HbA_{1c} testing for diabetes diagnosis: The new standard?

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American Diabetes Association (2010) Standards of medical care in diabetes – 2010. *Diabetes Care* **33**: S11–61

International Expert Committee (2009) International Expert Committee report on the role of the A_{1C} assay in the diagnosis of diabetes. *Diabetes Care* **32**: 1327–34

Khunti K, Taub NA, Gillies CL et al (2010) A comparison of screening strategies for type 2 diabetes mellitus and impaired glucose tolerance in a UK community setting: a cost per case analysis. Presented at: *Diabetes UK Annual Professional Conference 2010*, 3–5 March, Liverpool

World Health Organization (2011) *Use of Glycated Haemoglobin (HbA_{1c}) in the Diagnosis of Diabetes Mellitus*. WHO, Geneva. Available at: http://bit.ly/fL24Mt (accessed 07.03.11)

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Historically, throughout the world, the oral glucose tolerance test (OGTT) has been used to diagnose diabetes. However, for some years, there has been debate within the diabetes community as to the validity of this test. The OGTT involves fasting for ≥12 hours prior to the test, taking a blood sample, consuming a glucose drink and fasting for a further 2 hours before another blood sample is taken. This procedure is often considered inconvenient and unpleasant for the individual being tested.

During the 2 hours between blood samples being taken the individual should remain at rest. In my experience, however, people have walked home during this "rest" time, which may invalidate the result. In addition, the concentration of Lucozade© has been changed in recent years, thus if the necessary adjustments are not made to the protocol, the validity of the test may be affected.

HbA_{1c} testing measures the average plasma glucose levels over the previous 2–3 months. This test has previously been used only to assess glycaemic control, but is now being considered as an alternative to OGTT for diagnosing diabetes. HbA_{1c} offers the advantages over OGTT of not involving fasting and also that it is not affected by day-to-day variability in blood glucose levels.

In January 2010, the American Diabetes Association formally advocated the use of HbA_{1c} testing for diagnosis of diabetes following recommendations by the International Expert Committee (2009).

The World Health Organization (WHO, 2011) has now published a report also recommending that HbA_{1c} testing be used for diabetes diagnosis where stringent quality assurance tests are in place, assays are standardised in accordance with international reference values and there are no medical conditions present that may cause inaccuracy in the measurement. WHO recommends an HbA_{1c} cut-off level of 6.5% (48 mmol/mol). A value of <6.5% (<48 mmol/mol) does not exclude diabetes diagnosed using glucose tests. The expert group (WHO, 2011) concluded that there is currently insufficient evidence to make any formal recommendation on the interpretation of HbA_{1c} levels <6.5% (<48 mmol/mol), although a person without diabetes would have an HbA_{1c} level of approximately 5% (31 mmol/mol).

In a recent WHO press release (http://bit.ly/edlcND), Dr Ala Alwan, Assistant Director General of WHO's Noncommunicable Diseases and Mental Health Cluster, stated that this recommendation is a positive development, "but its higher cost in comparison to other diagnostic tools will, for now, make it harder for developing countries to use. It also remains unreliable in medical conditions with rapid red-cell turnover, such as haemolytic or iron deficiency anaemias. So the priority for low-income countries will continue to be ensuring the availability of blood glucose measurement at the primary healthcare level before widely introducing HbA_{1c} for diagnosing diabetes".

Research indicates that switching from testing blood glucose levels to HbA_{1c} levels with a threshold of ≥6.5% (≥48 mmol/mol) could significantly increase GP workload as the number of people diagnosed with diabetes will greatly increase. A study (Khunti et al, 2010), presented at the Diabetes UK 2010 conference, compared the prevalence of type 2 diabetes as diagnosed by either OGTT or HbA_{1c} testing in 9500 people. OGTT identified 344 individuals (3.6%) with diabetes. Of these, 103 (1.1% of the entire cohort) had an HbA_{1c} level of <6.5% (<48 mmol/mol) and would not have been classified as having the condition using the new HbA_{1c} criteria. When using HbA_{1c} as the diagnostic tool, 591 individuals (6.2%) were detected with type 2 diabetes.

The European Association for the Study of Diabetes is now formally considering the move as with recent technological advances, HbA_{1c} assays are becoming highly standardised and most are not affected by haemoglobinopathies.

The debate of the value of introducing HbA_{1c} as a diagnostic tool continues among clinicians. However, it seems likely that this method of diagnosing diabetes will be adopted in the UK sometime this year – watch this space! ■