

HbA1c Point-of-Care Devices Improve Diabetes Management

By: Lana Bandoim

Diabetes mellitus affects 30.3 million Americans, about 9.4% of the total population in the United States.^{1,2} It is a chronic disease that impairs the body's ability to make or use insulin, which leads to higher than normal blood glucose levels.³ Having diabetes increases the risk of multiple complications such as stroke, heart disease, kidney disease, eye problems, nerve damage, lower-extremity amputations, ketoacidosis, and other health problems.⁴ Diabetes remains the seventh leading cause of death in the United States.¹

One of the key challenges for people with diabetes is managing the disease. In order to control the condition, it is crucial to have accurate long-term measurements of blood glucose levels. The Diabetes Control and Complications Trial (DCCT) showed that intensive therapy focused on controlling blood glucose levels could delay or prevent complications.⁵ The DCCT revealed that testing for the amount of hemoglobin A1c (HbA1c), also known as A1c, glycated hemoglobin, and glycosylated hemoglobin, was a powerful management tool to assess long term glucose control.⁵

HbA1c is a modified form of hemoglobin, a protein in red blood cells that carries oxygen in the body. When hemoglobin binds glucose at a specific location, it becomes HbA1c. By measuring the percentage of hemoglobin that has become HbA1c, a good estimate of the average blood glucose levels over a period of two to three months is available.⁶ For most patients, it provides a more reliable and convenient way to measure glycemic control than other methods such as fasting plasma glucose (FPG) and oral glucose tolerance tests (OGTT).⁷

Compared to the FPG and OGTT processes, which require fasting for hours and spending a considerable amount of time in a lab, HbA1c testing is easier for patients to handle.⁷ FPG and OGTT tests can be difficult to perform and can be time consuming.

Clinical studies have shown that HbA1c can predict the risk of patients developing microvascular complications such as diabetic neuropathy, retinopathy, and nephropathy.^{5,8} In addition, lowering HbA1c concentrations to less than 7% can reduce the risk of developing these types of complications or slow their progression.⁹ Moreover, the HbA1c test can be used for both type 1 and type 2 diabetes.^{5,8}

Historically, HbA1c has been a laboratory assay used for monitoring glycemic control in patients who have diabetes. However, for the past several years, the test has also been used as a screening test for diagnosing diabetes. Both the Endocrine Society and the American Diabetes Association (ADA) recommend the use of the HbA1c lab test within these parameters.⁷

The popularity and usage of the HbA1c laboratory assay has increased over time. In 2010, the central lab at Cleveland Clinic ran 200 HbA1c tests per day. Today, the number has increased to about 800 HbA1c tests per day.

Point-of-Care Devices

The ADA recommends that patients who have poorly controlled diabetes get the HbA1c test four times a year while patients with well-controlled diabetes get the test twice a year.¹² Nevertheless, despite the advantages of the HbA1c test, compliance continues to be an issue; only 7% of patients are following the guidelines to be tested.¹¹

Historically, patients had to go to the laboratory to get their HbA1c tested before seeing their primary care physicians or endocrinologists for a diabetes management appointment. Based on the results of the test, their diabetes medications would be adjusted, if necessary. However, many patients did not comply with this recommendation and would skip the test. They would get the HbA1c assay only after their appointment, which created workflow challenges for primary care physicians and endocrinologists. Often, patients would require follow-ups or additional appointments to discuss the results of their HbA1c and to modify their medication regimens.

To overcome the guideline adherence problems, HbA1c point-of-care (POC) devices are available in physician offices to manage patients who already have diabetes and are not compliant with pre-visiting testing orders.¹⁰ POC devices are available from several vendors and can measure HbA1c levels directly in the office instead of a laboratory.¹³ The devices simplify the care process by eliminating the need for patients to go to the lab for testing. However, it is important to note that the POC devices are neither appropriate nor approved for diagnosing new patients; they can only be used for patients who currently have type 1 or type 2 diabetes.

The National Glycohemoglobin Standardization Program (NGSP) has set specific performance criteria for HbA1c testing devices and has requirements for their certification. It maintains that certified devices are standardized to the Diabetes Control and Complications Trial Reference Method.¹⁴ For ongoing accuracy, manufacturers must recertify annually.¹⁴

The POC devices are not intended to replace laboratory-based testing for HbA1c. Instead, they create a way to help doctors manage non-compliant patients.

Implementation of POC Devices

Since 2017, the Cleveland Clinic has implemented 100 HbA1c point-of-care devices in Ohio and Florida. Both internal medicine and endocrinology offices have received the POC devices and continue to monitor their success.

“We were approached by our internal medicine physicians who were aware of the HbA1c point-of-care devices and wanted to use them to improve patient care,” says Edmunds Reineks, MD, PhD, medical director of the Center for Point of Care Testing at Cleveland Clinic.

The Center for Point of Care Testing worked with the supply chain and other colleagues at Cleveland Clinic to execute a formal competitive bidding process to select an appropriate POC device for HbA1c testing. A formal request for proposal (RFP) went out to vendors, and devices were evaluated during demonstrations. The Cleveland Clinic selected the Alere Afinion™ HbA1c assay, which is owned by Abbott, and initiated a 3-year contract with them through 2020.

Improving ACO Metrics

The U.S. Centers for Medicare & Medicaid Services (CMS) has established Accountable Care Organization (ACO) metrics that assess the quality of care patients receive in an effort to reward higher quality.¹⁵ These measures include the evaluation of preventive health measures, patient and caregiver experiences, care coordination and patient safety, and measures for at-risk populations.

“As an organization, we were interested in using the POC devices to improve our ACO metrics that track the quality of the care that is provided to patients,” says Dr. Reineks.

In particular, the Cleveland Clinic was interested in two ACO metrics related to HbA1c: ACO #22 and ACO #27.¹⁶ For ACO #22, the quality measure is HbA1c control indicated by patients who have HbA1c levels below 8%. This signifies that their diabetes is reasonably well-controlled.¹⁶ For ACO #27, the quality measure is the percent of patients with diabetes whose HbA1c is poorly controlled, with HbA1c levels above 9%.¹⁶ The goal is to have more patients who qualify for ACO #22 and fewer patients counted in ACO #27, so the Cleveland Clinic has been tracking both metrics.

Since the implementation of the HbA1c point-of-care devices at Cleveland Clinic, an improvement has been seen in both the ACO #22 and ACO #27 metrics. There was a 3.9% increase in ACO #22 and a 3.8% decrease in ACO #27. In addition, a chart edit revealed that in offices where the POC devices were implemented, follow-up testing in diabetes patients improved by 67% compared with patients seen in offices without a POC A1c device.

POC Device Advantages

Using point-of-care devices to measure HbA1c allows physicians to capture glycemic control data from non-compliant patients who do not get laboratory testing. The POC devices can also help capture data from patients who have received medication adjustments and have not done the proper follow-up testing.

It is easier and faster to assess HbA1c in a physician’s office. The test requires a simple finger stick to collect a sample of blood from the patient. Accurate results are available directly in the office in 3 minutes and are comparable in quality to results from the laboratory test.

The HbA1c POC devices improve patient management by allowing physicians to act immediately on the results and adjust diabetes medications. This type of instant therapeutic intervention is an essential component of providing higher quality care.

“The patient response to the HbA1c POC devices has been positive, especially among pediatric patients and their parents. It is hard to do a full venous blood draw on pediatric patients, so the devices are preferred. Pediatric endocrinology offices were clamoring to get the devices,” says Dr. Reineks.

Another advantage of using the POC devices is their ability to transmit data electronically to a patient's chart. The Cleveland Clinic has connected the POC devices throughout its network, so the results of the HbA1c tests are immediately included in patient charts. This data can be pooled and evaluated to examine the success of the devices, to see where testing is being done, and to check for changes in test volumes.

POC Device Risks and Disadvantages

One disadvantage is that currently the HbA1c POC test is expensive and costs six to seven times more to perform than a laboratory assay. However, as technology develops, the cost of the devices and testing may decrease over time.

Another disadvantage is the possible misuse of the HbA1c POC test by physicians who want to diagnose diabetes. The point-of-care devices are not meant to screen for diabetes in patients.

The limitations of the POC devices are similar to the laboratory assay for HbA1c. Since the lifespan of red blood cells is approximately 120 days, it is recommended that A1c tests be performed no more than every 3 months.⁷ HbA1c levels change slowly even if treatments and diabetic medications are adjusted, so the tests cannot show immediate progress or problems.

Both the HbA1c POC devices and laboratory assays are not appropriate for patients with anemia or other medical conditions that affect the normal lifespan of red blood cells. Since they both rely on measuring hemoglobin A, the tests cannot provide accurate data for glycemic control in patients who lack this type of hemoglobin or who have rare hemoglobin variants such as those seen in sickle cell disease.

In addition, HbA1c testing may not work for patients with hemolysis or heavy bleeding. Age, pregnancy, and ethnicity may also affect the accuracy of results.¹⁰

Looking Ahead

Although there are no plans to install additional HbA1c POC devices at this time, the success of the currently deployed devices will continue to be monitored. The response from both patients and physicians has been positive, and the evidence to date shows devices are helping clinicians to better manage diabetes. If ACO metrics keep improving, it will show the benefit of using the devices. If ACO metrics level off or start to decrease, the care process will be further examined and other improvements may be sought.

References

1. American Diabetes Association. Statistics About Diabetes. Available at <http://www.diabetes.org/diabetes-basics/statistics/>. Updated March 22, 2018. Accessed May 3, 2018.

2. National Institute of Diabetes and Digestive and Kidney Diseases Health Information Center. Diabetes Statistics. Available at <https://www.niddk.nih.gov/health-information/health-statistics/diabetes-statistics>. Updated September 2017. Accessed May 3, 2018.
3. National Institute of Diabetes and Digestive and Kidney Diseases Health Information Center. What is Diabetes? Available at <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes>. Updated November 2016. Accessed May 3, 2018.
4. Deshpande AD, Harris-Hayes M, Schootman M. Epidemiology of Diabetes and Diabetes-Related Complications. *Physical Therapy*. 2008;88(11):1254-1264. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3870323/>. Accessed May 3, 2018.
5. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977-986. Available at <https://www.nejm.org/doi/10.1056/NEJM199309303291401>. Accessed May 3, 2018.
6. Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, Bruns DE, eds. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 4th ed. St. Louis, MO: Elsevier Saunders; 2006:837-902.
7. Sacks DB. A1C Versus Glucose Testing: A Comparison. *Diabetes Care*. 2011;34(2):518-523. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3024379/>. Accessed May 3, 2018.
8. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352:837-853. Available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(98\)07019-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(98)07019-6/fulltext). Accessed May 3, 2018.
9. Little RR, Rohlfing CL. HbA1c Standardization: Background, Progress and Current Issues. *Laboratory Medicine*. 2009;40(6):368–373. Available at <https://academic.oup.com/labmed/article/40/6/368/2504849#>. Accessed May 3, 2018.
10. American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care*. 2016;39(suppl 1):S1-S112. Available at http://care.diabetesjournals.org/content/suppl/2015/12/21/39.Supplement_1.DC2/2016-Standards-of-Care.pdf. Accessed May 3, 2018.
11. Lian J, Liang Y. Diabetes management in the real world and the impact of adherence to guideline recommendations. *Curr Med Res Opin*. 2014;30:2233-2240. Available at <https://www.tandfonline.com/doi/abs/10.1185/03007995.2014.952716?journalCode=icmo20>. Accessed May 3, 2018.
12. American Diabetes Association. Glycemic Targets. *Diabetes Care*. 2015; 38(1): S33-S40. Available at http://care.diabetesjournals.org/content/38/Supplement_1/S33. Accessed May 3, 2018.

13. Whitley HP, Yong EV, Rasinen C. Selecting an A1C Point-of-Care Instrument. *Diabetes Spectrum: A Publication of the American Diabetes Association*. 2015;28(3):201-208. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4536639/>. Accessed May 3, 2018.
14. NGSP. List of NGSP Certified Methods. Available at <http://www.ngsp.org/docs/methods.pdf>. Updated May 2018. Accessed May 3, 2018.
15. U.S. Centers for Medicare & Medicaid Services. Program Guidance & Specifications. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html>. Accessed May 4, 2018.
16. U.S. Centers for Medicare & Medicaid Services. Table: 33 ACO Quality Measures. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf>. Accessed May 4, 2018.