

HbA_{1c}: An important and evolving indicator

For primary care teams helping people with diabetes to enhance their care, HbA_{1c} has become central to regular monitoring of the condition. Soon our approach to HbA_{1c} will change. Healthcare professionals will need to become comfortable with the new units of measurement of HbA_{1c} levels, as dual reporting of levels is phased out in June 2011. The round of changes to the QOF for 2011/12 has introduced a subtle change to the lower HbA_{1c} indicator. There is also an emerging consensus that HbA_{1c} has an important role in the diagnosis of diabetes. The importance of getting both diagnosis and classification correct has been highlighted by a recent report, confirming that we get this wrong more often than we realise, and should be addressing these anomalies at practice level (Royal College of General Practitioners [RCGP] and NHS Diabetes, 2011).

Changes to HbA_{1c} reporting

While HbA_{1c} was first discovered in the 1960s, it only emerged as an important part of routine diabetes care after publication of the two landmark trials: the UKPDS (UK Prospective Diabetes Study; UKPDS Group, 1998) and the DCCT (Diabetes Control and Complications Trial; DCCT Research Group, 1993). Both of these trials used HbA_{1c} measurement as outcome markers. Following publication of the results, clinical chemists began to accept this measurement, and standardise it between laboratories. The importance of HbA_{1c} was reinforced when the 2004 General Medical Services contract, with its QOF, made HbA_{1c} an important indicator for diabetes.

The bottom level of this indicator has fluctuated from $\leq 7.5\%$ (≤ 58 mmol/mol) to $\leq 7.0\%$ (≤ 53 mmol/mol) and will now return to $\leq 7.5\%$ (≤ 58 mmol/mol). While the General Practitioners Committee may welcome this easing of the achievement indicator, the changes may also have been in response to lobbying following the publication of the ACCORD (Action to Control Cardiovascular Risk in Diabetes) study data suggesting a hazard in pursuing too low an HbA_{1c} level especially in

older people (ACCORD Study Group et al, 2008). This was reinforced recently by follow-up data from this study suggesting that this hazard persisted in the active treatment group even after they switched to less intensive treatment (ACCORD Study Group et al, 2011). Other changes to the QOF for 2011/12 include changes to foot examination and tightened blood pressure indicators (NHS Employers, 2011).

The International Federation of Clinical Chemistry (IFCC) has changed the units used to report HbA_{1c} level and replaced the familiar percentage units with an IFCC-standardised mmol/mol measurement (Weykamp et al, 2008). Dual reporting of these figures was proposed for 2 years ending in June 2011. We know, however, that knowledge and understanding of HbA_{1c} is poor among people with diabetes, especially those with type 2 diabetes. It is therefore important that people with diabetes understand the concept of monitoring over a 3-month period, as grasping this concept, and accepting ownership, is associated with improvement in glycaemic control (Iqbal et al, 2008).

Misdiagnosis, misclassification, and miscoding

An important report has recently been published: *Getting it Right: Improving the Classification, Diagnosis and Coding of Diabetes* (RCGP and NHS Diabetes, 2011).

The report is significant: it begins by examining the results of a systematic review of the evidence on misdiagnosis, misclassification and miscoding produced by interrogating two primary care databases of nearly one million patients, to establish how common these faults are. The document goes on to introduce guidelines to improve diagnosis and classification, as well as providing audit tools to improve diagnosis, classification and coding in clinical practice and outlines the results of a pilot using them.

The report clarifies some definitions. Misdiagnosis occurs when someone is diagnosed with any form of diabetes when they do not have it. Misclassification is when the wrong type of



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diabetes is chosen, for example type 2 when the individual has latent autoimmune diabetes of adulthood. Miscoding is when the wrong computer Read code is used, meaning that it is not possible to determine the type of diabetes precisely.

HbA_{1c} use in diagnosis

What then is the future for using IFCC-standardised HbA_{1c} levels for the diagnosis of diabetes? The joint 2009 guidelines from the American Diabetes Association (International Expert Committee, 2009) and the recent World Health Organization (WHO, 2011) guidelines propose the measurement of HbA_{1c} as a diagnostic criterion for diabetes, suggesting a cut-off point of $\geq 6.5\%$ (≥ 48 mmol/mol) for diagnosis.

In response to these recommendations, a UK working group of representative healthcare professionals from the four nations in the NHS have been meeting to examine the consequences of this new WHO directive on diagnosis. They anticipate publishing clear guidance shortly, as although an HbA_{1c} of $\geq 6.5\%$ (≥ 48 mmol/mol) is attractive as a diagnostic threshold, there are important caveats about its use in certain circumstances, such as in people with haemoglobinopathies. The working group will also examine the use of fasting blood glucose results and how they can improve the sensitivity of the diagnosis when combined with HbA_{1c}.

Conclusion

Emerging events would appear to be altering current diagnostic practice considerably. Primary care teams will want to appraise the use of the audit tools for misdiagnosis, and use them with their clinical systems. With the WHO suggesting HbA_{1c} for diagnosis, this will mean important changes to practice guidelines. Many will wait for the UK consensus document, not just due to inertia, but also considering the medico-legal consequences of getting the diagnosis correct. The raising of the threshold payment for QOF payments from ≤ 7 to $\leq 7.5\%$ (≤ 53 to ≤ 58 mmol/mol) may help to achieve next year's indicators. Ultimately healthcare professionals will have to embrace these changes, as well as guiding people with diabetes through the consequences. ■

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