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 HbA1c testing provide over current practice?

Advantages over existing technology
In patients with existing diabetes, HbA1c 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 (HbA1c). On the basis that the half life of a red blood cell is approximately 120 days, the circulating HbA1c level reflects the blood glucose control over the preceding 3-month period. Typically, the point of care HbA1c 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 HbA1c 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 to 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 2020.1 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 HbA1c measurement.

NICE guidance states, providing there is no disabling hypoglycaemia, the target HbA1c concentration for children, young people, and adults with type 1 diabetes is 7.5% HbA1c and if the HbA1c is consistently >9.5% additional support should be offered.

Previous research
Accuracy compared to existing technology
A recent study comparing eight HbA1c 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.2

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 HbA1c results compared to standard care, found significant improvement in glycaemic control at 6 and 12 months.3 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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A Swedish before-and-after study compared the economic costs and benefits of implementing HbA\textsubscript{1c} home testing.\textsuperscript{10} 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\textsubscript{1c} 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 HbA1c 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.\textsuperscript{11}

What this technology adds

The point-of-care HbA\textsubscript{1c} test could improve management of the increasing numbers of patients with established diabetes being managed in primary care.

Relevant guidelines


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