

HbA_{1c} for Diabetes Diagnosis Now Mainstream

BY SHERRY BOSCHERT

SAN FRANCISCO — The use of a hemoglobin A_{1c} level of 6.5% or higher to diagnose type 2 diabetes is now mainstream, with formal endorsements from three major U.S. medical associations in 2010 supporting an International Expert Committee's 2009 consensus recommendations.

The World Health Organization and other groups are likely to follow suit, though with greater emphasis on this as an alternative to conventional means of diagnosing diabetes in regions that don't have easy access to standardized assays for HbA_{1c}. Dr. Richard M. Bergenstal said at a meeting sponsored by the American Diabetes Association

He welcomed the change, and the rationale for using HbA_{1c} to diagnose diabetes. "Why do we follow it so closely once you're diagnosed, but pay no attention to it before you're diagnosed?" asked Dr. Bergenstal, president of medicine and science for the ADA and executive director of the International Diabetes Center, Saint Louis Park, Minn.

The International Expert Committee, with members appointed by the ADA, the European Association for the Study of Diabetes, and the International Diabetes Federation, got the ball rolling by publishing a consensus opinion in July 2009 to make HbA_{1c} the preferred test for diagnosing type 2 diabetes (*Diabetes Care* 2009;32:1327-34).

The ADA translated the international consensus into clinical practice recommendations that were published in its annual update on standards of care in January 2010 (*Diabetes Care* 2010;33:S11-61). The ADA backed away from calling HbA_{1c} the preferred test, instead saying it's one of four options, but acknowledged that it may become the most popular diagnostic test for type 2 diabetes.

The other, conventional diagnostic criteria are a fasting plasma glucose level of at least 126 mg/dL, an oral

glucose tolerance test result of 200 mg/dL or higher, or classic symptoms of hyperglycemia plus a randomly obtained glucose level of at least 200 mg/dL.

The Endocrine Society endorsed the ADA clinical practice recommendations in a separate statement that was issued Jan. 20, 2010. The American Association of Clinical Endocrinologists followed with its own supportive statement on Feb. 1, 2010.

Inevitably, clinicians will have patients whose HbA_{1c} and glucose results conflict, Dr. Bergenstal noted. If one is abnormal and the other is not, repeat the abnormal test, the ADA recommendations say. "If that is still abnormal, you've made the diagnosis," he said. If, instead, you perform a third test method for confirmation and the result meets diagnostic criteria, diabetes is confirmed, he added.

Results are less clear when a patient has one normal and one abnormal test result, and repeating the abnormal test produces a normal result. "Then you have someone who is obviously on the edge" and who should be retested again in 3-6 months, he said.

Another gray area is the use of HbA_{1c} to define prediabetes (patients at high risk for developing diabetes or cardiovascular disease). The statements from the various groups differ somewhat in how they address this. "I think everyone agrees that for at-risk patients, that's a little bit more of a judgment call," Dr. Bergenstal said.

The International Expert Committee suggested avoiding the concept of prediabetes because the risk is a continuum with a fairly steady rise in risk as HbA_{1c} levels increase. They identified HbA_{1c} levels of 6.0%-6.4% as "very high risk" while noting that people with lower HbA_{1c} levels also may have increased risk for diabetes if other risk factors are present.

The ADA's 2010 clinical practice recommendations declare HbA_{1c} levels of 5.7%-6.4% to be indicative of high risk, and state that patients with these levels may be referred to as having prediabetes, Dr. Bergenstal said. "At 5.7% we thought the risk was really quite high, and that people deserved to have some kind of program" to prevent diabetes.

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DR. BERGENSTAL

The American Association of Clinical Endocrinologists suggested that an HbA_{1c} level of 5.5%-6.4% may be a better cut-off to identify higher-risk patients. Unlike the glucose tests, HbA_{1c} testing does not require patients to fast before testing and carries several other advantages. Each of the statements supporting HbA_{1c} testing for diabetes diagnosis acknowledged a number of caveats, however, such as recognition that marginally elevated HbA_{1c} values in certain ethnic groups do not necessarily indicate diabetes. HbA_{1c} testing should not be used for diabetes diagnosis in patients with conditions that impair the correlation between HbA_{1c} and average blood glucose, such as iron deficiency or renal disease.

Only standardized, validated laboratory assays for HbA_{1c} were endorsed. Some of the newer point-of-care tests may be sufficiently accurate, but others are not, and more testing is needed before these can be endorsed for diabetes diagnosis, he said. ■

Disclosures: Dr. Bergenstal has held stock in Merck & Co. and participated in research or consulted for Abbott Diabetes Care, Amylin Pharmaceuticals, Bayer, Eli Lilly & Co., Intuity Medical, Lifescan (Johnson & Johnson), Mannkind, Medtronic, Merck, Novo Nordisk, ResMed, Roche Diagnostics Corp., Sanofi-Aventis, Pfizer, and Takeda Pharmaceuticals.



Diabetes Patients and Physicians Have Different Priorities

BY DIANA MAHONEY

Diabetes patients with multiple health concerns and their physicians are not always on the same page regarding the relative importance of specific comorbidities, and this incongruity could have clinical management implications, according to a report by University of Michigan researchers.

In a prospective cohort study designed to assess concordance of patient and physician priorities, Dr. Donna M. Zulman and her colleagues from the University of Michigan, Ann Arbor, surveyed 92 primary care providers and 1,169 of their diabetic patients, asking the patients to rank their most important health concerns and asking the providers to rank the most important conditions likely to affect the patients' health outcomes.

For 60% of the patient-provider pairs, concordance was high, meaning that the provider ranked the same top three health concerns as the patient or that the provider ranked two of the same health concerns as the patient, and these two matched the patient's most important concerns, the authors reported. For 72%

of the patient-provider pairs included in the analysis, the patient's most important concern was on the provider's top three list, but only 16% of the pairs had three matches, 55% had two matches, and

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Major Finding: Diabetes patients with multimorbidity and their physicians commonly don't agree on the relative importance of comorbid health conditions.

Data Source: Prospective cohort study of 92 primary care providers and 1,169 of their diabetic patients with comorbid hypertension.

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25% had one match, while 4% had no matching health concerns, they wrote (*J. Gen. Intern. Med.* 2010 Feb. 2 [doi:10.1007/s11606-009-1232-1]).

The discordance between patient and physician perception of hypertension as the most important comorbidity in diabetic patients was especially notable, according to the authors. "Although providers ranked hypertension as the most important health condition for 384 (38%) patients, only 184 (18%) patients listed hypertension as their most impor-

tant health concern," they wrote. "Patients were more likely than providers to list 'losing weight or being more active' in their top three concerns (35% vs. 21%, respectively)." This finding is consistent with previous data suggesting that many diabetic patients are not aware of the importance of blood pressure control despite the available evidence and clinical guidelines that stress its importance, the authors said.

Another striking disconnect was observed between patients who listed pain or depression as their top health concern relative to the number of their providers who ranked these conditions as likely to affect the patient's health outcomes. For example, only 9% of patients who listed pain as their top health concern had a provider who ranked it among the top three, and only 32% of patients who listed depression as their most important comorbidity had physicians who agreed, the authors reported.

"This discordance is concerning, not only because it raises the possibility that providers are unaware of the extent to which these conditions affect their patients, but also because pain and depression can be barriers to effective diabetes self-management, and (in the case of depression) may worsen glycemic control and increase the risk of mortality," they

wrote. "By deemphasizing symptomatic conditions, providers are actually neglecting some of the most important medical concerns that are likely to affect health outcomes in these patients," they noted.

The study had several limitations, according to the authors. These include the inability of the concordance score to measure the concept of which conditions the providers thought the patients would prioritize. Another was that the patients and providers were aware that the study was looking at diabetic patients with an elevated blood pressure level at triage, thus making it more likely that hypertension and diabetes would be listed among the top three health concerns and potentially hindering the evaluation of concordance patterns among other health conditions.

Overall, the findings suggest the need for improved communication about the risks associated with comorbidities, according to the authors. Additionally, the results "reinforce the need for heightened provider recognition of patients' symptomatic conditions as well as their non-health competing demands," they wrote, adding that future research should focus on ways to encourage and implement these practices in primary care. ■