

Studies on Hemoglobin A1c (HbA1c), Pre-Diabetes, and Diabetes

This tab includes recent research on prevalence, screening, prevention, and costs related to pre-diabetes and diabetes. The summary document below summarizes the studies included in the tab.

Highlights:

- The American Diabetes Association’s revised clinical practice guidelines, which call for the use of the HbA1c lab test for the identification of pre-diabetes and diagnosis of diabetes.
- Seminal studies that show that people with pre-diabetes can prevent or delay diabetes through lifestyle changes; that such changes can last; and that such changes are often low-cost.
- Studies using an epidemiological model to project the federal costs for diabetes under alternative policies.
- Studies on ethnic disparities and clinician-patient communication challenges in populations with diabetes.

Study	Publication	Summary of Findings
<p>“The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement”; Overview and Case Study II: Screening for Type 2 Diabetes and Pre-diabetes with HbA1C, <i>The Lewin Group</i>, September 2009</p>	<p><i>The Lewin Group for American Clinical Laboratory Association</i></p>	<p>The evidence presented in this case study supports the value of HbA1c lab testing in screening and diagnosis for diabetes and pre-diabetes. The high association between HbA1c levels and cardiovascular risk and mortality makes it an important biomarker for diabetic and other high-risk individuals, according to the case study.</p> <p>HbA1c improves consistency in testing, as its test results are not affected by short-term glycemic fluctuations (due to current effects of diet, medications, and other factors) that affect other tests.</p> <p>Studies have confirmed the effectiveness of HbA1c testing in screening for identifying pre-diabetic individuals who will benefit from early interventions, contributing to substantial decreases in incidence of type 2 diabetes. Use of HbA1c increases patient-centeredness of care given the improved convenience and comfort of testing.</p> <p>Findings from cost-effectiveness modeling of various testing modalities for diabetes and pre-diabetes indicate that screening can be cost-effective, especially for certain at-risk groups.</p>
<p>“Glycated Hemoglobin, Diabetes, and Cardiovascular Risk in Nondiabetic Adults,” Selvin, Elizabeth. et al. <i>The New England</i></p>	<p><i>The New England Journal of Medicine</i></p>	<p>This population-based study of black and white non-diabetic adults in the community showed that glycated hemoglobin (HbA1c) is a strong predictor of individuals who will develop</p>

Journal of Medicine, Volume 362,
Number 9, March 4, 2010

diabetes, and also is an important marker of subsequent cardiovascular risk. The study showed that HbA1c was superior to fasting glucose for assessment of the long-term risk of subsequent cardiovascular disease, especially at values above 6.0%.

Fasting glucose has been the standard measure used to diagnose diabetes in the US. Recently, HbA1c was also recommended for this purpose.

“American Diabetes Association’s New Clinical Practice Recommendations Promote A1C as Diagnostic Test for Diabetes”;
press release, December 29, 2009

ADA media release

The media release announcing the ADA’s 2010 Standards of Care emphasized the role of HbA1c as a convenient, non-fasting test that could encourage people who are at-risk for diabetes to get tested. This would reduce the number of people who are undiagnosed but living with the disease.

Testing could also identify pre-diabetes, allowing individuals to make lifestyle changes that have been shown to delay or prevent a diabetes diagnosis.

American Diabetes Association, “Standards of Medical Care in Diabetes – 2010”, *Diabetes Care*, Volume 33, Supplement 1, January 2010, Executive Summary, pages 4-10

Diabetes Care

The American Diabetes Association’s revised clinical practice recommendations call for the addition of the HbA1C test to diagnose diabetes and pre-diabetes.

Unlike other tests for diabetes, the HbA1c test does not require patients to fast. The ADA believes this added convenience will encourage more people to get tested for type 2 diabetes; early diagnoses of pre-diabetes can enable patients to make lifestyle or drug therapy changes to thwart diabetes onset.

An HbA1c in the 5.7 to 6.4 range indicates blood glucose levels in the pre-diabetic range. An HbA1c of 6.5 percent or higher indicates a diagnosis of diabetes, according to the new guidelines. The guidelines also include new criteria for use of aspirin for primary prevention.

Diabetes Prevention Program Research Group, “10-Year Follow-up of Diabetes Incidence and Weight Loss in the Diabetes Prevention Program Outcomes Study,” *The Lancet*, Volume 374, November 14, 2009

The Lancet

Based on 10 years of data, the Diabetes Prevention and Outcomes Study (DPPOS) showed that individuals at risk for type 2 diabetes delayed its onset by 34% compared to placebo through intensive lifestyle changes such as modest weight loss. Participants delayed the onset of diabetes by 18% through use of the oral medication, Metformin.

		<p>The DPPOS looked at the persistence of the interventions tested in the Diabetes Prevention Program a decade earlier. The DPP showed that lifestyle interventions delayed type 2 diabetes 58%, while Metformin delayed onset by 31% compared to placebo.</p>
<p>“Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin,” Diabetes Prevention Program Research Group, <i>New England Journal of Medicine</i>, Volume 346, Number 6, February 7, 2002</p>	<p><i>The New England Journal of Medicine</i></p>	<p>This is the original Diabetes Prevention Program (DPP) study. The results supported the hypothesis that type 2 diabetes can be prevented or delayed in persons at high risk for the disease. The incidence of diabetes was reduced by 58% with the lifestyle intervention and by 31% with Metformin, as compared with placebo.</p> <p>People in the intensive lifestyle intervention group were to achieve and maintain a weight reduction of at least 7% of initial body weight through a healthy low-calorie, low-fat diet and to engage in moderate intensity physical activity for at least 150 minutes per week. Case managers taught a curriculum covering diet, exercise, and behavior modification on a one-to-one basis.</p>
<p>“Translating the Diabetes Prevention Program into the Community: The DEPLOY Pilot Study,” Ackermann, Ronald T, et al, <i>American Journal of Preventive Medicine</i>, Volume 35, Issue 4, October, 2008</p>	<p><i>American Journal of Preventive Medicine</i></p>	<p>This study evaluated whether a group-based DPP lifestyle intervention (exercise and diet), in partnership with the YMCA Diabetes Prevention Program, could continue the impact of lifestyle improvements shown in the DPP. After six months, body weight dropped by 6% in the intensive lifestyle group and 2% in controls. Cholesterol also dropped in the lifestyle group. The study concluded that the YMCA may be a promising channel for wide-scale dissemination of a low-cost approach to lifestyle diabetes prevention.</p>
<p>“The Economic Burden of Diabetes,” Dall, Timothy M, et al, <i>Health Affairs</i>, Volume 29, Number 2, February 2010</p>	<p><i>Health Affairs</i></p>	<p>New research provides revised comprehensive estimates that suggest that the U.S. national economic burden of pre-diabetes and diabetes reached \$218 billion in 2007. This estimate includes \$153 billion in higher medical costs and \$65 billion in reduced productivity.</p> <p>The paper noted that “the burden of diabetes to society is even higher when one considers intangible costs from reduced quality of life.” The statistics support the urgency to better</p>

		<p>understand ways to mitigate costs through prevention and treatment strategies, according to the paper.</p>
<p>“Medical Cost Associated with Prediabetes,” Zhang, Yiduo, et al, <i>Population Health Management</i>, Volume 12, Number 3, 2009</p>	<p><i>Population Health Management</i></p>	<p>The study estimates the national health care resource use and medical costs in 2007 associated with pre-diabetes. The findings suggest that pre-diabetes is associated with statistically higher rates of ambulatory visits for hypertension; endocrine, metabolic, and renal complications; and general medical conditions.</p> <p>The study suggests that the national annual medical cost for the 57 million adults with pre-diabetes exceeds \$25 billion, or an additional \$443 for each adult with pre-diabetes. Study findings support the business case for intervention to prevent or delay pre-diabetes.</p>
<p>“Projecting the Future Diabetes Population Size and Related Costs for the U.S.,” Huang, Elbert, et al, <i>Diabetes Care</i>, Volume 32, Number 12, December 2009</p>	<p><i>Diabetes Care</i></p>	<p>The diabetes population and the related costs are expected to at least double in the next 25 years, according to this study, which used projections from a population-level model.</p> <p>Between 2009 and 2034, the number of people with diagnosed and undiagnosed diabetes will increase from 23.7 million to 44.1 million; during the same period, annual diabetes-related spending is expected to increase from \$113 billion to \$336 billion (2007 dollars); for the Medicare-eligible population, the number of those with diabetes is expected to rise from 8.2 million in 2009 to 14.6 million in 2034; associated spending is estimated to rise from \$45 billion to \$171 billion.</p>
<p>“Using Clinical Information to Project Federal Health Care Spending,” Huang, Elbert, et al, <i>Health Affairs</i>, Volume 28, Number 5, published online September 1, 2009</p>	<p><i>Health Affairs</i></p>	<p>Federal cost projections for chronic illness are constrained by a 10-year budgeting window used by the Federal Government that captures near-term intervention costs but not changes in long-term cost savings. Yet type 2 diabetes is a prime example of a chronic illness with long-term health and cost consequences.</p> <p>The study looks at results from an epidemiologically-based model that projects to 25 years the federal costs and savings for treating diabetes under alternative policies. The findings show that the value of benefits for a more intensive approach in treating diabetes are about equal to the costs at 25 years, when the value of reduced complications from diabetes.</p>

<p>“Ethnic Disparities in Diabetic Complications in an Insured Population,” Karter, Andrew J, et al, <i>The Journal of the American Medical Association</i>, Volume 287, Number 19, May 14, 2002</p>	<p><i>The Journal of the American Medical Association</i></p>	<p>including blindness, kidney failure, and heart disease, are taken into account. Such savings are not realized, however, within the 10 year budgeting window.</p>
<p>“The Impact of Limited English Proficiency and Physician Language Concordance on Reports of Clinical Interactions Among Patients with Diabetes: The DISTANCE Study”, Schenker, Yael, et al, <i>Patient Education and Counseling</i>, published online February 2010</p>	<p><i>Patient Education and Counseling</i></p>	<p>This study confirms previous reports of elevated incidence of end-stage renal disease among ethnic minorities, despite uniform medical care coverage. It provides new evidence that rates of other complications are similar or lower relative to those of whites.</p> <p>The 3-year longitudinal study of a diabetic population with uniform health care coverage (Kaiser Permanente Northern California) looked at ethnic differences in the incidence of five major diabetic complications. “The patterning of ethnic disparities across the range of complications within a single health care environment is itself informative,” the authors note.</p> <p>The persistence of ethnic disparities after adjustment suggests a possible genetic origin, the contribution of unmeasured environmental factors, or a combination of these factors.</p> <p>Communication, trust, and perceived health care system discrimination are three separate but interconnected components of clinician–patient interactions, each with important effects on health outcomes among patients with diabetes. Clinician–patient communication, including the provision of information and efforts to involve patients in clinical decision making, has been associated with diabetes self-management and glycemic control.</p> <p>This study assessed the association of limited English proficiency and physician language concordance with patient reports of clinical interactions. It found that reports of suboptimal interactions among patients with limited English proficiency were more common among those with language-discordant physicians.</p>
