

# Primary care diagnostic technology update:

## point-of-care testing for glycosylated haemoglobin

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### Clinical Question

In the monitoring of patients with type 1 and type 2 diabetes, what advantages does point-of-care HbA<sub>1c</sub> testing provide over current practice?

### ADVANTAGES OVER EXISTING TECHNOLOGY

In patients with existing diabetes HbA<sub>1c</sub> monitoring is usually performed every 3–6 months. It typically involves a nurse visit or phlebotomist for venepuncture, with follow-up 1–2 weeks later to discuss results. Point-of-care testing (POCT) could provide more immediate therapeutic decisions and fewer patient visits. This might result in improved diabetic control and practice efficiency.

### DETAILS OF TECHNOLOGY

Blood glucose binds to haemoglobin, forming glycated haemoglobin (HbA<sub>1c</sub>). On the basis that the half life of a red blood cell is approximately 120 days, the circulating HbA<sub>1c</sub> level reflects the blood glucose control over the preceding 3-month period. Typically, the point of care HbA<sub>1c</sub> device uses a finger-stick drop of blood applied to a reagent cartridge, which is then inserted in a desktop analyser, where the analysis is performed, and HbA<sub>1c</sub> reported (as percentage and mmol/mol). The time-to-result is between 5 and 10 minutes. In some of the systems it is also possible to measure the urine albumin creatinine ratio using a different reagent cassette.

### PATIENT GROUP AND USE

- Patients with type 1 or type 2 diabetes mellitus to monitor glycaemic control.

### IMPORTANCE

Diabetes UK reports that currently 2.6 million people are diagnosed with diabetes in the UK (5.1% prevalence), which is on the increase in all age groups. For instance, a 70% increase in type 2 diabetes incidence is predicted in children aged <15 years by 2020.<sup>1</sup>

The National Services Framework for Diabetes highlights the importance of managing diabetes in primary care. In the National Diabetes Audit for 2008–2009, 88% of records from people with type 1

diabetes and 94% with type 2 included an HbA<sub>1c</sub> measurement.

NICE guidance states, providing there is no disabling hypoglycaemia, the target HbA<sub>1c</sub> concentration for children, young people, and adults with type 1 diabetes is 7.5% HbA<sub>1c</sub> and if the HbA<sub>1c</sub> is consistently >9.5% additional support should be offered.

### PREVIOUS RESEARCH

#### Accuracy compared to existing technology

A recent study comparing eight HbA<sub>1c</sub> measurement devices using three Clinical Laboratory Standards Institute Protocols to investigate imprecision, accuracy, and bias reported that only the DCA Vantage™ (Siemens) and Afinion™ (Axis-Shield) met the acceptance criteria (coefficient of variation <3%) in the clinically relevant range.<sup>2</sup>

#### Impact compared to existing technology

A trial which randomised patients with type 1 and 2 diabetes attending an academic diabetes centre to immediate feedback of HbA<sub>1c</sub> results compared to standard care, found significant improvement in glycaemic control at 6 and 12 months.<sup>3</sup> POCT was positively received by both patients and physicians. A prospective controlled trial comparing POCT and standard laboratory testing in an urban primary care

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clinic showed POCT availability resulted in more frequent intensification of therapy when baseline HbA<sub>1c</sub> was  $\geq 7.0\%$  (51% versus 32% of patients,  $P = 0.01$ ). In the subsequent two follow-up visits, HbA<sub>1c</sub> fell significantly in the POCT group (from 8.4 to 8.1%,  $P = 0.04$ ) but not in the standard care group (from 8.1 to 8.0%,  $P = 0.31$ ).<sup>4</sup> A primary care study among patients receiving active insulin titration (weekly monitoring) showed POCT resulted in a greater proportion achieving HbA<sub>1c</sub>  $< 7.0\%$  compared to those with laboratory measurement.<sup>5</sup>

In contrast, a second randomised controlled trial conducted in general practice in Leicestershire, UK, showed no significant change in the proportion of patients with HbA<sub>1c</sub>  $< 7.0\%$  when using POCT at 12-months' follow-up.<sup>6</sup> However the investigators noted it was 'difficult to organise their management of patients in such a way as to maximise the benefit from rapid testing for intervention group patients', implying the results were not discussed with the patient at the time of the clinic visit. The study also indicated that POCT was highly acceptable to patients and staff and confirmed there may be benefits such as time saving, reduced anxiety, and impact on patient management and job satisfaction.<sup>7</sup> However, the study also identified high pre-existing levels of satisfaction with diabetes care and the survey failed to confirm increased patient satisfaction as a result of rapid testing.

A large randomised controlled trial undertaken in Australia<sup>8</sup> found that POCT was non-inferior to pathology laboratory testing in relation to the proportion of patients showing an improvement in their test results from baseline: HbA<sub>1c</sub> (57.3% [POCT] versus 44.9% [laboratory]; difference, 12.4% [90% confidence interval = 6.5% to 18.4%],  $P < 0.001$ ).

#### Cost-effectiveness and economic impact

A study comparing laboratory and nurse near-patient testing for several diagnostic tests, including HbA<sub>1c</sub>, found that POCT led to improvements in the care process, significantly greater patient satisfaction, and lower mean levels of HbA<sub>1c</sub>, but higher visit costs reflecting the greater number of tests and higher equipment costs.<sup>9</sup> A pragmatic, randomised controlled trial where patients were randomised to receive instant results for HbA<sub>1c</sub> or routine care found a non-statistical total cost difference of diabetes related care; £390 in the control group and £370 in the POCT group.<sup>6</sup> However this study had not managed to change the way in which patients were managed and so presumably had not managed to influence the number of clinic visits.

A Swedish before-and-after study compared the economic costs and benefits of implementing HbA<sub>1c</sub> home testing.<sup>10</sup> They found a reduction in costs due to fewer clinic visits, reduction in total treatment costs, time saved and reduced labour costs in administration

and sampling, reduced travel costs, and a reduction in mean HbA<sub>1c</sub> levels.

#### Health Technology Assessments (HTAs)

One relevant HTA report was identified from the UK. A study in diabetes clinics indicated providing near-patient testing of HbA<sub>1c</sub> results seemed to improve the process of care and aspects of patient satisfaction. The report recommended a prospective randomised controlled trial of near-patient testing in diabetes clinics.<sup>11</sup>

#### What this technology adds

The point-of-care HbA<sub>1c</sub> test could improve management of the increasing numbers of patients with established diabetes being managed in primary care.

#### Relevant guidelines

NICE clinical guidance: *Diagnosis and management of type 1 diabetes in children, young people and adults*. <http://guidance.nice.org.uk/CG15>.

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