How to conduct chairside screening for heart disease and diabetes in a dental setting

Barbara Greenberg, MSc, PhD
New York Medical College
Michael Glick, DDS
University at Buffalo

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# Heart disease and diabetes: prevalence, mortality, morbidity in U.S.

<table>
<thead>
<tr>
<th></th>
<th>Heart disease &amp; stroke</th>
<th>Diabetes mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prevalence</strong></td>
<td>82 million</td>
<td>26 million (with DM) 79 million (pre-DM)</td>
</tr>
<tr>
<td><strong>Prevalence</strong></td>
<td><strong>29-71%</strong></td>
<td>30%</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td>Leading cause of death</td>
<td>7&lt;sup&gt;th&lt;/sup&gt; leading cause</td>
</tr>
<tr>
<td><strong>Morbidity</strong></td>
<td>Leading cause of hospital discharge &amp; diagnosis</td>
<td>Leading cause of blindness, end stage renal disease</td>
</tr>
</tbody>
</table>
# Heart disease and diabetes: economic cost, primary prevention, screening

<table>
<thead>
<tr>
<th>Cost</th>
<th>CVD $316 billion</th>
<th>Diabetes mellitus $174 billion $218 for undiag and re DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary prevention impact</td>
<td>21-37% reduction in incidence. Up to 71% reduction in risk prevalence.</td>
<td>Up to 43% reduction in relative risk. Up to 51% lower incidence.</td>
</tr>
<tr>
<td>Screening</td>
<td>Framingham Risk Score</td>
<td>Hemoglobin A1c level</td>
</tr>
</tbody>
</table>
Heart disease and oral health

✔ Periodontal interventions result in decreasing local periodontal inflammation, and reduction in systemic inflammation and endothelial dysfunction in short term studies.

✔ Observational studies suggest an association of heart disease and periodontal disease (mechanism uncertain).

✔ NO evidence that perio. interventions prevent heart disease or modify heart disease outcomes.

✔ NO evidence for causal relationship.

Note: Excellent systematic review: Lockhart et al. for ADA Council on Scientific Affairs; Circulation 2012
# DM and oral health

**Diabetes Mellitus** → **Perio. Disease**

<table>
<thead>
<tr>
<th>Poorly controlled DM 3x more likely to develop chronic PD</th>
<th>PD treatment improves glycemic control (0.4%) reduction in A1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 x higher prevalence of PD in patients with DM (27 of 49 studies)</td>
<td>Poor glycemic control increases risk of PD progression and tooth loss</td>
</tr>
<tr>
<td>Meta analysis show average 1mm CAL in DM patients</td>
<td>Gingivitis more prevalent in DM than healthy individuals</td>
</tr>
<tr>
<td>Poor glycemic control increases risk of PD progression and tooth loss</td>
<td></td>
</tr>
</tbody>
</table>
Why screen in a dental setting

- An under utilized resource for disease control and prevention.
- 60-70% of adults visit the dentist in a given year.
- 10-24% of those have not see a physician in the same time period.*

- Could be an effective component of a public health strategy.

- Point of care testing tools exist

* CDC Health US 2020; Glick, Greenberg JADA 2005; Poll;ack, Metsch, Abel AJPH 2010; Strauss et al. AJPH 2012.
Chairside screening strategy for the dental setting
Screening tool criteria

- Methodologically robust
- Well validated
- Easy to use
- Addresses clinically relevant risk factors
- Safe
- Acceptable to patients and clinician
Chairside screening technique

**CHD:** Calculation of Framingham Risk Score

Computer program to calculate score using:
- ✓ Age, smoker (yes, no), gender: medical history
- ✓ Blood pressure measurement
- ✓ Total cholesterol and HDL: finger stick blood

**DM:** Determination of Hemoglobin A1c
- ✓ Finger stick blood

Gick & Greenberg JADA 2005; Greenberg et al. JADA 2009
Framingham Risk Score

- Use web based Framingham Risk Score calculator from: National Heart, Lung and Blood Institute
  http://hp2010.nhlbihin.net/atpiii/calculator.asp

RISK

0-10%: no increased
11-19% moderately increased
20% and higher severely increased
A1c test

- A1c well-standardized measure of average glucose over 3 months
- 2010 endorsed for screening & diagnosis of DM
  - A1c ≥5.7% - 6.4% screen positive
  - A1c ≥6.5% diagnosis positive
**Guidelines: Critical Values for Referral**

<table>
<thead>
<tr>
<th>Clinical measurement</th>
<th>Critical value</th>
<th>Medical referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framingham Risk Score</td>
<td>&gt; 10 %</td>
<td>√</td>
</tr>
<tr>
<td>Hemoglobin A1c</td>
<td>&gt; 5.7 %</td>
<td>√</td>
</tr>
<tr>
<td>Systolic Blood Pressure</td>
<td>≥ 140 mm/Hg</td>
<td>√</td>
</tr>
<tr>
<td>Diastolic Blood Pressure</td>
<td>≥ 90 mm/Hg</td>
<td>√</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>≥ 240 mg/dL</td>
<td>√</td>
</tr>
<tr>
<td>Total Cholesterol/HDL</td>
<td>&gt; 5.0 (men)/&gt;4.5 (women)</td>
<td>√</td>
</tr>
<tr>
<td>BMI</td>
<td>&gt; 30</td>
<td>√</td>
</tr>
<tr>
<td>HIV/ HCV test</td>
<td>positive</td>
<td>√</td>
</tr>
</tbody>
</table>

Negative screening results should be interpreted cautiously as these are screening tests to identify the presence of risk factors indicative of increased risk of developing the diseases of interest. These patients should be instructed to visit their primary care physician regularly (yearly) to monitor their risk profiles.
Safety Precautions

Indicated for use when there is a possibility of exposure to blood or other body fluids, non-intact skin, etc are expected to be used as indicate when performing medical screening.

- Review and follow manufacturers directions
- Train all staff on testing procedures
- Establish standard operating procedures
- Calibrate machines/ & use quality controls
Remember

These precautions are procedurally based and can be anticipated so that you can develop SOPs for each procedure and train staff to follow them.
Standard precautions

☑ Wash hands or use an anti microbial hand rub
☑ Wear gloves
☑ Clean patient’s finger with alcohol wipe/wipe excess with gauze pad
☑ Use new test kit/materials for each patients
☑ Dispose of lancets, used materials appropriately

☑ Clean any contaminated or potentially contaminated environmental surfaces with intermediate level hospital disinfectant.
☑ Appropriately disinfect reusable test machine (CardioChek)
CardioChek: how to
CardioCheck Components

- MEMo Chip
- Enter Key
- Optical Glass
- capillary tube and plunger
- Next Key
- Test Strip
- Lancet
Performing a Fingerstick

• Position the lancet on the side of the fingertip perpendicular to the fingerprint
  – (Allows for a larger amount of blood to flow)

• Puncture skin using the lancet

• Wipe away first drop of blood with clean gauze
  – Important! The first drop of blood may contain traces of alcohol
Running the Test

- Install the MEMo Chip into the instrument.
- Turn on the instrument.
- Ensure the MEMo Chip Lot Number corresponds to the test strip lot number.
Running the Test

- Instrument displays: “INSERT STRIP”
- Ensure test strip is inserted fully and the display reads: “APPLY SAMPLE.”
Running the Test

Insert MEMo Chip®. Insert the MEMo Chip that matches the lot number on the test strip vial. Press either button ( or ) to turn the CardioChek PA instrument ON.
Applying Sample to Test Strip

- Ensure that a color change has occurred in all test windows
Inserting test strip

Insert test strip. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip firmly into analyzer. Push the test strip in as far as it will go. The analyzer will then display APPLY SAMPLE.
Applying Sample to Test Strip

- Place capillary tube with inserted plunger over test strip sample window (white area on strip).
- Avoid touching the surface of the strip.
Dispense blood. Hold capillary tube over test strip white blood application window and push plunger down slowly. Dispense all blood into application window. In about 2 minutes the CHOL result will appear on display. To display other lipid test, press arrow button (on right)
Applying Sample to Test Strip

- Once sample is applied, results will appear on the display within about two minutes.

- If running a multi test strip, strike the NEXT button to see subsequent results.
Framingham Risk Score

• Use web based Framingham Risk Score calculator from: National Heart, Lung and Blood Institute

RISK

0-10%: no increased
11-19% moderately increased
20% and higher severely increased
A1c: how to
Conducting the Screening

A1CNow

Glycosylated Hemoglobin
A1c Components

- Monitor
- Test Cartridge
- Sampler Body
- Blood Collector
Procedure – Before You Begin

Ensure that the lot number on following components match:

• back of the monitor
• pouched test cartridge #2
• sample dilution kit #1
1. Fully insert Blood Collector into Sampler body

2. Use a twisting motion as you insert Blood Collector

3. Make sure that Blood Collector is fully inserted
AC1 Blood Collection

- Obtain blood sample
  - Finger stick – requires 5μL of whole blood
Shake Sample

Shake sample well

Stand sampler on table
Insert Cartridge

- open pouch after blood sample has been collected.
- Insert cartridge into monitor
Prepare Sampler

- Wait for SMPL to appear on display before adding sample
- Remove base and apply sample to cartridge
Dispense Sample into Cartridge

- After display says SMPL, apply sampler and remove quickly.
Results

5 min to results

• If “QCOK” is not displayed please see list of error codes.
What is CLIA (clinical laboratory improvement act)
- 1988 act to establish quality standards for lab testing to ensure accuracy, and timeliness of results
- All facilities (e.g., dental office) examining human specimens must register with federal Centers for Medicare and Medicaid (CMS) and obtain CLIA certification

All tests discussed are CLIA waived
- Use unprocessed specimens
- Easy to use and little risk of incorrect results

Type of certificate is A Certificate of Waiver

Applications CMS website or state health department
"Machine" Accuracy: Bayer A1c

- Bayer A1c NOW (2014)
  - Compared Bayer A1c finger stick and HPLC venous sample among 1618 Chinese with DM
  - A1c highly correlated with HPLC (reference) ($R=0.945$)
  - 95% CIs for limits of agreement were -1.28% to 1.09%
  - 80.2% A1c NOW accurate; 17.7% acceptable; 2.2% may lead to inappropriate treatment

Jiang F et al. Diabetes Technology and Therapeutics 2014
“Machine accuracy”: CardioChek PA

2008: CardioChek vs Cholestech LDX comparison
- 34 fasting adults: venous vs finger stick
- LDX more reproducible
- LDX fewer misclassifications

2013: CardioChek vs Cholestech LDX laboratory based
- 15 non-fasting venous samples: limits of agreement with Roche Analyzer (LOA)
- LDX less bias for HDL:
  - mean= -12; 95% CIs: -33 to 9% vs. mean= -13; 95% CIs: -54 to 38%
- DX less bias for TC:
  - mean= -2; 95% CIS: -12 -8.3% vs. mean= -17; 95% CIs: -44 to 18%

Ref: Whitehead SJ et al. Clinical biochemistry and laboratory medicine 2013
“Machine” Accuracy: CardioChek

2014: (first three year performance improvements)

- 748 measurements of healthy adults: venous vs. finger stick
- CardioChek vs laboratory (COBAS 6000 machine)
- Total error 1.3% TC and 3.1% HDL
- Agreement with venous blood:
  - regression R values CardioChek vs. Lab TC: 0.99; HDL: 0.97
- Agreement with finger stick blood:
  - regression R values CardioChek vs. Lab TC: 0.97; HDL: 0.95

Comparison of CardioChek PA capillary sample results with laboratory values

<table>
<thead>
<tr>
<th>Parameter mmol/L</th>
<th>NO.</th>
<th>CardioChek</th>
<th>Laboratory</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol</td>
<td>153</td>
<td>4.5 ±0.8</td>
<td>4.5 ± 0.8</td>
<td>NS</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>151</td>
<td>1.5 ± 0.4</td>
<td>1.5 ± 0.4</td>
<td>NS</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>149</td>
<td>1.3 ± 0.8</td>
<td>1.3 ± 0.8</td>
<td>NS</td>
</tr>
</tbody>
</table>

Web-based resources

• American Diabetes Association website: http://www.diabetes.org/
• Diabetes clinical guidelines: http://care.diabetesjournals.org/content/34/Supplement_1
• American Heart Association website: http://www.heart.org/HEARTORG/
• Centers for Disease Control. Diseases and conditions website: http://www.cdc.gov/diseasesconditions/
Thank you!