Economic and Clinical Evidence Concerning Continuous Glucose Monitoring and the Medicare Covered Population

Michael J. O'Grady, PhD[1]

In diabetes care, Medicare is often at a disadvantage compared to other payers. Another payer's lack of investment for preventive care in younger patients generally results in higher spending by Medicare in later years. The continuous glucose monitor (CGM) has the opposite dynamic: Investments made before a patient is eligible for Medicare yield savings to the Medicare program. Major private payers have been willing to cover the use of continuous glucose monitoring. These private payers reap the short-term saving, but Medicare reaps the long-term saving in reduced spending on end-stage renal disease (ESRD), stroke, heart disease and the other serious and expensive complications of diabetes.

Background:

Diabetes is one of the Medicare program's biggest challenges, both debilitating and expensive. However, the treatment of diabetes has been improving dramatically, with breakthroughs in the scientific understanding of the dynamics and treatment of the disease. In addition, technologies to improve diabetes care have advanced considerably with the introduction of the insulin pump and continuous glucose monitor.

The Science Base

The Diabetes Control and Complications Trial (DCCT)—funded by the National Institutes of Health—was the landmark study demonstrating that controlling the glucose level of a person with diabetes could prevent complications such as kidney failure, heart attack, stroke, blindness, and amputation. Controlling glucose levels means avoiding high and low levels and keeping average levels as close as possible to those of someone without diabetes.

[1] Since resigning as Assistant Secretary for Planning and Evaluation (ASPE) at the end of the second Bush Administration, I have focused my work on health economic analysis of clinical trials in diabetes. In particular Type 1 diabetes. This work has resulted in eleven peer reviewed journal articles, including four on the economic impact of continuous glucose monitoring. I currently am involved in a clinical trial funded by the CGM maker Dexcom, as a subcontractor to the University of Chicago.

Well controlled diabetes, what the DCCT called intensive control, results the outcomes displayed below. Conventional therapy represents the typical treatment provided to patients.

Cumulative Incidence at Age 70 Years of Selected Health States for Patients Managed With Conventional or Intensive Therapy[2]

Health State	Conventional, _%	Intensive, _%
Background retinopathy	98	95
Proliferative retinopathy	70	30
Macular edema	56	35
Blindness	34	20
Microalbuminuria	86	64
Albuminuria	46	15
End-stage renal disease	24	7
Neuropathy	57	31
Lower extremity amputation	7	4

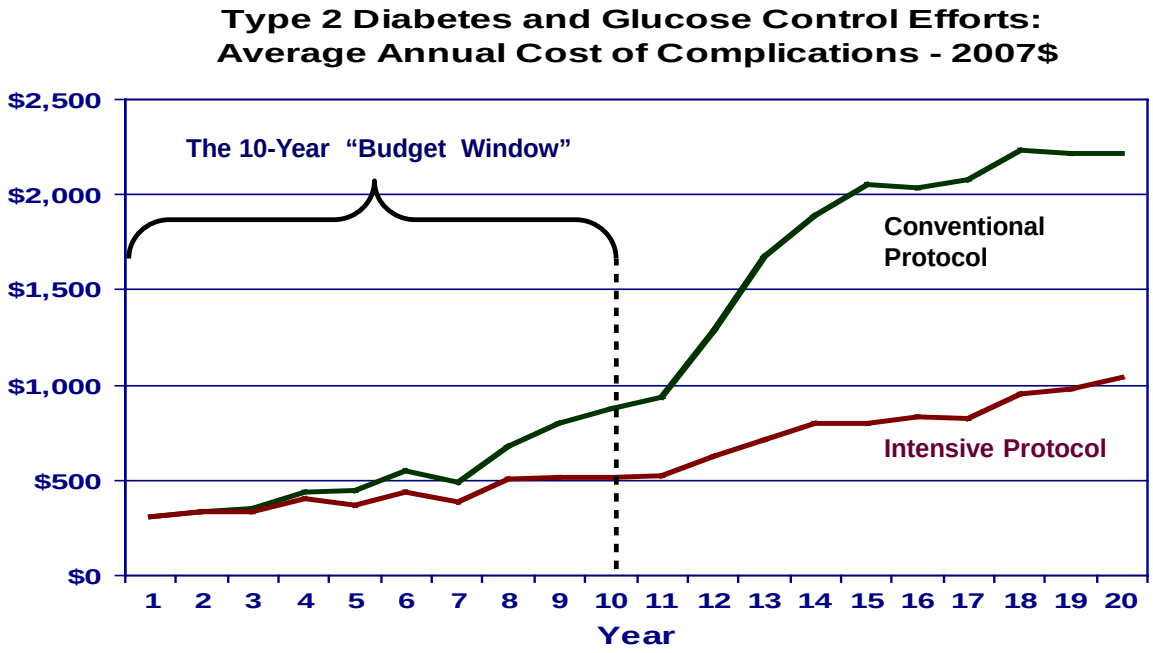
Of particular importance for Medicare are the effects on the incidence of end-stage-renal disease (ESRD). ESRD incidence drops from 24 percent to 7 percent – a 71 percent reduction. ESRD is one of the most debilitating and costly conditions Medicare covers.

The spending impacts can be seen in the chart below. The chart shows the progression of the disease for those under tight control (intensive) and conventional control and the difference in their spending over time. This data is for patients for Type 2 diabetes, but the disease progression is similar. The chart also highlights why the savings associated with tight control are often not captured by conventional costs estimates. With chronic disease like diabetes,

[2] Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. The Diabetes Control and Complications Trial Research Group. JAMA 1996;276(17), p. 1412.

the savings associated with tighter control often occur outside the traditional ten-year budget window.

Disease Progression, and Effect of Treatment – The NIDDK Model



Source: National Changing Diabetes Programs: Federal Health Care Cost Estimating: A Look at Current Practice and the Implications for Assessing Chronic Disease Prevention Proposals.

Controlling glucose levels is difficult, labor-intensive and costly for patients. In particular, nocturnal hypoglycemia is of great concern to caregivers of seniors and children with type 1 diabetes, given the danger that they could go into "insulin shock" or even die during the night.[3]

[3] Barnard, K., S. Thomas, P. Royle, K. Noyes and N. Waugh (2010). "Fear of hypoglycaemia in parents of young children with type 1 diabetes: a systematic review." BMC Pediatrics 10(1): 50.

The Clinical Picture

Continuous glucose monitoring allows the patient to see his or her glucose reading every five minutes, providing a powerful new tool in fine-tuning glucose control. Its introduction was a major breakthrough and an improvement over the traditional finger-stick tests, which are typically done five or six times a day. The latest generation of CGMs, those included in the CMS coverage decision, go even farther. FDA confirmed that his new generation can actually replace the finger stick test for determining accurate insulin doses. Greatly simplifying the patient's own clinical decision making and greatly reducing finger stick test costs for both patient and insurer.

In addition, the continuous glucose monitor has an alarm system that alerts patients when their glucose level is too high or low. This technology has greatly reduced the number of cases of dangerous or deadly hypoglycemia and improved patients' quality of life.[4]

In a patient-funded clinical trial, the clinical and cost effectiveness of continuous glucose monitoring was established.[5] The study had four test cohorts. Two of the four were found to be both clinically effective and cost effective. The two groups were patients 25 years of age and older and patients who were already had HbA1c scores below 7.0 (whatever age).[6] The other two cohorts, young children and teenagers, did not have clinically effective outcomes, so cost effectiveness was not calculated.

The Policy Context

Public insurers typically have been slow to cover these new technologies, e.g., CGMs and insulin pumps. In Medicare's case, this slowness to cover new technologies may be a function

[4] Huang ES, O'Grady M, Basu A, Winn A, John P, Lee J, et al. The cost-effectiveness of continuous glucose monitoring in Type 1 diabetes. Diabetes Care. 2010;33(6):1269-74.

[5] In 2006, the Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study was created. JDRF is the major patient group for people with type 1 diabetes.
"Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes," The New England Journal of Medicine; September 8, 2008. p. 1464-76. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group.

[6] HbA1c (Glycated hemoglobin) is the leading blood test used to both diagnose and manage diabetes, It is a form of hemoglobin that is measured primarily to identify the three-month average plasma glucose concentration. Clinical guidelines (Amer. Diabetes Assoc.) define well controlled diabetes as achieving an HbA1c of 7.0 or less.

of the changing demographics of the population with type 1 diabetes. Before the recent generation of clinical improvements, most patients with type 1 diabetes either did not live long enough to age into Medicare. The latest research shows a difference in life expectancy (at age 50) of only about two years between the general population and the Type 1 population diagnosed after 1965.[7]

At least, five of the largest insurance companies in the United States—UnitedHealth Group, Wellpoint, Kaiser Permanente, Aetna, and Humana[8]—all cover continuous glucose monitoring for the Type 1 cohorts where CGMs were shown to be both clinically effective and cost effective, e.g., adults and patients with HbA1c scores below 7.0.[9]

Cost and Spending Implications for Medicare

An analysis of the peer-review literature did not find estimates of Medicare spending associated with the coverage of CGMs. However, there are estimates of the effects on Medicare spending of covering an artificial pancreas (AP), which is the next level of technology. The AP links insulin pumps with CGMs with software that automatically dispenses insulin when needed.[10]

The artificial pancreas study is the closest in clinical and cost characteristics to the coverage of CGMs by Medicare. The cost is higher than simply the sum of the cost of a CGM and Insulin pump, given the cost associated with the additional software needed to link the insulin pump and CGM. At the same time, the potential reduction in HbA1c is less, so glucose management is not as controlled. Given that these two factors have an offsetting effect on costs, the analogy should prove illustrative.

---

[7] Miller, Rachel G., et al., "Improvements in the Life Expectancy of Type 1 Diabetes: The Pittsburgh Epidemiology of Diabetes Complications Study Cohort." Diabetes 61:2987–2992, 2012.

[8] US News and World Report. The top 25 health insurance companies [Internet]. US News and World Report [serial on the Internet]. 2012 [cited 2012 Jul 5]. Available from: http://health.usnews.com/health-plans/national-insurance-companies

[9] "Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes," The New England Journal of Medicine; September 8, 2008. p. 1464-76. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group.

[10] "Substantial Medicare Savings May Result If Insurers Cover 'Artificial Pancreas' Sooner For Diabetes Patients," O'Grady, Michael J., Priya John and Aaron Winn, Health Affairs, 31, no.8 (2012):1822-1829.

The study found that total Medicare spending would decrease greatly if the program covered the cost of an artificial pancreas. By reducing hypoglycemia, low glucose levels, that can lead to seizures and even death, short-term spending is reduced by avoiding emergency medical treatment. By reducing hyperglycemia, high glucose levels, spending on long-term complications such as stroke, heart disease, blindness, end-stage renal disease, and amputation was reduced.

The cumulative savings associated with avoiding costly complications build over time. By the 10-year mark, the traditional Office of the Actuary and Congressional Budget Office window for cost estimates, Medicare's cumulative spending had increased by $44 million compared to what it would be without the adoption of the artificial pancreas. By the 25-year mark, however, Medicare's cumulative savings were $937 million.

Because complications of type 1 diabetes often take more than 10 years to appear, the authors used a 25-year window to more accurately assess the impact. That window captures the full dynamics of costs and offsetting savings that result from reductions in complications.

Conclusion

As Medicare begins to cover and pay for CGM technology all evidence points to positive outcome in both clinical improvement and cost-effective care. The private sector has already made the investment in the younger population and have reaped the short-term savings associated with tight glucose control and reduced risk of both hyperglycemia and hypoglycemia. The extensive research on the disease progression of diabetes and its tragic and costly complications shows that "tight control" of glucose levels, combined with effective strategies to avoid the dangers of hypoglycemia (insulin shock) can reduce the likelihood of complications significantly and increase life expectancy to almost the same level as the general population.

This is an opportunity to reverse the typical scenario where lack of investment in preventive care by private insurers at younger ages results in higher spending by Medicare later in the

patient's life. The private sector has stepped up to provide coverage and pay for CGM. They have been willing to do this because it is the right thing clinically, but also because it is a cost effective new technology that makes actuarial sense, even if they leave the long term savings to the Medicare program.

CGM's provide Medicare with an opportunity to continue the wise investment made by the private insurers and continue uninterrupted this new technology that has proven itself both clinically and cost effective. The private insurers pay competitively for CGM technology, but as with other services no more than they need to. Medicare can embrace this opportunity and continue to build on the investments made by others. A scenario where patients who have successfully controlled their diabetes for years prior to aging into Medicare, only to lose access to CGM technology when they join Medicare, is both bad medicine and bad economics.