OAML
ONTARIO ASSOCIATION OF MEDICAL LABORATORIES

OAML Communiqué

Update on Glycated Hemoglobin Reporting & Test Utilization

May, 2015

Background

Glycated hemoglobin (HbA1c) is an established marker of long-term glucose control in patients with diabetes mellitus ("diabetes"). More recently, the Canadian Diabetes Association (CDA) has accepted HbA1C as a marker of increased risk of diabetes, and as a diagnostic test for type 2 diabetes.

Laboratory screening for diabetes can now be performed with non-fasting specimens, using either HbA1c (plasma) or glucose (serum, plasma) tests.[1]

Result Reporting

In Ontario, methods of analysis of HbA1c are certified and standardized to the National Glycohemoglobin Standardization Program (NGSP) and are traceable to the International Federation for Clinical Chemistry (IFCC) reference method. Results for HbA1c are currently reported either as decimals or as percentages of total hemoglobin, as recommended by Canadian Society of Clinical Chemists (CSCC) and the Canadian Association of Medical Biochemists (CAMB).[2] However, the CDA has recommended that HbA1c screening and diagnostic cut-offs, and monitoring targets as well, be reported only as percentages.[1]

Ontario community laboratories will implement standardized reporting of HbA1c in May, 2015. The CDA 2013 recommended HbA1c targets, in percentages, are contained in the table below.[1, 3, 4]

Table 1: CDA 2013 Recommended HbA1c Targets [1, 3, 4]

Reason for Analysis	Cut-off Value for HbA1c	Interpretation of HbA1c Results
Screening	< 5.5%	Normal glycemic control
	5.5 – 5.9%	At risk: More frequent rescreen is suggested.
	6.0-6.4%	Pre-diabetes: Increased risk of developing diabetes mellitus in the absence of factors that may affect accuracy of HbA1c quantitation.
Diagnosis	≥6.5%	Provisional diagnosis of diabetes in non-pregnant adults with suspected Type 2 diabetes.
Monitoring	≤ 7.0%	Goal for Type 1 or Type 2 diabetics - to reduce microvascular disease in most adults. **Note:** Other goals may be more appropriate for children, elderly patients or those with co-morbidities.
	7.1-8.5%	Goal for Type 1 or Type 2 diabetics with: • limited life expectancy • high level of functional dependency • coronary artery disease • multiple co-morbidities • history of hypoglycemia and/or unaware of hypoglycemia • long-term diabetes and difficulty in maintaining ≤ 7.0% goal.

Frequency of Monitoring

The CDA 2013 Guidelines recommend quantitative analysis of HbA1c as follows:

- Every 6 months for adult patients who have demonstrated good long-term glycemic stability.
- Every 3 months when goals for glycemic control are not being met, or when modifying a patient's therapy for glucose control.[1, 5]

Under-utilization of HbA1c has been reported in both the UK and Canada, raising concerns for long-term health outcomes.[6, 7] A recent review of an Ontario community laboratory database suggests that about 26% of HbA1c requests appear to conform to the CDA recommended frequency; however, in approximately 70% of the patients HbA1c appears to be under-ordered. In the remaining 4% of the patients, HbA1c was over utilized.

Limitations

HbA1c is not recommended as a diagnostic test for individuals suspected of having type 1 diabetes, children, pregnant women, elderly patients (> 65 years), or those with advanced kidney or liver disease.

In addition, HbA1c may not accurately reflect true glycemic control in patients with unusual hemoglobin molecule structures or abnormal red blood cell turnover rates such as is seen in hemoglobinopathies, in chronic renal failure, and in those with iron or vitamin B12 deficiencies.[1]

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