Guidance concerning the use of glycated haemoglobin (HbA1c) for the diagnosis of diabetes mellitus

A position statement of the Australian Diabetes Society

Reimbursement by Medicare of the costs of measuring glycated haemoglobin (HbA1c) for the diagnosis of diabetes mellitus was recently approved. An HbA1c value of 48 mmol/mol (6.5%) or more constitutes a positive result, suggesting the diagnosis of diabetes mellitus. This test provides an alternative to traditional glucose-based methods of diagnosis; it does not replace them. The correct use of the test may facilitate earlier diagnosis of people with elevated mean blood glucose levels who are at increased risk of long-term diabetes-specific microvascular complications. HbA1c assessment will be used predominantly for the diagnosis of type 2 diabetes mellitus.

It is important that medical practitioners who elect to use the test for diagnostic purposes understand its nature, its limitations and its benefits. The latter were outlined in the position paper of the HbA1c Committee of the Australian Diabetes Society published in this Journal in 2012. We recommend that medical practitioners read the earlier paper in conjunction with this new implementation document. Assessment of HbA1c levels during pregnancy is not discussed in this article.

This position statement of the Australian Diabetes Society is endorsed by the Royal College of Pathologists of Australasia and the Australasian Association of Clinical Biochemists.

Medicare reimbursement

The Medicare Benefits Schedule (MBS) entry for item 66841 describes the test as the “Quantitation of HbA1c (glycated haemoglobin) performed for the diagnosis of diabetes in asymptomatic patients at high risk”. When used for this purpose, the cost of the test can be reimbursed only once during a 12-month period. The brevity of the MBS description raises certain questions.

1. High-risk patients

Only patients at high risk of undiagnosed diabetes should be tested. These are patients with either (i) a medical condition or ethnic background associated with high rates of type 2 diabetes, or (ii) an Australian type 2 diabetes risk (AUSDRISK) score of 12 or greater, placing them at increased risk of diabetes. Patients with multiple classical symptoms of diabetes (weight loss, polyuria, polydipsia, blurred vision etc.), however, are not asymptomatic, and should have the diabetes diagnosis confirmed by blood glucose assessment; high blood glucose levels would be expected in these cases. Further, patients with rapidly evolving diabetes can theoretically have normal HbA1c levels because blood glucose levels have not been elevated for a significant period of time.

2. Asymptomatic patients

Medicare restricts diagnostic HbA1c assessment to asymptomatic patients. However, many symptoms of diabetes are, in isolation, non-specific, eg, tiredness and blurred vision. Patients presenting with such symptoms should be considered asymptomatic and appropriate for HbA1c testing if at high risk of developing diabetes. If one or more symptoms that suggest diabetes are present in a low-risk patient, blood glucose tests should be used.

Appropriately used, HbA1c assessment should provide a cost-effective, efficient and simple tool for the early diagnosis of type 2 diabetes.

3. Repeat assessment of HbA1c levels

An HbA1c test result of less than 48 mmol/mol (6.5%) indicates that diabetes is unlikely. As the test will have been performed in a high-risk patient, it should be repeated 12 months later, according to the National Health and Medical Research Council (NHMRC) guidelines. These patients should also be given appropriate lifestyle advice.

Labelling people with an HbA1c value slightly under 48 mmol/mol (6.5%) with prediabetes is not recommended, as there is uncertainty about using HbA1c levels to define prediabetes. This is consistent with the position of the World Health Organization. However, an HbA1c level of 42–47 mmol/mol (6.0–6.4%) suggests a higher risk of developing diabetes than that based on the AUSDRISK score alone; these individuals will also be at increased risk of the cardiovascular complications. They should be
counselled about lifestyle measures (weight loss, dietary change, exercise) and assessed for other modifiable cardiovascular risk factors (hypertension, dyslipidaemia, smoking). Unless they develop symptoms of diabetes, additional blood glucose measurements should not be performed to diagnose diabetes. They may have blood glucose levels consistent with impaired fasting glucose, impaired glucose tolerance, or diabetes, but, with an HbA1c level below 48 mmol/mol (6.5%), they are at minimal risk of developing microvascular complications. Even if diagnosed with diabetes or prediabetes, lifestyle advice should be the major intervention. Their HbA1c levels should be re-assessed 12 months later.

4. Confirmation
The NHMRC guidelines indicate that abnormal blood glucose levels in an asymptomatic patient should be confirmed to establish a diagnosis of diabetes. A single elevated HbA1c result is accepted by Medicare as evidence for established diabetes, although other organisations (WHO, American Diabetes Association) recommend that diagnoses made by HbA1c testing be confirmed by follow-up testing.11

5. Abnormal measurements
In a small but important minority of people, HbA1c levels are not a reliable indicator of plasma glucose levels. An inappropriately low HbA1c value is the major concern, as the diagnosis of diabetes will be missed in such patients. The possibility of medical conditions that invalidate the HbA1c result should be considered in all patients with an unexpectedly low HbA1c result, as discussed in our earlier paper. In summary, HbA1c assessment may not be appropriate in patients with significant chronic medical disease, anaemia or abnormalities of red blood cell structure (Box 1). A full blood count may reveal red blood cell abnormalities suggestive of a haemoglobinopathy or haemolytic anaemia, but a normal full blood count does not exclude the possibility of such conditions. Certain ethnic communities more frequently have underlying haemoglobin abnormalities, and this should be discussed with the testing laboratory when appropriate. Emerging methodologies are minimising this problem.

References are available online at www.mja.com.au.

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