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ORIGINAL ARTICLES

An Analysis of the Assessment of Glycated Hemoglobin Using A1cNow+™ Point-of-Care Device Compared to Central Laboratory Testing—an Important Addition to Pharmacist-Managed Diabetes Programs?

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Abstract

The diabetes epidemic is accelerating rapidly. If no progress is made in early detection, then early intervention and treatment-to-goal diabetes care will become an overwhelming burden on our health care system. Better utilization of self-monitoring of blood glucose in patients with type 2 diabetes not on insulin could be achieved with regular review of hemoglobin A1c (A1C) values. Educating patients about the importance of diet, exercise, and medication compliance is enhanced when evidence of average blood glucose control can be presented to the patient directly. Affordable, accurate point-of-care testing of A1C with A1cNow+™ (Bayer HealthCare, Terrytown, NY) utilized in pharmacist-managed outpatient diabetes programs may prove to be an important clinical tool for improving patient outcomes and reducing the cost of the expanding diabetes epidemic.

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Introduction

The Centers for Disease Control and Prevention (CDC) Division of Diabetes Translation recently revised estimates of diagnosed diabetes for all United States (U.S.) counties to nearly 24 million people, almost 8% of the U.S. population, reflecting an increase of more than 3 million cases in approximately 2 years. In addition to the 24 million diagnosed cases, another 57 million individuals are estimated to have pre-diabetes.[1] Extrapolating, the CDC numbers imply that the U.S. could face a 16% incidence of diabetes if just one-half of those currently with pre-diabetes incur a diabetes diagnosis. Pharmacists are uniquely trained and conveniently positioned to provide point-of-care testing and education in outpatient diabetes management.

Timely and accurate point-of-care monitoring in pharmacist-managed diabetes programs results in improved blood glucose (BG) control and decreased overall cost of care when appropriate patient education and medication therapy management is provided in collaboration with physicians.[2] Achievable goals for self-monitoring of blood glucose (SMBG) can be better described when changes in average BG control are detected in the presence of the patient. Pharmacists such as Lindsey *et al.* applied this approach using fructosamine as a point-of-care test that provided a 1–2 week average of BG control and achieved notable—but statistically insignificant—improvement prior to its manufacturer withdrawing it from the market.[3] Others

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Abbreviations: (A1C) Hemoglobin A1c, (CDC) Centers for Disease Control, (SMBG) self-monitoring of blood glucose, (U.S.) United States

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have found that increased patient understanding of the relationship of hemoglobin A1c (A1C) values to self-management improves overall BG control.[4] Availability of an inexpensive, accurate point-of-care test for A1C such as the A1cNow+™ (Bayer HealthCare, Terrytown, NY) could detect trending of average BG values and allow both pharmacist and patient to review simultaneously the impact (if any) of previous medication therapy and lifestyle changes.

Accuracy evaluation of the A1cNow+™ was limited to the A1C range between 7% and 8.5%, representing the American Diabetes Association's 7% goal for treatment, and 8.5% representing poorly controlled diabetes.[5] Given the delay of up to seven days between venous lab reference draw and A1cNow+™ measurements, some variance was expected. The reported correlation coefficient of $r = 0.893$, where a value of 1 indicates an exact match, likely reflects an accurate test detecting changes occurring between comparison sample draw dates. Since the normal red blood cell life span is 90–120 days, the variance between normal subjects during a one-week delay should be small. The A1cNow+™ sensitivity, specificity, and positive and negative predictive values dropped significantly only when below 7% and above 8.5%, making this point-of-care test useful for evaluating patient progress in an outpatient setting. Prediction of laboratory A1C values with the formula provided may not be applicable in other clinic locations due to potential alternate-laboratory variance. Additional trials utilizing other laboratory locations are needed to validate the accuracy of the predictive laboratory calculation.

The cost of the test is stated as averaging $11.90, confirmed by this author as the average cost as of July 25, 2008. The time required by the clinician to perform the test must be included in the final cost to the patient. Minimal training is required for this CLIA (Clinical Laboratory Improvement Amendments)-waived test, and total testing time should be less than 10 minutes from capillary blood draw to report of test results. The required CLIA waiver for a clinic to provide A1cNow+™ testing by a qualified health care professional may be obtained at www.cms.hhs.gov/clia. Reimbursement at the current Medicare National Limitation Amount of $21.06 should cover the cost of A1cNow+™ including the time required to perform the test. Central lab charges for patients without insurance are significantly higher, but are accurate for values outside the defined range. Establishment of patient baseline A1C using A1cNow+™ may not be clinically desirable, but once a laboratory baseline A1C is determined to be between 7% and 8.5% the A1cNow+™ test is a cost-effective alternative for evaluating changes in average BG control. The affordability of the test gives patients without insurance access to better care and improved knowledge of disease status. Improved outcome usually decreases overall lifetime disease cost, but is often ignored when budgets are short. This is true in both self-pay and insured populations. As government programs and payers institute performance-based bonus programs that reward practitioners for improved patient outcomes, tests such as the A1cNow+™ could improve clinician reimbursement for services if better average BG control is gained in the provider's patient population.

The A1cNow+™ test presents an opportunity for physicians, pharmacists, and other health care professionals to provide more frequent follow up of A1C values while consulting directly with the patient. Combined with regular SMBG testing in patients with type 2 diabetes not on insulin, point-of-care A1C result review could improve outcomes significantly. Currently, the value of SMBG in patients with type 2 diabetes not on insulin is controversial. Lack of education on the timing of testing and the meaning of BG values, and lack of clearly established glucose goals are cited as the most likely reasons why SMBG does not improve outcome in these cases.[6] A recent meta-analysis indicated that there is a statistically significant but clinically modest effect in controlling BG levels with SMBG under these circumstances, but SMBG alone has questionable value in helping patients meet target goals.[7] Patient motivation can be difficult, but regular review of average BG results with point-of-care A1C may reinforce the feedback loop of dietary and exercise compliance together with proper timing of SMBG testing and medication doses.

Type 2 diabetes, which accounts for 90–95% of all diabetes cases in the U.S.,[8] is frequently a disease of convenience; too much convenient food and lack of exercise options are broadening our risk factors (as well as our backsides). Current economic conditions in the U.S. may result in a decrease in consumption of fresh fruits, vegetables, lean meat, and fish. All of these products incur substantial shipping and handling costs. Cheaper alternatives such as processed meats, canned goods, and boxed dinners with high carbohydrate, fat, and sodium content will likely form a larger percentage of the average American diet. Lack of disposable income may result in less activity as individuals drop out of exercise groups to pursue less-expensive forms of recreational exercise. An acceleration of the obesity crisis would drive the diabetes epidemic to even greater heights. Perhaps now is the time to expand pharmacy-managed outpatient diabetes programs to

include medication therapy management, SMBG, point-of-care A1C, and population-based weight-management information. The U.S. Army developed the H.E.A.L.T.H. Web-based interactive nutrition and fitness lifestyle program, which provides personalized plans for soldiers and their family members.[9] Adapting such a program for use by individuals and diabetes case managers seeking accurate and reliable information about nutrition and fitness seems prudent.

Affordable early detection of diabetes risk could be accomplished through public screening initiatives utilizing a dual test methodology of fasting capillary blood glucose and an accurate, portable A1C test such as the A1cNow+™. Pharmacist-directed dual-test screening of workplace populations has been performed using the home testing device InCharge™ (LXN Corp., San Diego, CA).[10] Though this device and its fructosamine testing options are no longer available, the methodology used could be adapted for A1cNow+™ and utilized in workplaces, outpatient clinics, and community pharmacies. As evidenced in the article written by Arrendale and colleagues in this issue of Journal of Diabetes Science and Technology,[11] incorporating accurate point-of-care A1C testing technology such as A1cNow+™ in pharmacist-managed outpatient diabetes programs could be a cost-effective way to turn the tide in the expanding diabetes epidemic.

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