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Analysis of the Accuracy and Precision of the Axis-Shield Afinion Hemoglobin A1c Measurement Device

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Abstract

Point-of-care (POC) hemoglobin A1c measurement is now used by many physicians to make more timely decisions on therapy changes. A few studies have highlighted the drawbacks of some POC methods, e.g., poor precision and lot-to-lot variability. Evaluating performance in the clinical setting is difficult because there is minimal proficiency testing data on POC methods. In this issue of *Journal of Diabetes Science and Technology,* Wood and colleagues describe their experience with the Afinion method in a pediatric clinic network, comparing these results to another POC method as well as to a laboratory high-performance liquid chromatography method. Although they conclude that the Afinion exhibits adequate performance, they do not evaluate lot-to-lot variability. As with laboratory methods, potential assay interferences must also be considered.

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There are data in the literature, showing that use of point-of-care (POC) hemoglobin A1c (HbA1c) measurement is associated with improvements in glycemic control.[1–3] These studies prompted the American Diabetes Association to begin recommending the use of POC HbA1c testing to allow "for timely decisions on therapy changes when needed."[4] However, systematic reviews (cited in the American Diabetes Association (ADA) 2012 recommendations) have found no significant differences in patient HbA1c levels for POC versus laboratory HbA1c. Regardless of the impact of POC HbA1c testing on glycemic control and patient outcomes, most clinicians seem to agree that it is more convenient for physicians and that patients seem to like having results at the time of the visit.

There have also been a few studies highlighting some of the problems with some POC methods,[5,6] while some demonstrate performance comparable to that of many laboratory methods, others have poor precision and/or quite a bit of lot-to-lot variability. Perhaps the main reason that the ADA chose not to recommend POC methods for use in diabetes diagnosis is the very limited availability of proficiency testing (PT) data for POC methods. Proficiency testing is required for laboratory testing, but most POC methods are waived by the Clinical Laboratory Improvement Amendments, meaning that PT is not required. Thus, the PT data that is so critical to evaluation of a method's performance in the actual patient care environment is minimal or absent for most POC methods. For example, a College of American Pathologists

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Abbreviations: (ADA) American Diabetes Association, (CAP) College of American Pathologists, (HbA1c) hemoglobin A1c, (HPLC) High-performance liquid chromatography, (NGSP) National Glycohemoglobin Standardization Program, (POC) point-of-care, (PT) proficiency testing

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(CAP) survey for HbA1c included over 200 Siemens DCA (DCA 2000 and DCA Vantage) users but only ~50 users of three other listed POC methods combined; thus the DCA is the only POC method with any significant amount of supporting PT data. In addition, users of POC devices that do actually participate in the CAP survey may not be representative of most users of these devices. Participating sites are more likely to be associated with a CAP-accredited laboratory and have more experienced testing personnel.

In this issue of *Journal of Diabetes Science and Technology*, Wood and colleagues[7] evaluate the accuracy and precision of the Axis-Shield Afinion POC device for HbA1c measurement in a pediatric care setting by comparing results obtained in a pediatric clinic to laboratory-run high-performance liquid chromatography (HPLC) results (Tosoh G7 HPLC). They also compared these results to results from another POC device (Siemens DCA) currently in use in these clinics; both of these POC methods are National Glycohemoglobin Standardization Program (NGSP) certified. However, NGSP certification involves method data collection under optimal circumstances (manufacturer site) using only one lot of reagents. Although Wood and colleagues'[7] evaluation of precision is quite limited (testing only over a 3-day period) and we don't know the level of experience of their testing personnel, their study was done in a clinical setting using multiple clinic sites. However, as the authors point out, the DCA analyses were performed using different lots of reagents while the Afinion results were obtained from 1 lot provided by the manufacturer even though at least 10 lots are available in the field at any one time for most methods. This may explain slightly higher DCA CVs across sites compared to those for the Afinion. Between-lab CVs for the Afinion are generally comparable to that of the DCA in CAP surveys. Interestingly, CAP data also generally show slightly higher mean values for Afinion users compared to DCA users as was found in the current study[7], although the differences were very small and both were close to the NGSP assigned value.

Point-of-care users, in general, should be aware of potential lot-to-lot variability and recognize that, because most POC users do not participate in proficiency testing, there is minimal performance data available for most POC methods. It is primarily for this reason that the ADA chose to exclude POC methods from their recommendation to use HbA1c for diabetes diagnosis. Given that a change of 0.5% HbA1c is generally considered to be a clinically significant change in a patient's glycemic status, lot-to-lot differences can potentially impact patient monitoring as well.

As with laboratory methods, potential assay interferences must also be considered. The Afinion (and for that matter the DCA) have been shown to be unaffected by the most common hemoglobin variants (HbS, HbC, HbE and HbD heterozygotes). However, HbF greater than ~10–15% can interfere with results from both method types (boronate affinity and immunoassay) whether POC or laboratory instruments are used[8] and any physiological condition which causes altered red-cell lifespan will affect HbA1c results regardless of assay methodology. Inexperienced users may not be aware of these potential interferences, which can have a negative impact on clinical treatment because of resultant under or over-estimation of glycemic control.

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