unweighted NHANES respondents for the diabetic category. There was a significant difference in the mean values forA1c, SBP, and PHQ9 between the diabetic clinic patients and unweighted NHANES respondents in the red zone. Table 7 shows these results.

Next, we assessed the percentage of missing values for A1c, SBP, DBP, LDL and PHQ9. For both the prediabetic and diabetic categories, there were no missing values in either the clinic patients or the unweighted NHANES respondents in the green zone. In the

yellow zone, for the both prediabetic and diabetic categories, the clinic patients had missing values for LDL and PHQ9 (Table 8). The unweighted NHANES respondents had missing values for SBP, DBP, and PHQ9. Most striking is that 77% of prediabetic clinic patients and 64% of diabetic clinic patients were missing PHQ9 values. In the red zone, for both the prediabetic and diabetic categories, the clinic patients had missing values for A1c, LDL and PHQ9 (Table 9). The unweighted NHANES respondents had missing values for SBP, DBP and LDL. The red zone prediabetic category had the most striking missing values with 78% clinic patients missing A1c, 66% missing LDL and 76% missing PHQ9. Red zone prediabetic NHANES respondents were missing 69% of SBP values and 75% of DBP values. For the diabetic clinic patients in the red zone, 70% were missing PHQ9 scores.

We then assessed the impact of having insurance on being assigned to red zone for clinic patients. We calculated the odds ratio using the risk levels of the data before performing the above mentioned simulation. Having insurance provided a nonsignificant protective effect for being to the red zone for both prediabetic clinic patients (OR 0.84, 95% CI: 0.40-1.71) and diabetic clinic patients (OR 0.70, 95% CI: 0.43-1.15) (Table 10).

After noting the high percentage of missing PHQ9 scores, we performed a post-hoc analysis designed to simulate what the risk distribution might look like if these scores were not missing. First, we determined that the average PHQ9 score in the clinic population is 6.1. We then substituted this value for any missing PHQ9 scores in the clinic population to create a simulation. The risk stratification tool was then reapplied to this simulated data. This shifted the distribution of patients into lower risk zones for both the prediabetic and diabetic clinic patients. In the simulation, 33% of the prediabetic and 18% of the diabetic clinic

patients now fall into the green zone. The simulation put 51% of the prediabetic patients and 38% of the diabetic patients into the yellow zone. The red zone contained 16% of the prediabetic and 44% of the diabetic patients in this simulation. (Table 11) This simulated distribution was also compared to the unweighted NHANES respondent distribution. There remained a significant difference between the simulated distribution for prediabetic patients. (Table 12) However, the simulated diabetic patient distribution is not significantly different than the risk zone distribution for the unweighted diabetic NHANES respondent distribution. (Table 13)

DISCUSSION

We began the analysis by applying the appropriate weighting factors to the NHANES 2015-2016 data and then applying the risk stratification tool. This allowed us to assess how the risk stratification tool might apply to a sample that represents US demographics and provide important context. For the rest of the analysis, we used the unweighted NHANES data limited to the participants who could be identified as prediabetic or diabetic based on A1c. We recognize that the unweighted data is not a probability sample and therefore does not represent the US population without the adjustment. However, since we planned to compare the means of individual values that drive the risk stratification scoring from the NHANES data set with those from our clinic population, the statistical analysis needed to use these weighted values is beyond the scope of this project. Given that this is a pilot study of the risk stratification tool, the unweighted NHANES data still serves as an adequate comparison group.

Our sample of clinic patients was largely Hispanic, with a high percentage of uninsured (Table 2). This is not surprising as these data reflect the demographics of the geographic area. However, it was somewhat surprising that this sample was also mostly female (78.4%).

While we recognize this risk stratification tool is designed to be applied to diabetic patients, we decided to also apply it to prediabetic patients. We theorized that the tool might also be useful to help identify prediabetic patients at risk for progression to diabetes. In addition, applying the tool to prediabetic patients helps to show the impact of the components to the tool other than A1c. Prediabetic patients by definition have A1c values less than 6.5, which is assigned a value of 0 in the risk stratification tool. Therefore, any patients who fall in the higher risk zones of yellow or red should do so because they are assigned higher scores for the other data components that make up the risk stratification score.

For both prediabetic and diabetic patients, the distribution of risk zones in our sample of clinic patients was different than the distribution of risk zones for the unweighted NHANES respondents. In the clinic, there was a higher percentage of diabetic patients in the highest risk red zone than there was for the unweighted NHANES respondents. (Tables 4 and 5) This was anticipated given the higher rates of diabetes in the area that our clinic serves (Fisher-Hoch, Vatcheva, Rahbar & McCormick, 2015). Our clinic population had a higher percentage of prediabetic patients (Table 4) but a lower percentage of diabetic patients (Table 5) in the moderate risk yellow zone than was true for the unweighted NHANES respondents.

For both prediabetic and diabetic patients, within each risk zone the mean values of the continues data points that comprise the risk score (A1c, SBP, DBP, LDL, PHQ score) are

generally not significantly different in the clinic patients when compared to the unweighted NHANES respondents. (Tables 6 and 7). However, there are some values that are different. Of particular note, the mean value of A1c (9.62, SD 1.89) in the red zone for the unweighted diabetic NHANES respondents is higher than the mean A1c (9.09, SD 1.74) for the diabetic clinic patients in this zone ($p=0.004$). This was unexpected, as we anticipated that our clinic patients would have higher A1c values. This trend was also reflected in the diabetic category for the yellow and green risk zones as well, with the mean A1c values in those zones being significantly higher for the unweighted NHANES respondents than for our clinic patients.

The possible role of missing values became evident throughout the data analysis. Our sample of clinic patients had a number of missing data values (Table 8 and 9) which could impact the risk zone assignment. For each data component that is used in calculating the total risk score, the tool assigns the highest value to any data point that is unknown or unavailable. For example, referring to the tool (Appendix 1) a PHQ9 score of > 14 is given 3 points, a PHQ9 score of 10-14 is given 2 points, and a PHQ9 score of 5-9 is given 1 point. If the PHQ9 score is unknown, 3 points are assigned. Once the score from all the components is totaled, a total score of <3 puts the patient in the green zone, a total score of 3-6 puts the patient in the yellow zone, and a total score >6 puts the patient in the red zone. A missing value can easily cause a patient to be assigned to a higher risk zone than he or she would otherwise be assigned to. The high percentage of missing values for clinic patients, especially PHQ9 in the yellow and red zones, and A1c and LDL values in the red zone, suggests that at least some of our clinic patients have been miscategorized into higher levels as a result. The missing A1c in the clinic population are largely in the prediabetic red zone. This suggests

that our clinic prediabetic distribution skewed into higher zones than it should be. By definition, a patient with prediabetes would have a A1c <6.5, which would be assigned a score of 0 in that component of the tool. Missing values are assigned a score of 7. This means that prediabetic patients with missing values are automatically assigned to a high risk zone based on the missing A1c value alone. Our study is not designed to assess reasons for missing data. We did not assess number of missing values for smoking status or presence of statin because these components only impact total score by one point.

Regarding missing PHQ9 scores, our data does not indicate the reason for the missing PHQ9 scores. Current recommendations are for depression screening to occur in two steps. First, the Patient Health Questionnaire 2, a two question screening tool is used to screen for depression. The PHQ9 questionnaire is then administered to those individuals who screen positive on the PHQ2. We did not have access to the PHQ2 scores or any indicator that PHQ2 screening had been performed. If the PHQ9 scores are not present because the PHQ2 screening had been done and the PHQ9 is therefore not indicated, the tool in its current form does not have a way to indicate this. A clinic seeking to use this risk assessment tool might need to adjust their recording of the PHQ9 score to include a "not indicated" option. This would prevent PHQ9 scores that were not indicated from being interpreted as "missing" and therefore stratifying the patient into a higher risk zone.

Missing PHQ9 scores in a diabetic population is of particular interest. A relationship between depression and diabetes has been shown. The prevalence of depression in individuals with diabetes has been estimated to be 2 to 5 times higher than the prevalence in the general population. Approximately 25% of diabetic patients have been shown to have

concomitant depression (Semenkovich, Brown, Svrakic, & Lustman, 2015). One study of a cohort of Mexican Americans in the same county as our clinic found that 41% of participants with a known diagnosis of diabetes met the diagnostic criteria for depression (Olivera, Fisher-Hoch, Williamson, Vatcheva, & McCormick, 2016). Other work has demonstrated that depression is risk factor for poor compliance with medical treatment (DiMatteo, Lepper, & Croghan, 2000). These factors suggest it is important to assess diabetic patients for depression, and if depression is diagnosed, provide appropriate treatment. Since at least 64% of our clinic patients falling into the yellow or red zones are missing PHQ9 scores, this suggests that there are quite possibly diabetic patients in whom depression exists but has not been identified. Undiagnosed depression might be a factor that puts the patient at increased risk for complications. It would be important for a risk stratification tool to identify these patients as accurately as possible.

Since our clinic patients had a much higher percentage of uninsured that the unweighted NHANES respondents (44.4% vs 14.2%) we calculated the association between having insurance and red zone categorization. (Table 10). This calculation was done prior to our simulation for missing PHQ9 values. We did not find a statistically significant association. However, the possible impact of missing values on risk zone assignment is enough to confound any possible associations, limiting the utility of drawing conclusions about association between any other variable and risk zone assignment.

Our simulation of the risk zone distribution conducted by substituting the average PHQ9 score for missing values was an informal approach. Nevertheless, it is illustrative of the possible degree of misclassification resulting from missing data. The average PHQ9 score

for our clinic sample was 6.1, corresponding to minor depression. Following the scoring procedure of the tool, this would result in assignment of a score of 1 for that component of the risk stratification tool. Since a missing value is given the same score, 3, as major depression (PHQ9>14), this means all of our clinic patients with missing PHQ9 scores in essence had 2 points subtracted from their total risk score. This shifted the risk stratification profile of the diabetic clinic patients to align quite closely with the risk stratification profile of the diabetic unweighted NHANES respondents. Our simulation shifted risk stratification distribution of the prediabetic clinic sample as well, however it remained significantly different from the comparison group. Nevertheless, this simulation illustrates the potential for missing values to lead to inaccurate risk stratification, and to limit the utility of the risk stratification tool.

CONCLUSION

To our knowledge this is the first time an assessment of the validity of this risk assessment tool has been done. Previous data about this particular tool is limited to its development (Christopher et al, 2015). The tool is appealing in its potential for ease of use in a busy primary care clinic, and in the questions it poses for each risk stratification level to help with allocation of resources. Our analysis shows that it can be easily applied to a set of clinic data, and risk zones can be easily determined.

One main reason for a clinic to adopt a risk stratification tool such as this is to assist with resource allocation. For example, patients in the low risk green zone might be able to be seen most of the time by an Advanced Practice Provider (APP), such as a physician's

assistant or nurse practitioner, with only occasional physician visits. These patients might benefit from other low cost interventions, such as group classes. Patients in the green zone might also need less frequent clinic visits. Patients in the moderate risk yellow zone might need more frequent visits, more physician oversight of APP visits and behavioral counseling. Patients in the high risk red zone might need close follow up by the physician and aggressive case management.

However, our analysis revealed a pitfall in that missing data can easily drive the assignment of the risk zone. Therefore, before adopting this tool or a similar one, a clinic would need to asses the level of missing data and attempt to capture data points that are missing. Our study was not designed to assess the reasons for missing values or the effort it might take to capture missing data. For a clinic seeking to implement this tool, allocating personnel to evaluate and capture missing data might offset some of the potential savings realized from the resource allocation driven by the tool.

We uncovered a possible weakness in the tool relative to PHQ9 scores. The PHQ9 score was the most frequent missing value in our clinic population. Our informal simulation of PHQ9 scores to replace missing values suggests that it can be difficult to accurately perform risk stratification when these scores are missing. We were unable to determine from the data set provided if these values were missing because the PHQ9 was not indicated. This suggests that any clinic seeking to implement this tool should pay close attention to how the staff records, and how the EHR captures, PHQ9 scores. Systems would need to be in place to prevent those without PHQ9 scores because it was not indicated from being assigned the points for missing PHQ9 scores. Particular attention should be paid to ensuring capture of

PHQ9 scores when using this tool, as the PHQ9 score indicates the severity of diabetes, which is known to be a risk factor adverse outcomes in diabetes.

Our study is not designed to assess the impact of applying this tool, either in terms of patient outcomes or cost savings. We also did not asses the ease of use in the clinical setting. These are areas for future research.

TABLES

Table 1: Entire Weighted NHANES 2015-2016 by Risk Zone

	No Diabetes		Prediabetes		Diabetes		Total	
Category	Count	Percent	Count	Percent	Count	Percent	Count	Percent
Green	119,028,730	50%	38,064,614	65%	4,416,131	21%	161,509,474	51%
Yellow	53,585,794	23%	19,642,166	34%	8,876,583	42%	82,104,542	26%
Red	64,242,020	27%	876,603	1%	7,748,404	37%	72,867,027	23%
Total	236,856,544		58,583,383		21,041,118		316,481,043	

P<0.001

Table 2: Descriptive Statistics, Clinic and Unweighted NHANES

	Clinic (N=500)	NHANES (N=2173)	p value
Sex			< 0.001
Male (%, (n))	25.2% (126)	49.5% (1076)	
Female (%, (n))	74.8% (374)	50.5% (1097)	
Race/Ethnicity			<0.001
Hispanic (%, (n))	99% (495)	27.8% (604)	
Non-Hispanic White (%, (n))	0.2% (1)	34.5% (750)	
Non-Hispanic Black (%, (n))	0.4% (2)	24.8% (539)	
Other (%, (n))	0.4% (2)	12.9% (280)	
Age Group, Years			<0.001
26-30	1.8% (9)	2.8% (61)	
31-35	0.2% (1)	4% (87)	
36-40	0.6% (3)	5.1% (110)	
41-45	3.2% (16)	7.5% (164)	
46-50	13.2% (66)	8.1% (175)	
50-55	19.8% (99)	11.4% (247)	
56-60	20.8% (104)	11.6% (253)	
61-65	24.2% (121)	14.3% (311)	
66-70	8% (40)	11.8% (257)	
71-75	8.2% (41)	8.5% (184)	
>75	0% (0)	14.9% (324)	
Insurance Type			<0.001
Commercial (%, (n))	12% (60)	31.6% (687)	
Medicare (%, (n))	22.8% (114)	16.9% (367)	
Medicaid (%, (n))	5.6% (28)	13.3% (288)	
Medicare + Commercial (%, (n))	0% (0)	13.9% (301)	
None (%, (n))	44.4% (222)	14.2% (308)	
Other/Unknown (%, (n))	15.2% (76)	10.2% (222)	

p values from chi 2

Table 3: Clinic by Risk Zone

	Prediabetes		Diabetes		Total	
Category	Count	Percent	Count	Percent	Count	Percent
Green	35	17%	29	10%	64	13%
Yellow	127	63%	102	34%	229	46%
Red	41	20%	166	56%	207	41%
Total	203		297		500	

P<0.001

Table 4: Prediabetic Risk Zone Comparison

	Clinic N=203	NHANES N=1482	p value
Green zone Stratification Score <3	35 (17%)	966 (65%)	<0.001
Yellow zone Stratification Score 3-6	127 (63%)	500 (34%)	<0.001
Red Zone Stratification Score > 6	41 (20%)	16 (1%)	<0.001

p value from chi 2

Table 5: Diabetic Risk Zone Comparison

	Clinic N=297	NHANES N=691	p value
Green zone Stratification Score <3	29 (10%)	124 (18%)	<0.001
Yellow zone Stratification Score 3-6	102 (34%)	276 (40%)	<0.001
Red Zone Stratification Score > 6	166 (56%)	291 (42%)	<0.001

p value from chi 2

Table 6: Prediabetes Mean Values

	Green Zone			Yellow Zone			Red Zone		
	Su Clinica N=35	NHANES N=966	p value	Su Clinica N=127	NHANES N=500	p value	Su Clinica N=41	NHANES N=16	p value
A1c (%), mean (SD)	5.86 (0.29)	5.91 (0.2)	0.15	5.76 (0.3)	5.95 (0.2)	< 0.001	5.79 (0.24)	5.93 (0.2)	0.13
SBP (mmHg), mean (SD)	121 (12)	125 (13)	0.07	123 (14)	143 (21)	< 0.001	139 (14)	162 (18)	< 0.001
DBP (mmHg), mean (SD)	70 (8)	69 (11)	0.59	72 (10)	74 (15)	0.16	75 (9)	85 (6)	0.04
LDL (mg/dL), mean (SD)	97 (29)	107 (36)	0.10	107 (29)	111 (37)	0.28	108 (15)	127 (36)	0.08
PHQ 9, mean (SD)	2 (2)	2 (3)	1.00	11 (8)	11 (10)	1.00	9 (7)	23 (7)	< 0.001

p value from 2 tailed t test

Table 7: Diabetes Mean Values

	Green Zone			Yellow Zone			Red Zone		
	Su Clinica N=29	NHANES N=124	p value	Su Clinica N=102	NHANES N=276	p value	Su Clinica N=166	NHANES N=291	p value
A1c (%), mean (SD)	6.44 (0.53)	6.75 (0.21)	< 0.001	6.61 (0.75)	7.29 (0.54)	< 0.001	9.09 (1.74)	9.62 (1.89)	0.004
SBP (mmHg), mean (SD)	124 (10)	125 (13)	0.70	128 (15)	133 (20)	0.02	130 (18)	138 (20)	< 0.001
DBP (mmHg), mean (SD)	69 (9)	67 (10)	0.33	70 (9)	69 (13)	0.48	70 (10)	72 (13)	0.09
LDL (mg/dL), mean (SD)	74 (35)	93 (44)	0.03	85 (37)	92 (33)	0.08	84 (34)	100 (46)	< 0.001
PHQ 9, mean (SD)	3 (4)	2 (3)	0.13	6 (7)	6 (7)	1.00	8 (8)	7 (9)	0.47

p value from 2 tailed t test

Table 8: Missing Values, Yellow Zone

	Prediabetes		Diabetes	
	Clinic (N=127)	NHANES (N=500)	Clinic (N=102)	NHANES (N=276)
A1c				
SBP		14%		7%
DBP		16%		8%
LDL	8%	3%	6%	1%
PHQ9	77%		64%	

Table 9: Missing Values, Red Zone

	Prediabetes		Diabetes	
	Clinic (N=41)	NHANES (N=16)	Clinic (N=166)	NHANES (N=291)
A1c	78%		5%	
SBP		69%		10%
DBP		75%		11%
LDL	66%	6%	20%	3%
PHQ9	76%		70%	

Table 10: Clinic Patients, Red Zone, Any Insurance

Category	OR	95% CI	p value
Prediabetic	0.84	0.40-1.77	0.618
Diabetic	0.70	0.43-1.15	0.135

Table 11: Simulated PHQ9 Replaced Clinic by Risk Zone

	Prediabetes		Diabetes		Total	
Category	Count	Percent	Count	Percent	Count	Percent
Green	67	33%	52	18%	119	24%
Yellow	104	51%	114	38%	218	44%
Red	32	16%	131	44%	163	33%
Total	203		297		500	

Table 12: Prediabetes Simulated PHQ9 Replaced Clinic by Risk Zone and Unweighted NHANES Comparison

	Clinic	NHANES	p value
Green Zone	67 (33%)	966 (65%)	<0.001
Yellow Zone	104 (51%)	500 (34%)	<0.001
Red Zone	32 (16%)	16 (1%)	<0.001

Table 13: Diabetes Simulated PHQ9 Replaced Clinic by Risk Zone and Unweighted NHANES Comparison

	Clinic	NHANES	p value
Green Zone	52 (18%)	124 (18%)	p=0.842
Yellow Zone	114 (38%)	276 (40%)	p=0.842
Red Zone	131 (44%)	291 (42%)	p=0.842

FIGURES

Figure 1: Distribution of Risk Zones in Weighted NHANES, 2015-2016, by Diabetes Category

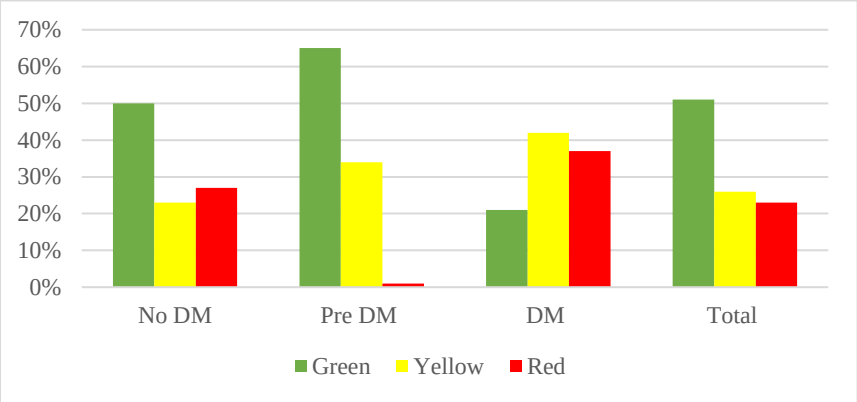
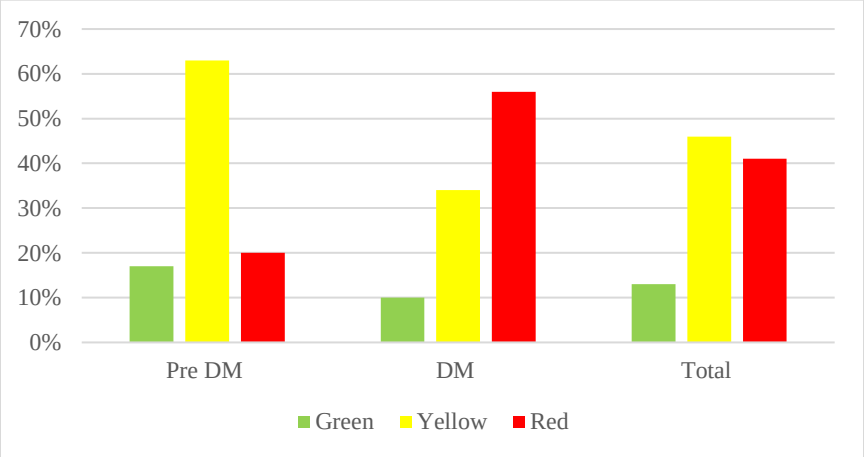


Figure 2: Distribution of Risk Zones in Clinic, by Diabetes Category



APPENDICES

Appendix A: Risk Stratification Tool

RISK STRATIFICATION SCORING (Circle Patient Score)

1. Patient A1C*	Points
>9.0% or Unknown	7
8.5% to 9%	6
8.0% to 8.4%	5
7.5% to 7.9%	4
7.0% to 7.4%	2
<7%	0

2. Blood Pressure	Points
Unknown	3
SBP>160 **or** DBP>95	3
SBP 140 to 160 **or** DBP 90 to 95	2
SBP 130 to 139 **or** DBP 80 to 89	1
SBP<130 **or** DBP<80	0

3. Statin Use/LDL	Points
Lipids not available	2
Statin absent **and** LDL>100 or non HDL>130	2
Statin present **and** LDL>100 or non-HDL>130	1
Statin absent **and** LDL<100	1
Statin present **and** LDL<100	0

4. Tobacco Status	Points
Unknown	1
Current every day smoker	1
Current some day smoker	1
Tobacco Positive (pipes, smokeless, etc.)	1
Never Smoker or Recently Quit	0

5. PHQ-9 Score	Points
Unknown	3
> 14 (moderately severe to severe depression)	3
10 to 14 (moderate depression)	2
5 to 9 (mild depression)	1

*Patient A1C: Points are based on the widely recognized goal of 7%. In some instances, this goal may not be warranted or safe in which case the goal would be set at 8% and all data sets would be adjusted upward (+1% to each parameter).

Scoring	Points
1. Patient A1C	
2. Blood Pressure	
3. Statin Use/LDL	
4. Tobacco Status	
5. PHQ-9 Score	
TOTAL	

RED ZONE
Maximum support needed.
Overall Stratification Score > 6

YELLOW ZONE
Moderate support needed.
Overall Stratification Score 3 to 6

GREEN ZONE
Minimal support needed.
Overall Stratification Score < 3

YES	NO	N/A	RED ZONE (Maximum Support Needed)
			Did you address the patient's readiness to change? If so, what stage is the patient? _____
			Did you address any known community barriers? If so, what are they? _____
			Did you enlist a specific visit or phone call follow-up strategy (recommended someone call patient 2 weeks before and after all encounters)? If so, who called the patient? _____
			Did you enlist a specific "no show" strategy (recommended someone call patient same day if no show)? If so, who called the patient? _____
			Did you enlist a specific follow-up strategy for ED/Admin alerts (recommended someone contact the patient within 24 hours to schedule an appointment and follow-up within 72 hours)? If so, who contacted the patient? _____
			Did you assist the patient with coordination of other care services during their visit? If so, what did you coordinate? _____
			Did you address the need for ongoing education and self-management support?
			Did you make a referral to a CDE? If so, to whom? _____
			Did you schedule a class? If so, when/where? _____
			Did you set self-management goals with the patient? If so, what are they? _____
			Did you address the need for increased frequency of visits to the MD? CDE? Other?
YES	NO	N/A	YELLOW ZONE (Moderate Support Needed)
			Did you consider assessing the patient's readiness to change? If so, what stage is the patient? _____
			Did you consider any known community barriers? If so, what are they? _____
			Did you enlist a specific visit or phone-call follow-up strategy? If so, who contacted the patient? _____
			Did you consider the need for education and self-management support?
			Did you recommend an encounter with a dietician? If so, who? _____
			Did you schedule a class? If so, when/where? _____
			Did you set self-management goals with the patient? If so, what are they? _____
YES	NO	N/A	GREEN ZONE (Minimal Support Needed)
			Do you anticipate any future problems with the patient? If so, what are they? _____
			Did you offer education and self-management support?
			Did you offer a class for new or recent onset patients? If so, when/where? _____
			Did you offer an encounter with a dietician? If so, who? _____
			Did you offer to set self-management goals with the patient? If so, what are they? _____

Christopher, et al (2015)

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