



Use of Haemoglobin A_{1c} (HbA_{1c}) in the diagnosis of diabetes mellitus The implementation of World Health Organisation (WHO) guidance 2011

Professor W Garry John, Clinical Biochemist, Norfolk and Norwich Hospital
Dr Rowan Hillson MBE, National Clinical Director for Diabetes
Professor Sir George Alberti, Chair, Diabetes UK and expert group*

WHO Recommendation 2011¹

HbA_{1c} can be used as a diagnostic test for diabetes providing that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement.

An HbA_{1c} of **48 mmol/mol (6.5%)** is recommended as the cut point for diagnosing diabetes. A value of less than 48 mmol/mol (6.5%) does not exclude diabetes diagnosed using glucose tests.

An expert group* have discussed the WHO report. The group agree that the WHO requirements are met in the UK. HbA_{1c} is not suitable for use in everyone. Do not use HbA_{1c} to diagnose diabetes in pregnancy.

The test

Analysis of venous HbA_{1c} in UK laboratories participating in national quality assurance schemes currently fulfils WHO requirements. HbA_{1c} should usually be measured on a laboratory venous blood sample. Point-of-care HbA_{1c} should not be used for diagnosis unless the healthcare staff have been appropriately trained and the HbA_{1c} method used can demonstrate an internal quality control and external quality assessment performance that matches that of a laboratory method. Confirm a point-of-care diabetes diagnosis with laboratory venous HbA_{1c}.

Most patients

HbA_{1c} ≥ 48 mmol/mol can be used to diagnose diabetes in most situations. In patients without diabetes symptoms repeat venous HbA_{1c} in the same lab within 2 weeks. If the second sample is < 48 mmol/mol (6.5%) treat as high risk of diabetes and repeat the test in 6 months or sooner if diabetes symptoms develop. In symptomatic adults with relatively slow onset of symptoms a single result ≥ 48 mmol/mol will suffice.

Situations where HbA_{1c} must not be used as the sole test to diagnose diabetes

HbA_{1c} reflects glycaemia over the preceding 2 – 3 months so may not be raised if blood glucose levels have risen rapidly. Examples:

ALL symptomatic children and young people
Symptoms suggesting Type 1 diabetes (any age)
Short duration diabetes symptoms
Patients at high risk of diabetes who are acutely ill
Taking medication that may cause rapid glucose rise e.g. corticosteroids, antipsychotics
Acute pancreatic damage/pancreatic surgery

Do an immediate quality-assured finger-prick capillary glucose test. Check blood/urine ketones if available. If glucose is >11.0 mmol/l seek same-day specialist diabetes advice. For children and teenagers phone the specialist paediatric diabetes team same day. Send same day laboratory venous glucose, adding HbA1c to exclude stress hyperglycaemia and/or for baseline, but do not delay seeking advice whilst awaiting the result.

Presence of factors that influence HbA1c and its measurement

See Annex 1 from WHO report. Discuss the patient with your local laboratory or specialist diabetes team or use glucose testing. Factors include abnormal haemoglobins, anaemia, altered red blood cell lifespan.

Patients whose HbA1c is <48 mmol/mol (6.5%)

These patients may still fulfil WHO glucose criteria for the diagnosis of diabetes which can be used in patients with symptoms of diabetes or clinically at high risk of diabetes. Glucose tests are not recommended routinely in this situation.

WHO did not provide specific guidance on HbA1c criteria for people at high risk of diabetes. Clinicians should consider the individual patient's personal risk of diabetes and provide advice and monitoring accordingly. Pending NICE² guidance (see consultation) the expert group suggested using HbA1c values below.

High risk of diabetes HbA1c 42-47 mmol/mol (6.0 – 6.4%)

Provide intensive lifestyle advice. Warn patients to report symptoms of diabetes. Monitor HbA1c annually.

HbA1c <42 mmol/mol (6.0%)

Some of these patients may still be at risk of diabetes. If clinically at high risk manage as above.

A detailed report will be available shortly. This guidance is supported by the Association of British Clinical Diabetologists (ABCD), Association for Clinical Biochemistry (ACB), Community Diabetes Consultants (CDC), Diabetes UK, NHS Diabetes, Primary Care Diabetes Society (PCDS), Training, Research, and Education for Nurses in Diabetes UK (TREND UK).

Reference

- 1 http://www.who.int/diabetes/publications/report-hba1c_2011.pdf
- 2 <http://guidance.nice.org.uk/PHG/Wave19/62>

*** Members of the expert group**

George Alberti, WHO committee on HbA_{1c}, Chair Diabetes UK
Barbara Bain, Professor of Diagnostic Haematology, Imperial College
Ian Barnes, National Clinical Director Pathology, DH
Julian Barth, President Association for Clinical Biochemistry
Felix Burden, Commissioning Director Heart of Birmingham PCT
Fiona Campbell, Paediatric lead NHS Diabetes
Marie Cummins, Regional Programme Manager/NHS Health Checks, NHS Diabetes
Melanie Davies, Professor of Diabetes Medicine, University of Leicester.
Alison Daykin, Policy manager NHS Health Checks DH
Jane French, National External Quality Assurance Scheme, glycated haemoglobin
Roger Gadsby, Associate clinical professor, University of Warwick, NHS Evidence Diabetes
Geoff Gill, Chair Joint Specialty Committee for Endocrinology & Diabetes, RCP
Martin Hadley Brown, Chair Primary Care Diabetes Society
Rowan Hillson, National Clinical Director for Diabetes England, DH (Chair)
Richard Holt, Professor in Diabetes and Endocrinology, University of Southampton
Garry John, Consultant Clinical Biochemist, Norfolk and Norwich University Hospital;
Professor of Clinical Biochemistry, University of East Anglia
Brian Karet, Past diabetes lead RCGP. Primary care lead Diabetes UK, Primary Care
Diabetes Society
Kamlesh Khunti, Professor of Diabetes, Head of Division of General Practice and Primary
Health Care, University of Leicester.
Eric Kilpatrick, Professor of Clinical Biochemistry, Hull Royal Infirmary
Elizabeth Lynam, Branch Head, Vascular programme DH
Sally Marshall, Professor of diabetes, University of Newcastle
John McKnight, Consultant Diabetologist, Scotland
Nathan Moore, Diabetes Policy Lead, DH
Anna Morton, Director NHS Diabetes
Simon O'Neill, Director of Care, Information and Advocacy, Diabetes UK
June James Training, Research & Education for Nurses in Diabetes
Maurice O'Kane, Consultant Chemical Pathologist, Altnagelvin Area Hospital, and
University of Ulster, Northern Ireland
Naveed Sattar, Professor of Metabolic Medicine, University of Glasgow, Scotland
Robert Sheriff, Consultant in Public Health Medicine UK National Screening Committee
Nicola Strother-Smith, Director NHS Diabetes & Kidney Care, NHS Health Checks
Annette Thomas, Welsh External Quality Assurance Scheme, Wales
Chris Walton, Chair, Association British Clinical Diabetologists
Nick Wareham WHO committee on HbA_{1c}, Chair Prevention prediabetes to diabetes NICE,
Director MRC Epidemiology Unit)
Heather White Deputy branch head, vascular programme, NHS Health Checks, DH
Peter Winocour, past Chair, Association British Clinical Diabetologists