



AADE Practice Advisory Role of the A1C Assay in the Diagnosis of Diabetes—Role of the Diabetes Educator

In July 2009, the International Expert Committee published the consensus view of the committee to consider the use of the A1C assay for the diagnosis of diabetes. This committee, with members appointed by the ADA, European Association for the Study of Diabetes (EASD) and the International Diabetes Federation (IDF) made several recommendations to support the change for the diagnosis of diabetes.

Because the relationship of glycaemia and the presence of long-term micro vascular complications (retinopathy, neuropathy and nephropathy) can be plotted along a continuum of glucose levels, the committee sought to determine the level at which the risk substantially increases. Comparisons of fasting plasma glucose (FPG), 2 hour plasma glucose (2hPG) during a 75-g OGTT, and HbA1c each indicated equivalent correlation.

The Committee's key recommendations include the following:

1. Use of the A1C assay compared to glucose measurements for the use of diagnosis of diabetes will capture chronic glucose exposure compared to a single measure of glucose. Because it is more convenient (i.e., fasting not necessary) and because it may be more stable pre-analytically (i.e., after specimen collection), it should be viewed as the 'preferred' test over FPG and 2hPG.
2. Diabetes should be diagnosed when A1C is $\geq 6.5\%$ with a confirmatory repeat A1C test. If symptoms are present, confirmation is not required.
3. If the A1C assay is adopted as the preferred diagnostic test, the use of FPG and OGTT for diagnosis would be expected to decrease. So, the high-risk states of 'impaired fasting glucose (IFG)' and 'impaired glucose tolerance (IGT)' may no longer be used. The relationship between all glycemic measures and future diabetes risk is a continuum, without any specific threshold. The term 'pre-diabetes', therefore, should be replaced with a term that simply indicates the increased risk of diabetes, but not a future absolute conversion to diabetes. The Expert Committee felt that based on A1C, a level of 5.7% to 6.4% identified a very high-risk group for which diabetes prevention interventions might be especially worthwhile.
4. If A1C testing is not possible due to specific patient factors, previously recommended laboratory testing of fasting plasma glucose or 2 hour post glucose is acceptable.
5. In children and adolescents, the A1C assay should be performed when diabetes is suspected but classic symptoms and a casual plasma glucose ≥ 200 mg/dl are not found.

The Committee, however, identified limitations to consider:

- The current limitation of using the A1C assay is the need for a standardized laboratory standard. This has already been agreed to by manufacturers, clinical chemists, and diabetes professional organizations.
- Point of care instruments would not be appropriate for use in the diagnosis of diabetes.
- Factors that may affect interpretation include hemoglobin variants or abnormal erythrocyte turnover, e.g. during pregnancy.
- Factors that may affect interpretation include hemoglobin variants such as hemoglobin traits of HbS, HbC, HbF, and HbE and conditions that change red blood cell turnover such as hemolytic anemia, chronic anemia, major blood loss, blood transfusions and pregnancy. Clinicians need to be aware that these conditions can affect results in populations where they are more prevalent.

ADA has released clinical guidelines ([2010 Standards of Medical Care in Diabetes](#), Diabetes Care, January 2010) on the topic. The Endocrine Society supports the ADA recommendation for use of A1C as an option to diagnose diabetes; but notes that “there are certain caveats that must be understood by clinicians and the public as this diagnostic test increases in use.” The Endocrine Society has issued a [Statement on A1C Use](#) (available at: <http://www.endo-society.org/advocacy/loader.cfm?csModule=security/getfile&pageid=30809>).

The other main diabetes global organizations (EASD, and IDF) are expected to release their own position statements on the Expert Committee’s recommendations over the next 2-3 months. While the A1C cut-point of $\geq 6.5\%$ is being endorsed by these groups, it is unlikely that it will be viewed as ‘preferred’ over the more conventional glucose-based tests.

Also, the specific lower A1C cut point chosen for what defines a ‘high-risk’ individual (i.e., akin to ‘pre-diabetes’) may actually be lower than the 6.0% threshold identified by the Expert Committee.

Finally, the traditional terms ‘IFG’ and ‘IGT’ (and for that matter, ‘pre-diabetes’) will likely still be accepted, especially if glucose-based tests (i.e., FPG, 2hPG) continue to be used.

Role of the Educator:

1. Become familiar with the existing evidence and emerging recommendations of the ADA on the use of the A1C level as a diagnostic test for diabetes.
2. Understand the specific A1C assay being used for diagnosis and the diagnostic cut points, including the cut point to identify individuals at high-risk for diabetes.
3. Acknowledge that the threshold to begin preventative measures to prevent diabetes do not necessarily begin solely at this A1C cut point, but may be advantageous even at an earlier stage in persons who have other risk factors for diabetes (obesity, family history, etc.)
4. Be prepared to help your patients understand the terms and definitions used in relation to the screening and diagnosis of ‘pre-diabetes’ and diabetes.

References:

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