



Considerations regarding point-of-care testing

To the Editor: I read with interest the article by Abbai *et al.*^[1] regarding the evaluation of a point-of-care (POC) HbA1c analyser, which appeared in a recent issue of SAMJ. In the context of the current medical landscape in southern Africa, there is clearly a place for POC devices, but there are certain important caveats to their use – in particular with HbA1c – that end-users should be aware of and that were not touched on in the article. Firstly, importance of sample type: the Afinion AS100 analyser (Alere, South Africa (SA)) and most other POC devices would utilise finger-prick patient samples (capillary blood) for analysis in most clinical contexts. In the abovementioned article, the authors have not evaluated the diagnostic accuracy of the use of finger-prick samples compared with formal blood collection. Some studies have reported significant differences in composition of capillary v. venous blood. With regard to HbA1c, Schalk *et al.*^[2] found capillary values of Hb to be significantly higher than the corresponding venous values. Incorrect capillary blood sampling can cause significantly inaccurate results. Secondly, importance of location: most POC devices are placed in non-laboratory environments that are not temperature controlled and that do not have sufficient access to refrigeration. Many of the currently available POC devices and reagents have been designed to operate in more temperate climates. Extremes of environment, particularly the high temperatures experienced in SA, may affect the functioning of devices and stability of reagents. In the article by Gounden and George^[3] that evaluated various POC devices in the SA context, a scoring system was developed to evaluate the devices in terms of features, such as ability to be used in extremes of temperature, as well as other important considerations, such as information technology connectivity (to enable transmission of results to electronic medical record/laboratory information systems), water requirements and costs. These need to be considered when choosing a POC device. Thirdly, importance of interferences: Afinion HbA1c results are reported to be affected by the presence of fetal Hb (HbF).^[4] Elevated HbF levels may be found in neonates, hereditary persistence of

HbF, thalassaemias and late pregnancy. Fourthly, precision studies: precision performance forms the cornerstone for the assessment of clinical utility of a test or an instrument. Abbai *et al.*^[1] have not presented data with regard to imprecision performance of the POC analyser for the tests evaluated. Shephard *et al.*^[5] have proposed desirable imprecision goals for POC devices for HbA1c (coefficient of variation 3%) and lipid parameters. The American Diabetes Association also provide recommendations for HbA1c precision. Abbai *et al.*^[1] only evaluated performance of Afinion HbA1c with regard to correct categorisation of patients at one medical decision point (HbA1c 6.5%). As one of the primary roles of POC testing (POCT) is the monitoring of diabetic patients receiving treatment in order to allow for a more prompt change in management, evaluation at other important medical decision limits, e.g. HbA1c 7%, would have been clinically relevant. It must be emphasised that POCT also requires implementation of a complete quality management system that includes analysis of internal and external quality assurance samples.

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