

# Detection of Undiagnosed Prediabetes and Diabetes in Dental Patients: A Proposal of a Dental-Office-Friendly Diabetes Screening Tool

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## Abstract

**Objective:** This study was designed to develop a dental-office-friendly diabetes self-screening tool for diabetes mellitus (DM) and prediabetes (PreDM). **Methods:** Consecutive dental patients, aged 18 years or older, without history of DM or PreDM, completed a 14-question questionnaire without assistance. They subsequently underwent onsite finger-sticks for capillary blood collection for glycohemoglobin (A1c) measurement. **Results:** Of the total 500 patients who completed the study, 302 were women (60.4%) and 198 were men (39.6%), with a collective mean age of 47.8 ( $\pm 16.8$ ) years old. The prevalence of PreDM and DM was 19.2% and 1.2%, respectively. Predictors of PreDM or DM included age, >10% above ideal body weight, waist size above 40" for men or 35" for women, reported hypertension, reported abnormal lipids, tingling of hands or feet, and visual symptoms or conditions (blurring, cataracts, glaucoma). **Conclusions:** This study introduces a newly developed, user-friendly, PreDM and DM self-screening tool, abbreviated as DiDDO (Diabetes detection in the dental office). This screening tool requires no body weighing or BMI calculation (undesirable by dentists) nor laboratory tests or blood pressure measurement, allowing dentists to identify patients at moderate and high risk for DM/PreDM, and perform (or refer for)

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**diagnostic A1c testing. This dental-office-friendly self-screening tool is proposed for validation in other dental populations.**

## Keywords

**Diabetes Screening, Dental Office, Screening Test, A1c**

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## 1. Introduction

Diabetes Mellitus (DM) is considered as an epidemic, which principally applies to type 2 diabetes mellitus (T2DM) the “natural history of which can be changed” [1] by detection and management of prediabetes (PreDM) with life-style modifications and simple pharmacotherapy [1] [2]. Once established, especially with complications, DM has escalating health and financial burdens in the USA and globally [1] [3] [4]. The prevalence of DM continues to rise steadily; in the USA, DM and its precursor, PreDM, together affect over 1/3 of the US population [4] at present. More concerning is that about 90% of patients with PreDM [5] and 30% of patients with DM [4] [6], respectively, remain undiagnosed, and that at the time of DM diagnosis, one or more of the diabetes complications would have already occurred in many patients [7]. In the dental domain, periodontal disease (PD) is considered as one of the complications of uncontrolled DM [8]-[10], and a bi-directional relationship has been observed between uncontrolled DM and PD [8]-[12]. Furthermore, PD has also been reportedly associated with PreDM [13], which underscores the notion that even mild degrees of hyperglycemia (also referred to as dysglycemia) can cause diabetic complications, including PD.

Ineffective screening was cited as a major contributing factor [14] [15] to the high prevalence of undiagnosed DM and PreDM. Hence there is the need for more effecting screening campaigns. Opportunistic screening has recently emerged as a new means towards this goal. The dental office appeals as an ideal example. Dental offices encounter a large sector of the population annually; Herman *et al.* reported that up to 70% of Americans saw dentists at least once a year [16]. They also reported that a national survey of dental patients over the age 50 found a prevalence of 10% of DM and 40% of PreDM, and that up to 50% and over 90% of these patients, respectively, were undiagnosed. It was also reported that many dental patients may not see a family physician on a regular basis [17]-[20]. By taking these data and observations together, it is thus conceivable that amongst the dental populations, there is potentially a significant prevalence of undiagnosed DM and PreDM, in parallel with national statistics.

Furthermore, Greenberg *et al.* [21] reported a satisfactory response by American dentists (n = 1945) for screening for systemic diseases, with 76.6% favoring screening for DM. Recently, several studies have been published that proved the effectiveness of diabetes screening in the dental office [16] [19] [22]-[26]. Therefore, dentists can benefit from a simple DM self-screening questionnaire that will help them identify patients at risk for PreDM and DM who should be appropriately referred for diagnostic testing by any of the established American Diabetes Association (ADA)’s criteria [27].

Therefore this study was conducted to design a self-screening tool and compare it to a standardized laboratory diagnostic test to evaluate its predictive ability. The major objective of the study was to develop a dental-office-friendly screening tool (questionnaire) that would potentially garner wide-spread acceptance by dentists: Simple, chair-side, self-screening questionnaire from which dentists could refer patients for diagnostic confirmation. This questionnaire requires no clinical assistance from the dental team: No numerical measurement of body weight, no discussion of body weight, no calculation of BMI and no additional medical screening tests such as blood pressure recording, or blood lipid panel. Another objective of the study is to design an online simple, dental- focused, diabetes self-screening tool for public use.

## 2. Subjects and Methods

### 2.1. Subjects

Five-hundred eligible patients completed the study between June, 2014 and September, 2014. Inclusion criteria: non-pregnant adults over the age of 18 years who are able to complete the self-screening questionnaire and agreeable to undergo finger-prick testing. Exclusion criteria included: Current pregnancy; known diagnosis of,

or treatment for DM or PreDM. The Institutional Review Board of Michigan State University approved the study, and all participants gave a written consent for study participation.

## 2.2. The Initial Screening Questionnaire

Each participant completed the proposed PreDM/DM screening tool by answering 14 binary yes-or-no questions without assistance or discussion (**Table 1**). In an attempt to include all relevant questions in the study questionnaire, we searched the literature for any/all published diabetes self-screening tools. Several screening tools have been developed thus far for the detection of undiagnosed DM and PreDM in non-dental settings [16] [28]-[38], varying in methodology and ease of application. Nevertheless, Bang *et al.* found limited evidence for use of these tools in clinical practice [6]. In searching the literature for an existing screening tool for PreDM and DM which was developed specifically for use in dental offices, we only found one such screening tool that was published recently by Herman *et al.* [16], at the time of the completion of our study.

However, we found that the questionnaire utilized by Herman *et al.* included actual calculation of body mass index (BMI), based on self-reported weight and height [16]. This particular issue is undesirable in dental offices [39]; in general, dental patients and providers are not comfortable with discussing exact weight or BMI during dental visits. Furthermore, in Herman's multi-staged study (requiring participants to return for further confirmatory laboratory testing), and while initially enrolling 1033 subjects, the authors reported that only 28% of participants returned for completion of subsequent study protocol [16]. This diluted the number of the study subjects to only 181. We believe these are 2 significant limitations to the findings of this study.

In the proposed survey, we included the self-reporting of established variables, as collected from previously published risk and screening tools [2] [6] [16] [28]-[38], to be evaluated in a real life dental setting—a general dental office. We ultimately selected risk factors or symptoms that we incorporated into a 14-questions survey (**Table 1**). As noted, the risk factors included questions about risk for T2DM, hyperglycemic symptoms and diabetic complications. The questions did not include exact measurements nor reporting of weight, BMI or waist circumference (WC).

Furthermore, we found that the majority of the published diabetes screening tools [2] [6] [16] [28]-[38] included either performing physical measurements such as blood pressure or drawing labs such as lipid profiles.

**Table 1.** The 14-point self-screening questionnaire developed exclusively for the purpose of this study. The questions were based on: 1) known risk factors for metabolic syndrome, diabetes, insulin resistance; 2) symptoms of hyperglycemia; and 3) diabetic complications. Proposed were risk factors related to obesity that did not depend on patient weight or BMI. There were no medical tests included. The survey also included direct questions about age and gender.

### Survey Questions:

1. Are you more than 10% above ideal body weight?
2. Is your waist above 35" (women) or 40" (men)?
3. Do you have any biologic family member with a history of DM?
4. Are you African American, Alaskan Native, American Indian, Hispanic, or Arabic descent?
5. Do you have a history or take medication for HBP?
6. Do you have, or take medications for, high cholesterol or abnormal good/bad cholesterol ratio?
7. Do you seem to be slow to heal from a cut or a bruise?
8. Do you experience tingling, pain or numbness in your hands or feet?
9. Do you experience unexplainable hunger, thirst OR frequent urination?
10. Have you experienced blurred vision, cataracts or glaucoma?
11. Have you had skin infections, foot ulcers, velvety skin or neck folds?
12. Do your gums bleed when you brush or floss?
13. Women: Did you ever have gestational diabetes during pregnancy?
14. Women: Do you experience recurring yeast infections?

Of similar relevance, most of these tools included measuring or reporting exact weight, BMI or exact WC as obesity-related risk factors. In general, there is a “stigma” associated with obesity, as reported by Wang *et al.* [39]. In particular, as opposed to medical offices, dental office staff is not accustomed to weighing patients, or openly discussing patient weight, as reported by Lalla *et al.* [22].

We proposed two alternative cut-off ranges: self-reported WC (or clothing waist size) above 40” for men or 35” for women; and self-reported weight that is over 10% above the upper limit of ideal body weight (10%IBW). Twenty-five study participants (5%) verbally expressed lack of confidence or inability to answer the ideal weight question. Those were given a simple printed chart for reference. We downloaded this chart from: [http://www.bannerhealth.com/Services/Bariatric+Surgery/Bariatric\\_Surgery/Ideal+Weight+Chart.htm](http://www.bannerhealth.com/Services/Bariatric+Surgery/Bariatric_Surgery/Ideal+Weight+Chart.htm).

### 2.3. Laboratory Tests

Each participant underwent a finger-stick for collection of capillary blood for laboratory A1c measurement. The finger-stick and capillary collection was performed by two research personnel trained by Sparrow Hospital phlebotomists, using a single-use device (10 uL of blood collected in a plastic capillary tube). The device was designed for A1c testing (Bio-Rad Laboratories, Hercules, CA). The capillary tube was then placed into the sample preparation vial which was then capped and shaken (**Figure 1**).

These blinded vials (with coded, blinded specimens) were sent in batches at 4°C to the Diabetes Diagnostic Laboratory (DDL) at the University of Missouri, Columbia, Missouri. A1c was measured from these pre-diluted samples by the Tosoh G8 ion-exchange HPLC method (Tosoh Corporation, San Francisco, California) in an NGSP (National Glycohemoglobin Standardization Program) Secondary Reference Laboratory (SRL9). The method of capillary collection has previously been validated for the Tosoh G8 assay by comparison of paired samples from fresh whole blood and capillary collection vials (unpublished data). The results of the samples, A1c blood levels were reported back and correlated with the corresponding surveys for statistical analysis of each individual question.

### 2.4. Analytical Methods

All survey questions were queried as binary “yes” or “no” answers except primary data including gender and age. Associations between variables and the need for further intervention were analyzed using Chi-square, anova, and t-tests as appropriate. Patient demographics and survey responses were analyzed using tabulations if binary or mean (standard deviation) if continuous and further stratified by hemoglobin A1c. Values of less than 5.7% were categorized as normal, values between 5.7% and 6.4% as pre-diabetic, and values above 6.4% as diabetic. As the incidence of previously undiagnosed diabetes in our population was later found to be low (1.2%), the categories were further categorized as “Normal A1c” and “Abnormal A1c” (inclusive of PreDM and DM categories).

Associations between variables and the need for further intervention were analyzed using Chi-square, anova, and t-tests as appropriate. Inclusion into our final scale (Model 1) was based on *a priori* knowledge or an associated p-value of less than 0.10. A second model was built inclusive of only statistically significantly associated



**Figure 1.** Blood Collection Method. (Developed by Bio-Rad Laboratories, Hercules, CA). See detailed description in the text, below.

variables. A third model was built inclusive of all of the survey components. In each model, each item was weighted with 1 point with the exception of age which was weighted as 1 point for ages 35 - 65 and 2 points for ages greater than 65 years (0 points for age below 35). Scale performance for each model was evaluated using sensitivity and specificity at a number of possible cutoffs. All analyses were done in Stata/SE 13.0.

### 3. Results

Of the study's 500 participants, 302 were women (60.4%) and 198 were men (39.6%), with mean age of  $47.8 \pm 16.8$  years old, with a range of 18 to 89 years old. The majority of the patients (454) were Caucasian (90.8%), The average A1c was  $5.4\% \pm 0.5\%$ , with a range of 4.3% to 11%. The prevalence of PreDM was 19.2%, while prevalence of DM was only 1.2%. For each abnormal A1c result levels ( $\geq 5.7\%$ ), the participant was notified and a letter was sent to the family physician, for further management.

**Table 2** depicts the associations between study characteristics and A1c. The A1c cut-off for upper limit of

**Table 2.** Associations between study characteristics and normal vs. abnormal ( $\geq 5.7$ ) hemoglobin A1c.\*

	Normal A1c	Abnormal A1c		p-value
	n (%)	n (%)	OR (CI)	
Percent Male	160 (40.2)	38 (37.3)	0.9 (0.6 - 1.4)	0.587
Age Groups:			3.2 (2.2 - 4.6)	<0.001**
<35	124 (31.2)	8 (7.8)		
35 - 65	224 (56.3)	58 (56.9)		
>65	50 (12.6)	36 (35.3)		
Survey Questions				
Are you more than 10% above ideal body weight?	172 (43.2)	69 (67.7)	2.7 (1.7 - 4.4)	<0.001**
Is your waist above 35" (women) or 40" (men)?	99 (24.5)	52 (51.0)	3.2 (2.1-5.1)	<0.001**
Do you have any biologic family member with a history of DM?	201 (51.3)	59 (57.8)	1.3 (0.9 - 2.1)	0.237
Are you African American, Alaskan Native, American Indian, Hispanic, or Arabic descent?	34 (8.5)	12 (11.8)	1.4 (0.7 - 2.9)	0.315
Do you have a history or take medication for HBP?	72 (18.1)	41 (40.2)	3.0 (1.9 - 4.9)	<0.001**
Do you have, or take medications for, high cholesterol or abnormal good/bad cholesterol ratio?	48 (12.1)	35 (34.3)	3.8 (2.3 - 6.3)	<0.001**
Do you seem to be slow to heal from a cut or a bruise?	35 (8.8)	13 (12.8)	1.5 (0.8 - 3.0)	0.23
Do you experience tingling, pain or numbness in your hands or feet?	73 (18.3)	30 (29.4)	1.9 (1.1 - 3.0)	0.014**
Do you experience unexplainable hunger, thirst OR frequent urination?	58 (14.6)	19 (18.6)	1.3 (0.8 - 2.4)	0.311
Have you experienced blurred vision, cataracts or glaucoma?	42 (10.6)	28 (27.5)	3.2 (1.9 - 5.5)	<0.001**
Have you had skin infections, foot ulcers, velvety skin or neck folds?	7 (1.8)	4 (3.9)	2.3 (0.7 - 8.0)	0.184
Do your gums bleed when you brush or floss?	115 (28.9)	24 (23.5)	0.8 (0.5 - 1.3)	0.281
Women: Did you ever have gestational diabetes during pregnancy?	16 (7.3)	6 (9.5)	1.3 (0.5 - 3.6)	0.556
Women: Do you experience recurring yeast infections?	12 (5.2)	4 (6.4)	1.2 (0.4 - 4.0)	0.715

\*Data are stratified into groups of normal A1c ( $< 5.7$ ) and abnormal A1c ( $\geq 5.7$ ). Values are presented as absolute number (n), percentage of stratified subgroup (normal vs. abnormal), odds ratios (OR), 95% confidence intervals (95% CI), and p-values. \*\* Statistically significant at  $p < 0.05$

normal is 5.7%, according to national diabetes guidelines (27). In view of the low DM prevalence, we lumped all abnormal A1c results (>5.7%) together (inclusive of PreDM and DM). There were no gender differences ( $p = 0.59$ ). The prevalence correlated with age ( $p < 0.001$ ). Of the questionnaire questions, in addition to age, the following variables, as reported by participants, were significant: weighing 10% above ideal body weight; waist size above 35" for women or 40" for men; hypertension; abnormal lipids; and visual symptoms (all with  $p < 0.001$ ); and tingling in hands or feet ( $p = 0.014$ ). Other variables obtained  $p > 0.05$ , but close.

**Table 3** depicts three models that were developed: Model 1 includes variables that were suspected *a priori* to be significant; Model 2 included only significant variables; and Model 3 includes all variables. **Table 3** depicts the sensitivities, specificities, positive predictive values (PPV) and negative predictive values (NPV) of the three models. Each variable was allocated a score of 1, but the age variable was allocated one point for age above 35 and an additional point if also above 65 (0 points for age below 35). Finally **Figure 2** depicts the receive operator curve (area under the curve) for each of the three models.

It is noted from **Table 4** that the three risk assessment models had excellent sensitivity for scores of  $\geq 2$  (85.3% - 91.2%), as well as NPV, of 88.5% - 92.4%. However, the specificity and PPV were low, at 17.3% - 46.0% and 22.0% - 28.8%, respectively. To improve specificity, another optional cut off would be score  $\geq 3$  (Sensitivity: 81.4% - 84.3%; specificity: 41.5% - 70.6%). Finally, **Figure 3** depicts the proposed screening survey (DiDDO Screening Survey, available for public use at <http://selfscreen.net/1/diabetes> ). DiDDO survey (acronym for diabetes detection in the dental office) is an approximate survey derived from the variables that were statistically significant ( $p$ -value  $< 0.05$ ) in our study, plus those which were close to  $p = 0.05$  in view of validation as risk scores in the literature. Three scoring levels were developed to help patients identify their risk of PreDM or DM: Low for scores below 2; Medium for scores between 2 and 5; and High for scores equal or above 6.

**Table 3.** Variables included in three evaluated screening models.\*

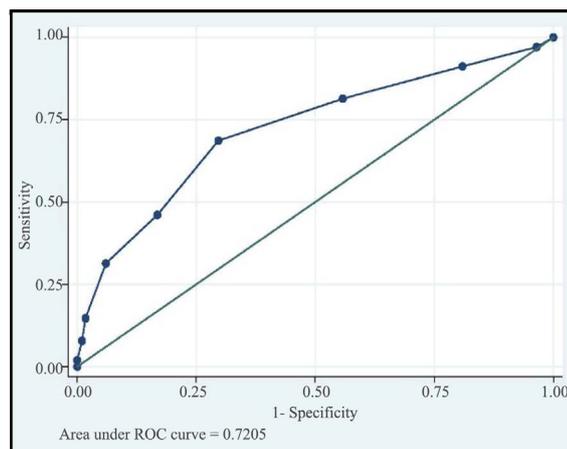
	Model 1	Model 2	Model 3
Sex			
Age	X	X	X
Survey Questions			
Are you more than 10% above ideal body weight?	X	X	X
Is your waist above 35" (women) or 40" (men)?	X	X	X
Do you have any biologic family member with a history of DM?	X		X
Are you African American, Alaskan Native, American Indian, Hispanic, or Arabic descent?	X		X
Do you have a history or take medication for HBP?	X	X	X
Do you have, or take medications for, high cholesterol or abnormal good/bad cholesterol ratio?	X	X	X
Do you seem to be slow to heal from a cut or a bruise?			X
Do you experience tingling, pain or numbness in your hands or feet?	X	X	X
Do you experience unexplainable hunger, thirst or frequent urination?	X		X
Have you experienced blurred vision, cataracts or glaucoma?	X	X	X
Have you had skin infections, foot ulcers, velvety skin or neck folds?			X
Do your gums bleed when you brush or floss?	X		X
Women: Did you ever have gestational diabetes during pregnancy?			X
Women: Do you experience recurring yeast infections?			X

\*Left column details variables included in the three multivariate models. Cells marked with an "X" indicate variables included in each of the three models.

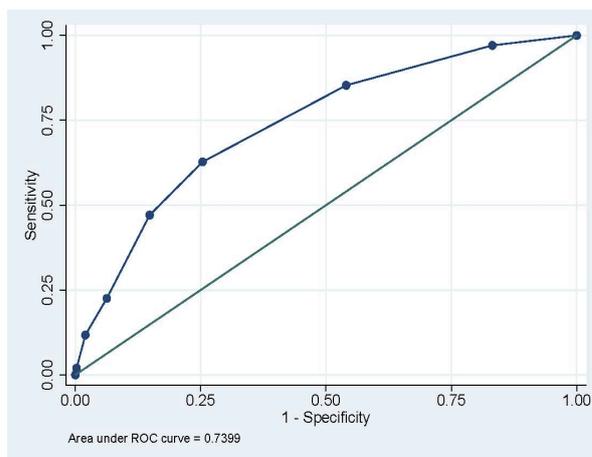
**Table 4.** Sensitivities, specificities, positive predictive value (PPV) and negative predictive value (NPV) of screening models at various cut-off points (one point only is given to either or both: 10% above ideal body weight or waist size)\*.

Model 1 AUC: 0.72 95% CI: 0.66, 0.78		Model 2 AUC: 0.74 95% CI: 0.68, 0.80		Model 3 AUC: 0.72 95% CI: 0.66, 0.78		
Scale cutoff	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
≥2	91.2%	19.1%	85.3%	46.0%	91.2%	17.3%
≥3	81.4%	44.2%	62.8%	74.6%	84.3%	41.5%
≥4	68.6%	70.4%	47.1%	85.2%	70.6%	66.3%
≥5	46.1%	83.2%	22.6%	93.7%	51.0%	79.9%
≥6	31.4%	94.0%	11.8%	98.0%	35.3%	91.0%
Scale cutoff	PPV	NPV	PPV	NPV	PPV	NPV
≥2	22.4%	89.4%	28.8%	92.4%	22.0%	88.5%
≥3	27.2%	90.3%	38.8%	88.7%	27.0%	91.2%
≥4	37.2%	89.7%	44.9%	86.3%	35.0%	89.8%
≥5	41.2%	85.8%	47.9%	82.5%	39.4%	86.4%
≥6	57.1%	84.2%	60.0%	81.3%	50.0%	84.6%

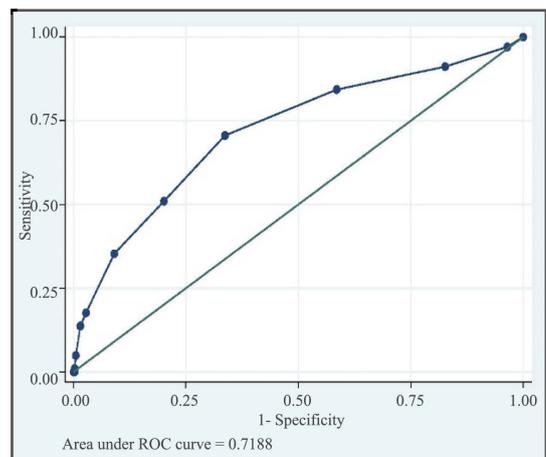
\*Calculated comparing calculated models as compared to measured hemoglobin A1c.



(a)



(b)



(c)

**Figure 2.** The receiver-operator curve ROC, Area under the Curve, (AUC) for the 3 screening models that were developed, (see text for details). (a)-(c) Models 1-3.

### Assess Your Diabetes Risk

<p><b>1. Are you more than 10% above ideal body weight?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>2. Is your waist size over 35" (for women) or over 40" (for men)?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>3. Do you have any biologic family member with a history of diabetes?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>4. Are you African American, Alaskan Native, American Indian, Hispanic or of Arabic descent?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>5. Do you have a history of, or take medication for high blood pressure?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>6. Do you have or take medications for high cholesterol or abnormal good/bad cholesterol ratio?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>7. Do you experience tingling, pain or numbness in your hands or feet?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>8. Do you experience unexplainable hunger, thirst or frequent urination?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>9. Have you experienced blurred vision, cataracts or glaucoma?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>10. Do your gums bleed when you brush or floss?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>11. Are you over 35 years old?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p><b>12. If you are over 35, are you also over 65?</b></p> <p><input type="radio"/> Yes <input type="radio"/> No</p>

Click here to submit responses:



Figure 3. Proposed PreDiabetes and diabetes self-screening survey. Available at <http://selfscreen.net/1/diabetes>.

## 4. Discussion

In this study, we report the feasibility, acceptability and effectiveness of screening for DM and Pre DM in the dental office, confirming findings of previously published dental studies [16] [19] [22]-[26]. Furthermore, we report the development a simplified, user-friendly self-screening survey for the detection of undiagnosed PreDM and DM, designed for ease of use in the dental office. We derived our screening variables from the 13 published diabetes screening tools/questionnaires [6] [16] [28]-[38]. These screening tools represented the following populations: US (4 tools); UK (2 tools); Dutch (2 tools); and 1 tool each from Finland, Denmark, Italy, Germany and Australia.

We sought to develop a screening tool applicable to the US population, and hence we limited our in-depth review to US published screening tools. The first US screening tool was developed in 1995 by Herman *et al.* [28] and was based on the National Health and Nutrition Survey (NHANES) population, cohort II. The questionnaire included age, weight above 20% of IBW, based on medium body frame (derived from height and weight), family history of diabetes, delivery of a baby > 9 lbs. and level of physical activity. The questions were given “Yes” or “No” option, and were stratified into 3 categories per age groups, 20 - 44, 45 - 64 and  $\geq 65$  years.

In 2008, Heikes *et al.* [37] developed a well-designed, but conceivably sophisticated new screening tool, also utilizing the NHANES population (but a more recent cohort, III). The authors added more variables of known diabetic risk factors: Age; family history, hypertension, physical activity, and prior gestational diabetes. For weight, the authors used cut-offs for WC (38.4”) and Weight (168 lbs.) based on height above or below 63.1”. The model begins with stratification of patients into age above or below 44 years, and then if WC is above or below 38.4”.

In 2012, Bang *et al.* developed the third US diabetes screening tool [6]. The authors also utilized the NHANES population (II and III). This model was derived from multiple available screening tools including instruments developed by the Center for Disease Control, the American Diabetes Association (ADA) and the US Preventive Services Task Force. The model was then validated on the NHANES, ARIC (Atherosclerosis Risk in Communities) and the CHS (Cardiovascular Health Study) cohorts. The weight variable was based on BMI.

Most recently, and at the time of completion of our study, Herman *et al.* published a new study that is similar to ours [16]. However, as reviewed earlier, Herman’s recent study suffered from lack of response of participants, thus diluting the ultimate study sample size to 181 participants. Furthermore, Herman *et al.* used BMI in the study, which is an issue that poses some inconvenience at the dental office, as alluded to earlier. Finally, Herman *et al.* did not derive an online/digital screening tool from their study.

Based on the models of Herman [28], Heikes [37], and Bang [6], the ADA developed a diabetes questionnaire that allows individuals to estimate their diabetes risk, which is available online for public use at the ADA website [40]. While this ADA score is an easy tool, especially the online version, we felt the score did not include all possible variables such as history of cholesterol problems, nor symptoms of hyperglycemia such as polyuria or symptoms of complications such as numbness or visual changes (which can also be a symptom of hyperglycemia). The ADA score included seven questions about: Age, gender, prior gestational diabetes, family history of diabetes, hypertension, physical activity, and weight status. The latter is derived from a chart that lists three categories of weight ranges. The score uses points, and a score over 5 indicates a high risk.

Features of our study include: 1) It is the first prospective study to validate a newly developed self-screening tool for DM and PreDM that can be comfortably and easily implemented in any dental office; 2) the use of more appropriate weight-related measures as surrogates of overweight/obesity (WC above 40” for men and 35” for women, and above 10% IBW); 3) the use of a unique finger-stick collection method with an A1c test that is scientifically validated for diagnostic accuracy, as part of the National Glycohemoglobin Standardization Program (NGSP) network; 4) and no use of physical exam, laboratory testing (e.g., lipid levels) or clinical measurements of blood pressure recordings.

With regards to the obesity variable: For WC, our study patients were asked to report if WC is above the cut-offs (40” for men or 35” for women), based on what they knew about their clothing waist size. Similarly, we are not aware of the use of “10% IBW” either in dental studies or in prior diabetes risk scores or screening tools [2] [6] [16] [28]-[38]. Few investigators, such as Herman *et al.* [28] used 20% above upper limit of IBW. We opted to use 10% for ease of estimation by patients without using a calculator (*i.e.*, easy math). While this newly utilized measure (10%IBW) has not previously been validated as a risk factor for PreDM or DM, our study confirmed its validity,  $p < 0.001$  (Table 1).

In developing this screening survey, we sought to include and then test all possible variables that have been

established to be predictors T2DM such as obesity or PreDM, or suggestive of hyperglycemic symptoms (e.g., polyuria) or diabetic such as numbness. The hyperglycemic symptoms are of paramount importance for dentists embarking on dental treatment on patients who could have a severe case of undiagnosed DM, which would pose risk of post-op infection and/or poor healing response. By disseminating this easy diabetes screening tool, we hope that dental offices will be more effective in diabetes screening. As important, dentists can effectively detect PreDM, assisting the medical community in preventing DM, which can be achieved easily [1].

We acknowledge limitations in our study: Our study cohort is mostly Caucasian (90.8%), from a suburban community, and most of these patients are expected to have primary care physicians, which may explain the low prevalence of undiagnosed DM (1.2%). Therefore, the study conclusions need to be tested in more diverse population. Another limitation is that WC may not reflect the actual estimate of weight in obese men who wear their belts under their abdomens. Similarly, some people may not know their ideal body weight. We did not analyze the accuracy of the 10%IBW without the help of the chart. However, for both measures, study results confirmed their validation.

Finally, the specificity and PPV of the screening model are both low. Increasing the screening score from 2 to 3 will improve both measures but will result in lower sensitivity. While it is not desirable to have low specificity and PPV in any screening model, it is our belief that sensitivity matters more in screening for DM and PreDM. Of note, there are examples of screening lab tests in clinical settings that have low specificity and PPV (e.g., low titers of anti-nuclear antibodies in lupus screening). Given the low cost of the validating diabetes screening tests (e.g., FPG or A1c), the lower specificity and PPV may not be erroneously unacceptable. Furthermore, we believe that over-diagnosis of PreDM and DM will not necessarily have a significant negative impact on patients or on the health care system. Hopefully, these patients may experience a three-fold benefit; Education/awareness of Pre-DM and DM, the concept of prevention, and the opportunity/encouragement to initiate life style modifications that will have better health outcomes. Thus, we believe that “over-diagnosis” of DM or PreDM, a general concern related to low specificity and PPV of a screening test, may not be as bad as conceivable.

## 5. Conclusion

In this study we have proposed a simple, dental-office-friendly self-screening survey, which is also posted as a self-screen for diabetes screening at <http://selfscreen.net/1/diabetes> for DM and PreDM in the dental office and for the use of the public. Given the low prevalence of DM in this study cohort, we believe this survey is more strongly validated for PreDM screening, although it can be argued that the risks for PreDM and DM are the same. We suggest validating this screening test on other populations to test its utility.

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An abstract of this study was accepted as a poster to the annual meeting of the American Association of Clinical Endocrinologists (AACE), in Nashville, Tennessee (May 13-17, 2015). The abstract was selected as the Best Abstract, winning the First Place Award. The media office of AACE has selected this abstract to be featured in the press room, for national media coverage and the story about the study was made public in the media. Also the study was briefly mentioned in a new book by Susan Maples, DDS (the first author) titled “Blabber Mouth” on page 77-78. Finally, Dr. Maples posted a self-screen for diabetes screening based on this study on her website <http://selfscreen.net/1/diabetes>.

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## Disclosures

SA: Speaker for Takeda, Janssen, Sanofi. Advisory for Sanofi.

SM: Originator of SelfScreen.net.

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