



CHERYL ANN BORNE
Cheryl has type 2 diabetes

In This Issue:

- National Diabetes Prevention Program to be expanded after proven results
- Study shows text messaging helps people with prediabetes lose weight
- ADA issues new diabetes primary care standards

Administration set to expand Diabetes Prevention Program under Medicare

- The Department of Health and Human Services (HHS) announces plans to provide reimbursement for diabetes prevention program services and referrals for Medicare beneficiaries with prediabetes
- The high-profile decision is based on an independent validation of the YMCA of the USA's Center for Medicare and Medicaid Innovation demonstration project
- The demonstration saved \$2,650 in Medicare expenditures per enrollee over 15 months

On March 23, 2016, HHS announced that it is prepared to have Medicare pay for comprehensive diabetes prevention services for beneficiaries with prediabetes. **The decision is based on an actuary's determination that the National Diabetes Prevention Program (National DPP) improves health and saves money.**¹

HHS Secretary, Sylvia M. Burwell, said the department's plan to expand the National DPP into Medicare is made possible by the Affordable Care Act, which created the Center for Medicare and Medicaid Innovation to test new models of care that enhance the quality of health and health care and reduce health care costs. The

continued on next page

National DPP is the first disease prevention program to gain actuarial certification through this pathway.

"There is little doubt it will go into force before Mr. Obama leaves office."

– New York Times

Burwell's announcement said the Obama administration "supports expansion of the Diabetes Prevention Program" and now "is considering how it would expand this model broadly throughout the Medicare program." More details about implementation of the benefit are expected this summer as part of the annual update of Medicare physician fees. The HHS announcement can be found [here](#). The Diabetes Advocacy Alliance (DAA), which is co-chaired by Novo Nordisk, the American Diabetes Association, and the Pediatric Endocrine Society, has long advocated for the National DPP and was heartened by Secretary Burwell's announcement. The DAA's press release can be found [here](#).

new & news in diabetes policy

June 2016

Following successful initial research, the YMCA of the USA, a DAA member, piloted the National DPP in 17 communities in 8 states. There, Medicare beneficiaries participating in the program lost an average 5% of their body weight. In addition, 4 in 5 participants attended at least 4 weekly meetings, and Medicare expenditures averaged \$2,650 less for participants than for matched controls over 15 months – “more than enough,” says HHS, “to cover the cost of the program.” The evaluators also found the program improved health outcomes, as measured by hospital admission and readmission rates and emergency department visits. HHS funding helped support the YMCA pilot.

The potential reach of the program is extremely wide. The HHS announcement notes that one-third of U.S. adults have prediabetes. Older people are at greater risk than younger adults. Of the 37% of U.S. adults aged 20 years or older with prediabetes, 51% are aged 65 years or older and may qualify for Medicare coverage.²¹

A *New York Times* article reporting the HHS decision says, “there is little doubt it will go into force before Mr. Obama leaves office,” because the decision does not require congressional approval.² That article can be found [here](#). The actuarial report can be found [here](#).³ And, the evaluation itself, prepared by RTI International, can be found [here](#).⁴



JESSE CRUMPLER
Jesse has type 2 diabetes

new & news in diabetes policy

Research institute scopes out review of diabetes prevention program

The Institute for Clinical and Economic Review (ICER) released a “scoping document” on March 3 for its upcoming report on the comparative effectiveness of various diabetes prevention programs.⁵ The report will include a systematic review of the evidence, cost analyses, and a description of the policy landscape affecting diabetes prevention efforts. On June 24, the California Technology Assessment Forum panel will vote at a public meeting in Los Angeles on “key questions raised in the report.” The deadline for comments on ICER’s scoping document, however, was March 10, only one week after the document was made public. A draft report will be released May 9 and be open for comments. The final report is expected in late July. ICER’s announcement can be found [here](#).

30 years after: Intensive therapy shows lasting benefits for people with type 1 diabetes

- Results of a 30-year follow-up study of the Diabetes Control and Complications Trial (DCCT) support the use of intensive insulin therapy¹¹
- Intensive therapy “has long-term, clinically beneficial effects” on cardiovascular disease rates in people with type 1 diabetes, say the researchers¹¹
- People receiving intensive therapy had a statistically significant 30% fewer initial cardiovascular events, over the 3 decades they were tracked, than people receiving conventional therapy. This was not significant in the original trial¹¹

A 30-year follow-up study of 1,441 patients (85% of original subjects) in the Diabetes Control and Complications Trial (DCCT) has found intensive, rather than conventional, insulin therapy generates enduring benefits in preventing cardiovascular disease in people with type 1 diabetes.⁶

Cardiovascular disease (CVD) is the nation’s number 1 killer⁷ and is accelerated in type 1 diabetes, which was the focus of the DCCT. CVD often develops slowly. Previously reported DCCT results show the intensive therapy regimen reduced the risks of developing CVD over a horizon of 17 years on average.⁸ In addition, results reported last year show such intensive therapy slightly reduced the risks of mortality from all causes of death over the 30-year period.⁹

Intensive insulin therapy has also been found to reduce the risks of diseases of the eye, kidney, and nervous system in patients with type 1 diabetes.

Over the 30 years, people receiving intensive therapy had a statistically significant 30% lower rate of sustaining an initial cardiovascular event.

continued on next page

new & news in diabetes policy

P.J. PIMPINELLI
P.J. has type 1 diabetes



Further, the long-term follow-up study showed a significant difference in mean A1c levels. These levels were 7.8% for the intensive group and 8.2% for the conventional group after an average of 26 years and a maximum of 30 years.⁸ The authors indicate lower blood glucose levels are the reason for the CVD risk reduction from intensive therapy.⁸

In addition, the acceleration of atherosclerosis “appears to have been reduced by a 6-year period of DCCT intensive therapy, a benefit that has continued to be evident many years later,” the authors note.⁶ And, they offer a “preliminary observation” that intensive therapy has a “potentially stronger effect” than conventional therapy in preventing fatal, as opposed to nonfatal, coronary artery disease.⁶

The new results of the study are reported in *Diabetes Care* and published online in February. The abstract can be found [here](#).

Besides CVD, earlier DCCT reports also found intensive therapy reduced the risks of retinopathy (disease of the retina)^{10,11}, nephropathy (kidney disease)^{11,12}, and neuropathy (disease of the nervous system)¹².

The authors conclude that DCCT’s intensive therapy “has long-term, clinically beneficial effects on the incidence of CVD” in the cohort of individuals with type 1 diabetes.⁶

new & news in diabetes policy

With a little help from text messages, people with prediabetes may lose weight, study shows

- Among Spanish-speaking people treated for prediabetes at a federally qualified health center in Colorado, weight loss was greater when they received health-promotion text messages
- English-speaking patients did not experience a weight-loss benefit from the text-messaging intervention
- The message content included skill-teaching, problem-solving, motivation, stress reduction, food recipes, resource links, and promotion of physical activity

Spanish-speaking people with prediabetes lost, on average, 4.6 pounds more in one year than other Spanish-speaking people with prediabetes in a small randomized clinical trial if they received frequent text messages about diabetes

prevention. The comparative effectiveness study was completed in 2015 and reported online in *Diabetes Care*.¹³

Some participants in the study mainly spoke Spanish, while others mainly spoke English. Mean weight loss among the Spanish and English speakers combined, who received the text messages, was 2.6 pounds, compared with 0.6 pounds for the combined Spanish and English control group. On the whole, though, only Spanish speakers (those who chose to receive the text messages in Spanish), not English speakers (who chose English messaging), showed the weight-loss benefit of the text-messaging intervention. (See Table 1 below.)

Both the intervention and control groups had access to diabetes prevention classes as well as

Table 1. Changes in Health Status in People with Prediabetes in a Study of Text Messaging Support in Spanish and English, 2014-2015.

Study participant group	Mean weight change (in pounds)	P value	Percent of participants losing 3% of original weight	Mean systolic blood pressure change (in mm Hg)	Mean A1c change (in percent)
Spanish-speaking intervention	- 5.1 pounds	$P = <0.01$	47% of participants	+ 1.6	- 0.12%
Spanish-speaking controls	- 0.5 pounds	$P = <0.01$	21% of participants	+ 8.5	+ 0.42%
English-speaking intervention	+ 1.9 pounds	$P = 0.41$	22% of participants	- 1.9	- 0.03%
English-speaking controls	- 0.6 pounds	$P = 0.41$	22% of participants	+ 4.9	0.00%
All intervention	- 2.6 pounds	$P = 0.05$	38.5% of participants	+ 0.35	- 0.09%
All controls	- 0.6 pounds	$P = 0.05$	21.6% of participants	+ 6.4	+ 0.19%

Source: Fischer, et al.¹³

continued on next page

new & news in diabetes policy



JIM SHEEDER
Jim has type 2 diabetes

individual sessions with a nurse or nutritionist about diet. The intervention group members further received weekly texts requesting them to report their weight. Members of the intervention group also could schedule sessions, usually conducted by telephone, with a health coach.

Nearly half (47%) of the Spanish-speaking participants who received the intervention met the goal of losing 3% of their original weight. By contrast, only a fifth (21%) of Spanish-speaking members of the control group met the 3% goal.

Spanish-speaking participants who received the intervention also fared far better than Spanish-speaking controls in measures of blood pressure and blood glucose levels. English-speaking participants who received the intervention

“Text messaging offers an opportunity to improve health as advances in technology have made cell phones less expensive and more accessible to the poor.”

fared significantly better than English-speaking controls in blood pressure measures but not in blood glucose levels.

Members of the intervention group received 6 text messages per week. The content of the messages included skill-teaching, problem-solving, motivation, stress reduction, food recipes, resource links, and promotion of physical activity. The content was based on the curriculum of the National Diabetes Prevention Program (see our lead article, above) and was tailored, with the help of focus groups, to enhance impact with the significant local Latino population.

The study was conducted at a federally qualified health center affiliated with Denver Health, an integrated health care system. The study included 157 participants.

“Text messaging,” conclude the authors, “offers an opportunity to improve health as advances in technology have made cell phones less expensive and more accessible to the poor.”¹³ The article abstract can be found [here](#).

new & news in diabetes policy

Improving quality of care: Federal and private payers agree on diabetes measures for evaluating primary care providers

- A1c control and testing, eye and foot exams, and kidney disease screening are now part of core standards for primary care jointly developed by federal and private sector authorities
- Core standards may influence payment of physicians and risk-based integrated health systems
- Many organizations helped develop the new standards

Five diabetes-related standards are included in a list of 22 new core standards for primary care providers and accountable care organizations (ACOs). The Centers for Medicare and Medicaid Services (CMS) joined with the nation's largest health insurance trade association in announcing the new consensus standards of quality of care in February.¹⁴

The development of core standards may lead to a workable, easily monitored set of quality measures. Previous standards development efforts produced multiple sets of measures. The overlap and duplication resulting from multiple lists could confuse providers and consumers and impede quality improvement and the credible evaluation of providers.

All 5 comprehensive diabetes care standards focus on the percentages of patients, ages 18-75, with type 1 or type 2 diabetes. The standards are¹⁴:

- **HbA1c poor control** – the percentage of these patients whose latest blood glucose level exceeded 9.0% or whose level was not measured or recorded during the past year

- **Eye exam** – the percentage of these patients who had a retinal exam performed during the past year
- **Hemoglobin testing** – the percentage of these patients who received an A1c test during the past year
- **Foot exam** – the percentage of these patients who received a foot exam during the past year that included visual inspection and a sensory exam with monofilament and a pulse exam; and
- **Medical attention for nephropathy** – the percentage of these patients who received a kidney disease screening test or showed evidence of kidney disease during the past year

The standards likely will serve as a widely accepted basis for performance-related adjustments to how much physicians and certain integrated health systems are paid. Besides CMS and the insurer trade association America's Health Insurance Plans (AHIP), several other organizations helped develop the standards, including the National Quality Forum and the American Medical Association.

The complete set of standards for primary care and ACOs can be found [here](#). Through ACOs, "pay-for-performance," and other innovations, CMS and private insurers are seeking to create financial incentives for health care providers to produce better health outcomes. Because this effort requires recognized standards of care, the announcement of the new core consensus standards is an important step.

new & news in diabetes policy

Omada Health diabetes prevention effort now aims to serve uninsured people

Omada Health, a digital health firm in San Francisco that offers a diabetes prevention program to employers and insurers, has developed a new version of its program to meet the needs of Medicaid beneficiaries and uninsured people. The firm launched the new version in February.

The program, known as Prevent, provides people at risk of type 2 diabetes with a digital scale and pedometer, 16 weekly interactive lessons in the form of streaming videos, and the services of a health coach.¹⁶ The program is based on the Diabetes Prevention Program

clinical trial (see our lead article above). The new version includes access to bilingual coaches and a curriculum geared to people with low-level literacy and those for whom English is a second language. It also takes into account difficulties in accessing nutritious food.

A clinical trial of this new version of Prevent is slated for two sites in California and one site in Washington state. Omada Health has received substantial funding from foundations, venture capital firms, and large health systems. The announcement of the new effort can be found [here](#).

Use electronic health records to select patients for diabetes testing, say study authors

- A 50-state study of 131,000 patient records suggests a new way to identify patients who should be tested for undiagnosed diabetes
- Using electronic medical records, as a screening tool, could boost the cost-effectiveness of diabetes screening – and could benefit more patients
- The accuracy of the electronic approach is found to exceed that of the conventional method

A cross-sectional, retrospective study examining the electronic health records (EHRs) of 9,948 patients in all 50 states over 3 years has demonstrated the value of EHRs in identifying people who can cost-effectively be tested for type 2 diabetes.¹⁷

The study compared 3 models:

1. A full EHR model used 298 features, including commonly prescribed medications, diagnoses (as ICD9 categories), and conventional predictors¹⁷
2. A restricted EHR DX model that used all features as in the EHR model, but excluded medications¹⁷
3. A conventional model containing basic predictors and their interactions (smoking status, sex, age, BMI, and hypertensive status)¹⁷

Even though many EHRs were incomplete or poorly transmitted between health care providers, the researchers' EHR model outperformed conventional screening factors in identifying patients with undiagnosed diabetes. Moreover, the EHR model appears less costly

continued on next page

new & news in diabetes policy

than conventional screening techniques.

The research team used 131,000 records from 2009 to 2012 available through a major EHR vendor. The team's EHR model consisted of 150 common diagnoses, 150 common medications, certain personal information (such as age, family diabetes history, and smoking status), and selected additional risk factors (such as obesity, heart attack, and skin infection).

By contrast, the conventional alternative relies on risk scores based on smoking status, sex, age, body mass index, and hypertension. These factors are used to determine the need for laboratory testing. Because laboratory testing usually requires fasting, patient monitoring, phlebotomy, and costly blood analysis, it can tend to strain the resources of health care providers serving poor patients and, consequently, may be used only sparingly in medically underserved communities.

Take patient's view of illness into consideration, researchers tell clinicians

How patients with type 2 diabetes perceive what's at stake and how they cope with diabetes challenges affect their risk of cardiovascular disease, researchers have found. For example, patients who felt under stress were more likely to have high LDL cholesterol. The study population consisted of 300 people, of whom 98% were male, treated for diabetes at a veterans affairs medical center in the southeast in 2004.¹⁸

"The findings of this study," the researchers say, "show that meaning of illness has an influence on cardiovascular risk factors and is an important factor to consider when treating

The research suggests a more cost-effective way of identifying patients with undiagnosed diabetes would improve screening, and therefore, avoid much of the high cost of treating patients whose diabetes has progressed to an advanced stage. The authors say insurers could use the EHR approach, or "EHR phenotype models," not only to identify people with undiagnosed diabetes but also to identify people at high risk of diabetes, who then could be referred to patient education or diabetes prevention programs. In other words, EHRs could serve as the basis of step-testing of patients for diabetes status.

"These promising results," the authors conclude, "showed that EHR phenotypes provided superior predictive accuracy for assessing diabetes status, compared to traditional non-laboratory information."¹⁷ The article abstract can be found [here](#).

patients with type 2 diabetes."¹⁸ The abstract of their article, appearing in *Diabetes Educator*, can be found [here](#).

In a similar approach, researchers working at a large health care system in Minnesota examined patient activation. Among 14,700 patients at high risk of generating high health care costs, patients' scores on the Patient Activation Measure correlated with lower costs of care over the following 3 years.

The researchers explain: "For high-risk patients with multiple chronic illnesses [not just

new & news in diabetes policy

diabetes], their ability to monitor conditions, follow treatment regimens, and manage their own symptoms is likely to determine whether they will need costly care.”¹⁹

In short, more activated patients were hospitalized less frequently and made fewer

visits to emergency departments. The researchers say their findings “suggest that adding a behavioral assessment to current risk models may improve the ability to target people most in need of additional support.”¹⁹ The abstract of the article, appearing in *Health Affairs* in March, can be found [here](#).

Endocrinology associations address glucose monitoring needs

The American Association of Clinical Endocrinologists and American College of Endocrinology are advising clinicians to undertake “meaningful monitoring” of diabetic patients’ glucose levels, taking into account both individual needs and ongoing improvements in the accuracy of capillary blood glucose monitoring (BGM) and in the design of interstitial fluid sensors for continuous glucose monitoring (CGM). The advice comes in the form of a “consensus statement” prepared by a joint 10-member task force.²⁰

The consensus statement promotes education of patients and clinicians about glucose monitoring data. It generally supports routine BGM of patients with type 1 diabetes. It supports CGM for “patients with a history of severe hypoglycemia or hypoglycemia unawareness, as well as for patients not at goal-based A1c.”²⁰

The recommendations are based largely on the task force’s review of previously reported studies and other guidelines. The statement notes that data on CGM for people with type 2 diabetes are limited.²⁰ The full statement can be found in *Endocrine Practice*, [here](#).



CAMERON HUBBARD
Cameron has type 2 diabetes

new & news in diabetes policy

References

1. U.S. Department of Health and Human Services. Independent experts confirm that diabetes prevention model supported by the Affordable Care Act saves money and improves health. News release. <http://www.hhs.gov/about/news/2016/03/23/independent-experts-confirm-diabetes-prevention-model-supported-affordable-care-act-saves-money.html>. Published March 23, 2016. Accessed March 23, 2016.
2. Pear R. Medicare proposal takes aim at diabetes. *New York Times*. March 23, 2016. <http://www.nytimes.com/2016/03/23/us/politics/medicare-proposal-takes-aim-at-diabetes.html>. Accessed March 23, 2016.
3. Spitalnic P. Certification of Medicare Diabetes Prevention Program. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of the Actuary. Memorandum. 2016. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf>. Published March 14, 2016. Accessed March 24, 2016.
4. Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015 – Awardee-Level Findings: YMCA of the USA. Research Triangle Park, N.C.: RTI International. 2016. <https://innovation.cms.gov/Files/reports/hcia-ymcadpp-evalrpt.pdf>. Published March 2016. Accessed March 24, 2016.
5. Institute for Clinical and Economic Review. Scoping document for ICER review of diabetes prevention programs. Notice posted for public comment. 2016. Boston, Mass.: Institute for Clinical and Economic Review. <http://www.icer-review.org/dpp-initial-scope-posted/>. Accessed March 24, 2016.
6. Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular outcomes in type 1 diabetes: The DCCT/EDIC Study 30-year follow-up. *Diabetes Care*. 2016. doi 10.2337/dc15-1990.
7. Centers for Disease Control and Prevention. Heart disease facts. 2015. <http://www.cdc.gov/heartdisease/facts.htm>. Accessed March 6, 2016.
8. Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *New England Journal of Medicine*. 2005. 353(25): 2643-2653.
9. Writing Group for the DCCT/EDIC Research Group. Association between 7 years of intensive treatment of type 1 diabetes and long-term mortality. *Journal of the American Medical Association*. 2015. 313(1): 45-53.
10. Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group, Lachin JM, White NH, Hainsworth DP, Sun W, Cleary PA, Nathan DM. Effect of intensive diabetes therapy on the progression of diabetic retinopathy in patients with type 1 diabetes: 18 years of follow-up in the DCCT/EDIC. *Diabetes*. 2015. 64(2): 631-642.
11. Nathan DM for the DCCT/EDIC Research Group. The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study at 30 years: Overview. *Diabetes Care*. 2014. 37(1): 9-16.
12. Martin CL, Albers JW, Pop-Busui R, DCCT/EDIC Research Group. Neuropathy and related findings in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study. *Diabetes Care*. 2014. 37(1): 31-38.
13. Fischer HH, Fischer IP, Pereira RI, et al. Text message support for weight loss in patients with prediabetes: A randomized clinical trial. *Diabetes Care*. 2016. doi 10.2337/dc15-2137.
14. Centers for Medicare and Medicaid Services. Quality measures: Core measures. 2016. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf>. Accessed February 26, 2016.
15. Chamberlain JJ, Rhinehart AS, Shaefer CF, Jr., Neuman A. Diagnosis and management of diabetes: Synopsis of the 2016 American Diabetes Association Standards of Medical Care in Diabetes. *Annals of Internal Medicine*. 2016. doi 10.7326/M15-3016.
16. Omada Health Inc. 2016. The Patient Experience. <http://omadahealth.com>. Published February 18, 2016. Accessed May 3, 2016.
17. Anderson AE, Kerr WT, Thames A, Li T, Xiao J, Cohen MS. Electronic health record phenotyping improves detection and screening of type 2 diabetes in the general United States population: A cross-sectional, unselected, retrospective study. *Journal of Biomedical Informatics*. 2016. 60 (April): 162-168.
18. Lynch CP, Williams JS, Voronca D, Walker RJ, Egede LE. Meaning of illness and cardiovascular risk factors in patients with type 2 diabetes. *Diabetes Educator*. 2016. doi: 10.1177/0145721716631430.
19. Hibbard JH, Greene J, Sacks R, Overton V, Parrotta CD. Adding a measure of patient self-management capability to risk assessment can improve prediction of high costs. *Health Affairs*. 2016. 35(3): 489-494.
20. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient glucose monitoring consensus statement. *Endocrine Practice*. 2016. 22(2): 231-261.
21. Centers for Disease Control and Prevention. National diabetes statistics report, 2014. CDC website. <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>. Accessed June 1, 2014