Position Statement

Subject: Use of ‘Point of Care’ Testing for the Measurement of Haemoglobin A1c (HbA1c)

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Introduction
Several point-of-care (POCT) instruments are capable of generating HbA1c results from whole blood samples. This Position Statement is intended to provide guidance for appropriate use of these devices for the management of diabetes. At this stage, POCT testing for HbA1c does not appear to be sufficiently robust for diagnostic purposes. The report highlights potentially vulnerable areas such as the need for whole blood Quality Assurance material. Use of the appropriate external quality assurance (EQA) programs are essential.

Background
The earliest reports indicate that the performance of different devices for the POCT measurement of HbA1C varied considerably1-4. Haemoglobin variants were identified as a source of error from an early stage5. Randomised controlled studies did not reveal any outcome or cost benefit associated with POCT measurement of HbA1C in a primary care setting6, nor was it associated with increased patient or health professional satisfaction7. Nevertheless, the potential for improved management in specific settings, including rural and remote Australia, was recognised8. POCT was found to be non-inferior to pathology laboratory testing for measuring glycated haemoglobin (HbA1c), in an Australian primary care trial of its impact on therapeutic control9.

By 2009, evidence suggested that analytical performance was subject not only to the type of device, but also to the between batch variability in consumables10. Accordingly, participation in external quality assurance programs was recommended10. The technology was adapted to enable HbA1C kits to be sold over the counter for direct to consumer usage11. New devices were developed, but only a minority (25%) met analytical requirements12. Device-specific reference ranges were recommended, but this was in the era before standardization of HbA1C13. Additional outcomes trials permitted meta-analysis, but this continued to fail to demonstrate clinical benefit14.

Appropriate Use
It was recognised that longitudinal monitoring of patients was less of a problem than the determination of HbA1C in relation to diagnostic thresholds15. Participation in external quality assurance programs was associated with progressive improvement. Reports of validation of individual devices have become the predominant form of publication, but the importance of widespread problems with bias is widely reported. This has led to calls for periodic re-calibration16. Some studies have claimed that POCT devices in primary care can perform well enough to enable their use for diagnostic purposes, but the potential impact on population-wide diabetes prevalence may not have been considered17. Improved outcomes in Australian rural and remote settings, particularly aboriginal health services, persist as one of the most favourable applications of POCT HbA1C18.
Quality of results

Initiatives including the International Federation of Clinical Chemistry (IFCC) traceability suggest that POCT devices tended to be less precise, but differences in precision can be partially ameliorated by calibration procedures. It remains to be determined whether or not re-calibration can compensate for between-batch variability in reagents. The impact of imprecision on disease prevalence demands careful scrutiny of inaccuracy, no matter how trivial. Surveillance of both the instruments and their reagents via external quality assurance programs will remain an essential feature. At present, whole blood quality assurance materials are mandatory. It would be helpful if more stable EQA reagents could be developed to allow longitudinal monitoring.

Evaluation

Local evaluation by NSW Health Pathology has concluded that 2 of 6 devices were fit for purpose (a second device was re-evaluated following the presentation of new data). This occurs against a background in which several devices fluctuate between satisfactory and unsatisfactory. A small minority appear to meet requirements on a predictable basis.

Useful links:
https://www.rcpa.edu.au/getattachment/be70bab5-49f5-4e23-a671-5495c2f14b4a/Point-of-Care-Testing.aspx

References