Commentary

Presidents’ statement on WHO recommendation on HbA1c for diabetes diagnosis

Diabetes is a common and serious condition which results in premature mortality, significant morbidity and has a considerable economic impact. A diagnosis of diabetes has important implications for the individual. It not only commits them to a lifetime of treatment but also may affect work opportunities and social interactions, underlining the importance of making a correct diagnosis. While relatively easy to diagnose in people who are symptomatic, the diagnosis of diabetes may be challenging in an asymptomatic individual.

Since 1965 the WHO has published several guidelines for the diagnosis of diabetes. The last report published in 2006 confirmed the central role of fasting and post oral glucose tolerance test plasma glucose for diagnosing diabetes [1].

The potential utility of HbA1c in the diagnosis of diabetes was considered by a number of WHO consultations and each had concluded that it should not be adopted as a diagnostic test because the challenges of measurement accuracy outweighed the convenience of its use.

In March 2009, WHO convened another consultation to review the available evidence for HbA1c in diagnosing diabetes. The report of this WHO consultation has recently been released [2] and is published in this issue of Diabetes Research and Clinical Practice [3]. The key conclusion of this Consultation was that HbA1c can be used as a diagnostic test for diabetes and that an HbA1c of 6.5% is recommended as the cut point for diagnosing diabetes. This recommendation is supported by and now aligns the major diabetes organisations including the International Diabetes Federation (IDF), the European Association for the Study of Diabetes (EASD), and the American Diabetes Association (ADA).

Several important points in relation to the WHO Consultation report deserve highlighting.

- HbA1c is recommended as a diagnostic option in addition to and not replacing previously defined diagnostic tests.
- The use of HbA1c as a diagnostic option for diabetes is dependent on meeting stringent quality assurance tests, assays being standardised to criteria aligned to the international reference values, and also that there are no conditions present which preclude the accurate measurement of HbA1c. In particular, HbA1c is unreliable in medical conditions with rapid red cell turnover, such as haemolytic or iron deficiency anaemias, haemoglobinopathies (depending on the assay employed) and disorders associated with accelerated red cell turnover such as malaria. Therefore in many countries and locations throughout the world, HbA1c testing will not be a practical option for diagnosing diabetes at this time. Cost also represents a major barrier to the adoption of this recommendation in many parts of the world.
- The WHO Consultation has not made any specific recommendation in relation to the use of HbA1c for diagnosing "Intermediate Hyperglycaemia" but concluded that there is currently insufficient evidence to make any formal recommendation on the interpretation of HbA1c levels below 6.5%.

Diagnostic criteria for diabetes are an evolving process which will require ongoing review as new research data become available. While use of HbA1c has the potential to simplify the diagnosis of diabetes in many individuals, crucial questions remain unanswered such as whether diabetes diagnosed on the basis of glucose criteria or by HbA1c represent the same disease process. It should be noted that

<table>
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<tr>
<th>Table 1 – Diagnostic criteria for diabetes in an asymptomatic individual.</th>
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<tbody>
<tr>
<td><strong>Fasting plasma glucose</strong></td>
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<td><strong>2-h plasma glucose</strong></td>
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<td><strong>HbA1c</strong></td>
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* Venous plasma glucose 2-h after ingestion of 75 g oral glucose load.
the traditional methods using glucose and HbA1c will not
identify exactly the same sets of people with diabetes, and that
it is possible for the same person to be determined to have
diabetes with one method and not the other. It is therefore
preferable to confirm the diagnosis with the same method.

The current WHO pronouncement means that there is
global consensus on the potential role of HbA1c as a diagnostic
option while continuing to emphasise the limitations of HbA1c
testing and the processes which need to be adopted before it
can become a more widely applicable practical reality.

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