

Enhancing Hemoglobin A1c Analysis for Bowdoin Street Health Center

The Problem

Individuals with diabetes have an increased risk of developing retinopathy and neuropathy, as well as increased long-term risks of cardiovascular and kidney disease. The Hemoglobin A1c (HbA1c) laboratory test assesses long-term glycemic control over a period of 2 to 3 months by measuring the degree of hemoglobin glycation and also allows for the calculation of the estimated average glucose (eAG) concentration. The American Diabetes Association recommends that clinicians test diabetic patients for HbA1c at least every 6 months in an effort to improve glycemic control outcomes. Monitoring levels twice annually is also required to meet compliance guidelines for pay-for-performance payment models.

Aim/Goal

Scheduled visits with the healthcare provider to outline and assess individualized treatment plans are thought to improve patient outcomes. In addition, access to an instrument that utilizes a finger stick sample in the clinical setting would allow the provider to obtain HbA1c in real-time and less invasively. Immediate results also impact workflow in reducing the need for follow-up calls and return patient visits. Both patients and clinicians are reluctant to have blood collected by venipuncture; preferring instead finger stick samples. The ability to perform the HbA1c test in the clinical setting, at the point of care (POC) with a finger stick sample is thought to improve management of diabetic patients by allowing real time interventions while the patients are meeting with the provider.

The Team

Bowdoin Street Health Center

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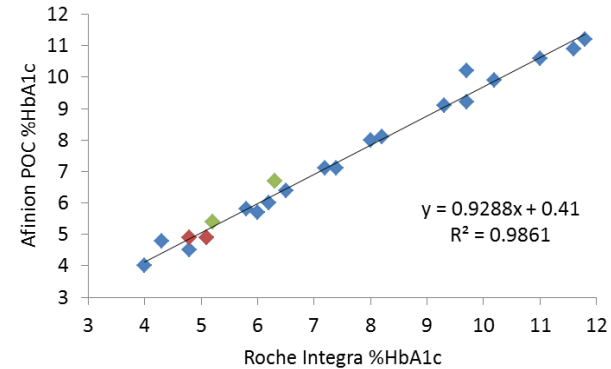
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The Interventions

- A review of CLIA Waived HbA1c analyzers was conducted by Laboratory Medicine because several methods are known to have interferences from hemoglobin variants. Given the diverse patient population, it is important to be able to obtain a result without interference from these variants.
- The Alere Afinion™ AS100 Hemoglobin A1c POC analyzer method is certified by the National Glycohemoglobin Standardization Program (NGSP) and is standardized to the Diabetes Control and Complications Trial (DCCT) assay.
- The method is reported to have no interference from the following hemoglobin variants: HbC, HbD, HbE, HbF, HbJ, and HbS.
- This method allows finger stick samples (sample size 1.5 µl of whole blood) to be used in place of venipuncture and gives HbA1c results within 3 minutes.

The Results/Progress to Date

- Laboratory Medicine validated the Afinion™ analyzer against the Roche Integra immunoassay method (Clinical Chemistry Laboratory) in August 2013. The manufacturer's reportable range was validated from 4.0 – 15.0% HbA1c.
- Samples with known HbS (red) and HbC (green) variants were included in the validation and showed acceptable correlation without any interference.
- Bowdoin Street Health Center staff members were trained to operate the analyzer and documented competency by comparing finger stick samples to venipuncture samples in October 2013.



- Bowdoin Street Health Center has replaced venipuncture for HbA1c with finger stick samples. In the month of January, 90 samples were tested – averaging 4 samples per day.
- Increased efficiency for clinicians and office staff by improving the test turn-around-time. Samples are no longer sent to the main lab where results are available the next day; eliminating the need for call-backs and follow-up visits.
- Overall, replacing off-site laboratory HbA1c measurement with POC has increased clinician and patient satisfaction.

Lessons Learned

Initiatives that change existing care practices can significantly improve patient care and outcomes, but require carefully planned multi-disciplinary and multi-departmental collaboration.

Next Steps/What Should Happen Next

- Implementation of a second Afinion™ analyzer at Bowdoin Street and assist MCCN Chelsea with the validation of the Afinion™ analyzer for their clinic.
- POCT may allow for better compliance with pay-for-performance guidelines. Evaluation of the number of HbA1c measurements for each patient will capture the potential improvement.
- Real time HbA1c results have been reported to improve the clinician/patient interaction by allowing clinicians to counsel their patients face-to-face. This may result in better patient understanding, compliance, and improved outcomes. Long-term, review of HbA1c patient-specific means will determine efficacy of POCT to reduce HbA1c and improve glycemic control.