Two Separate Issues

1. HbA1c for diagnosis
2. HbA1c point-of-care testing
The WHO Consultation concluded that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardized... and there are no conditions present which preclude its accurate measurement.

Quality of Evidence is moderate
Strength of Recommendation is conditional

WHO/NMH/CHP/CPM/11.1, 2011
Prevalence of Retinopathy by Deciles

HbA\textsubscript{1C}  
FPG (mg/dl)  
2hPG (mg/dl)

Hb = Hemoglobin; FPG = Fasting plasma glucose; Adapted from: The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 1997;20:1183-1197
A1c Diagnosis of Diabetes in ARIC and NHANES III (n=14,176)

Selvin et al. Diabetes Care 34:84, 2011
A1c versus Fasting Glucose in Obese Children and Adolescents

# Sensitivity and Specificity of A1c in Arabs

## Table 1. Sensitivity of A1C stratified by age, sex, and BMI

<table>
<thead>
<tr>
<th></th>
<th>Diagnosis by A1C</th>
<th>Diagnosis by FPG and/or OGTT</th>
<th>Sensitivity of A1C [% (95% CI)]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prediabetes</td>
<td>Diabetes</td>
<td>Prediabetes</td>
</tr>
<tr>
<td><strong>Age group (yr)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45 (n = 326)</td>
<td>17 (5)</td>
<td>3 (1)</td>
<td>141 (43)</td>
</tr>
<tr>
<td>45–64 (n = 126)</td>
<td>28 (22)</td>
<td>7 (6)</td>
<td>69 (55)</td>
</tr>
<tr>
<td>≥65 (n = 30)</td>
<td>9 (30)</td>
<td>2 (7)</td>
<td>13 (43)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n = 194)</td>
<td>19 (10)</td>
<td>5 (3)</td>
<td>109 (56)</td>
</tr>
<tr>
<td>Female (n = 289)</td>
<td>35 (12)</td>
<td>7 (2)</td>
<td>114 (39)</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18.5 (n = 2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (100)</td>
</tr>
<tr>
<td>18.5–24.9 (n = 128)</td>
<td>5 (4)</td>
<td>3 (2)</td>
<td>40 (31)</td>
</tr>
<tr>
<td>25.0–29.0 (n = 182)</td>
<td>20 (11)</td>
<td>4 (2)</td>
<td>88 (48)</td>
</tr>
<tr>
<td>≥30.0 (n = 170)</td>
<td>29 (17)</td>
<td>5 (3)</td>
<td>93 (55)</td>
</tr>
</tbody>
</table>

CI, Confidence interval.
ROC Curve for A1c and Fasting Glucose in Chinese

Men

- Sensitivity = 64.4%
- Specificity = 61.6%

Women

- Sensitivity = 62.3%
- Specificity = 63.3%

Zhou et al. Diabetes Care 33:545, 2010
“It is important to take age, race/ethnicity, and anemia/hemoglobinopathies into consideration when using the HbA1c to diagnose diabetes.”
Two Separate Issues

1. HbA1c for diagnosis
2. HbA1c point-of-care testing
“Use of point of care testing for HbA1c allows for timely decisions on therapy changes, when needed.”
Benefits/Advantages of POC for Diabetes Monitoring:

- Significant Improvement in glycemic control:
  
  Cagliero et al 1999  
  Thaler, et al 1999  
  Miller, et al 2003  
  Petersen, et al 2007

- Other benefits (more efficient communication, more frequent intensification of therapy, enhanced motivation):
  
  Agus et al 2010  
  Al-Ansary, et al (review of 7 trials) 2011
First recommended the use of HbA1c testing for diagnosis, but “Point of care HbA1c assays are *not sufficiently* accurate at this time to use for diagnostic purposes”
“Point of care HbA1c, for which proficiency testing is not mandated, are not sufficiently accurate at this time for diagnostic purposes.”
“Although point of care HbA1c assays may be NGSP certified, proficiency testing is not mandated for performing the test, so use of these assays for diagnostic purposes could be problematic and is not recommended.”
“Although point of care HbA1c assays may be NGSP certified, proficiency testing is not mandated for performing the test, so use of point of care assays for diagnostic purposes is not recommended.”
Concerns regarding POC HbA1c

- St John, et al 2005: only 1 of 4 POC devices tested were recommended for use outside of laboratory
- Lenters-Westra, et al 2009: high variability and lot-dependent results for 2 POC methods
- Lenters-Westra, et al 2010: 6 of 8 POC methods do NOT meet accepted performance criteria; there was considerable lot-to-lot variability
- Petersen et al 2010: can be used if physicians given instrument specific reference ranges
- Lenters-Westra, et al 2014: 3 of 7 POC methods do NOT meet performance criteria
- Dupuy, et al 2014: lot-to-lot variability for one POC method; reproducibility of reagent lot production appears inadequate.
Concerns regarding POC HbA1c

- Imprecision/Lack of Reproducibility
- Lot-to-lot variations in reagents/calibration
- Lack of proficiency testing (PT) data, especially at waived sites
“Community testing outside a healthcare setting is not recommended because people with positive tests may not seek, or have access to, appropriate follow-up testing and care. Community testing may also be poorly targeted; i.e., it may fail to reach the groups most at risk and inappropriately test those at very low risk or even those who have already been diagnosed."
“Although point of care HbA1c assays may be NGSP certified, proficiency testing is not mandated for performing the test, so use of point of care assays for diagnostic purposes is not recommended.”