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# Substantial Medicare Savings May Result If Insurers Cover 'Artificial Pancreas' Sooner For Diabetes Patients

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**ABSTRACT** Technologies to improve diabetes care have advanced considerably with the introduction of the insulin pump and continuous glucose monitoring. These two technologies are now being joined and enhanced to create an artificial pancreas. The current study models the impact of the artificial pancreas on clinical results and costs over time, based on early results from clinical trials. The modeling shows that insurers' coverage of the cost of an artificial pancreas at a relatively early point in the life of a patient with diabetes would greatly reduce future complications of the disease and spending needed to treat such complications. Projected Medicare savings are \$937 million in nominal dollars after twenty-five years. The results of this analysis support conducting a more comprehensive trial to assess the long-term impact of the artificial pancreas on glucose levels and the technology's related costs.

**D**iabetes is one of the Medicare program's biggest challenges. It is a debilitating and expensive chronic illness. In 2008, 25.4 percent of Medicare fee-for-service beneficiaries had a diagnosis of either type 1 or type 2 diabetes.<sup>1</sup> In the same year, diabetes and diabetes-related services accounted for an astounding 41.8 percent of Medicare's fee-for-service spending.<sup>1</sup> However, the treatment of diabetes has been improving dramatically, thanks to breakthroughs in the scientific understanding of the dynamics and treatment of the disease.

## The Science Base

The Diabetes Control and Complications Trial—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.<sup>2</sup> Controlling glucose levels means avoiding high and low levels and keeping average

levels as close as possible to those of someone who does not have diabetes.

However, controlling glucose levels is very difficult as well as very labor-intensive and costly for patients. The recommended treatment for patients with type 1 diabetes includes multiple daily insulin injections and finger-stick glucose tests to check glucose levels. A low glucose level, or hypoglycemia, is often an issue for insulin users, and severe episodes can result in emergency department visits or death. In particular, nocturnal hypoglycemia is of great concern to caregivers of children with type 1 diabetes, given the danger that a child could develop complications and even die during the night.<sup>3</sup>

## The Clinical Picture

There have been major advances over the last few decades in technologies to improve glucose control. Most notable are two new devices, the insulin pump and the real-time continuous glucose monitor. The pump gives the patient the ability to more precisely match his or her insulin doses

to the insulin secretions of a normal, healthy pancreas.

Continuous glucose monitoring allows the patient to see his or her glucose reading every three to 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. In addition, the continuous glucose monitor has an alarm system that alerts patients when their glucose level is too high or low. These technologies have greatly reduced the number of cases of dangerous or deadly hypoglycemia and improved patients' quality of life.<sup>4</sup>

The additional technology needed to "close the loop" between the monitor and the pump is currently being refined. Although using an insulin pump and continuous glucose monitor separately requires the patient to make dosing decisions throughout the day, this new technology adds a dosing algorithm that allows the device to select the appropriate amount and deliver the insulin, allowing for much more refined insulin dosing. This refinement further increases the ability to more precisely match insulin doses to the insulin secretions of a normal, healthy pancreas. This combination of technologies is referred to as an artificial pancreas.

The idea of an artificial pancreas has been around for some time, and recent pilot studies have demonstrated its feasibility.<sup>5-7</sup> The goal is to give patients better glucose control than ever before possible, without the current danger of hypoglycemia. Early clinical trial results show glucose control that is better and sustained over a longer period than current practice permits.<sup>6,7</sup>

Currently the artificial pancreas is intended for people with type 1 diabetes. However, it is not uncommon to try a treatment first on the type 1 population and introduce it later to the type 2 population. An example is insulin therapy. If the artificial pancreas proves effective in both the type 1 and type 2 populations, the savings could be substantial.

Although the short-term results of the artificial pancreas are very promising, there is little evidence so far about the efficacy of its longer-term use and the associated treatment and complication costs. However, it is possible to model the effects of good glucose control over time, based on decades of data from a range of clinical trials conducted by the National Institutes of Health, the Centers for Disease Control and Prevention, and others.<sup>2,8,9</sup>

Initial results from the pilot tests that have utilized the artificial pancreas indicate that the system allows patients who use it to stabilize their glucose level throughout the day. The

results also indicate that patients will be able to have much better long-term glucose control than is possible with the technology that is standard today.

## The Policy Context

The artificial pancreas is still in development and has not yet been approved by the Food and Drug Administration (FDA). However, the agency has included the artificial pancreas as part of its Critical Path Initiative. This initiative is the agency's national strategy to drive innovation in the scientific processes through which medical products are developed, evaluated, and manufactured.<sup>10</sup> The FDA has also offered design and testing recommendations aimed at easing the approval process, while still meeting statutory requirements for safety and effectiveness.<sup>11</sup> The trials required for that approval are still in the planning stages, and an FDA-approved artificial pancreas available outside a clinical trial setting is still a number of years in the future.

Coverage and reimbursement decisions will not be made until the FDA has approved the artificial pancreas, but the history of coverage and reimbursement for both insulin pumps and continuous glucose monitors offers some lessons.

Public insurers have been slow to cover these new technologies. Insulin pumps have been on the market for at least fifteen years and are generally covered by Medicare. However, continuous glucose monitoring is covered by Medicare only on a case-by-case basis. Medicaid is even slower than Medicare: Only seventeen states cover insulin pumps in their Medicaid programs, and no state Medicaid program appears to cover continuous glucose monitoring.

In Medicare's case, this slowness to cover new technologies may be a function 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 be enrolled in Medicare or lived long enough to be in the program for only a few years. However, current estimates of Medicare claims data indicate that there may be at least 900,000 Medicare beneficiaries with type 1 diabetes.<sup>12</sup>

Given this substantial number of beneficiaries and the potential implications of the new technologies for future use by people with type 2 diabetes, Medicare will be under increasing pressure to consider covering effective new technologies. The number of people with diabetes who are eligible for Medicare is expected to rise from 8.2 million in 2009 to 14.6 million in 2034; associated spending is predicted to rise from

\$45 billion to \$171 billion per year.<sup>13</sup>

Although there is no comprehensive compilation of coverage decisions in the private sector, commercial insurers appear to have been much more receptive to these new technologies. For example, private insurers have covered insulin pumps for people with type 1 diabetes for many years (Cynthia Rice, vice president for government relations, Juvenile Diabetes Research Foundation, personal communication, October 28, 2008). The Juvenile Diabetes Research Foundation has actively campaigned for coverage of continuous glucose monitors and, as part of that effort, has found that most commercial insurers cover them.<sup>14</sup>

For example, the five largest insurance companies in the United States—UnitedHealth Group, Wellpoint, Kaiser Permanente, Aetna, and Humana<sup>15</sup>—all cover continuous glucose monitoring for at least some populations. In an interesting example of the use of both clinical and cost-effectiveness analyses, the subpopulations most likely to have coverage are those for which the peer-reviewed literature showed both types of effectiveness.<sup>4,16</sup>

In the studies of both types of effectiveness of continuous glucose monitoring, the trial population was broken into the following four subpopulations: subjects ages 8–14 with hemoglobin A1c (the current best measure of glucose control) of 7.0 percent or less; those ages 15–24 with the same HbA1c percentage; those age 25 or older with the same HbA1c percentage; and those of any age with HbA1c below 7.0 percent.<sup>4,16</sup> Continuous glucose monitoring was found to be effective in both clinical and cost terms for the last two subpopulations. In the subpopulation with HbA1c levels below 7.0 percent, subjects also had an improvement in quality of life associated with the reduction in the number of dangerously low hypoglycemic events.

The insurers operationalized these results as follows: Kaiser Permanente covers all patients with type 1 diabetes; Aetna and Wellpoint cover all patients with type 1 diabetes over age twenty-five and younger patients who have recurrent severe hypoglycemia; UnitedHealth Group covers patients with type 1 diabetes who have not achieved optimum control or have experienced hypoglycemic unawareness (that is, hypoglycemia that causes a person to be nonresponsive); and Humana covers patients with type 1 diabetes who have poor glycemic control, recurring severe hypoglycemia, or hypoglycemic unawareness despite compliance to prescribed treatment.<sup>14</sup>

## Study Data And Methods

Simulation modeling is an efficient way to take pilot trial findings and project the results for a larger population. Additionally, simulation modeling can help determine if a technology could potentially result in health improvements or cost savings and if a large-scale randomized controlled trial is warranted.

Over the past decade there have been important advances in the modeling of the complications of diabetes and its treatments, with the availability of data from groundbreaking clinical trials such as the Diabetes Control and Complication Trial and the UK Prospective Diabetes Study.<sup>8,9</sup>

To extrapolate the effects of the use of the artificial pancreas and analyze the lifetime risk of major diabetes complications, we developed a computer simulation model that used clinical inputs—such as blood pressure, cholesterol, and HbA1c—from an average group of people with type 1 diabetes. This framework of clinical inputs and complications has been used by prior cost-effectiveness analyses of treatments in type 1 diabetes.<sup>4</sup> The cost and savings estimates were based on the type of modeling used by the Congressional Budget Office and the Office of the Actuary at the Centers for Medicare and Medicaid Services to measure changes in Medicare spending both with and without patients' adoption of the artificial pancreas.

For this analysis, the effect of the artificial pancreas was an improvement in glucose control. As demonstrated by the Diabetes Control and Complications Trial and UK Prospective Diabetes Study, improved glucose control reduced the lifetime risk of major diabetes complications and mortality due to complications.<sup>8,9</sup> For example, if using the artificial pancreas resulted in the avoidance of a patient's stroke, our model captured this as a saving of the average amount spent by Medicare when a beneficiary with type 1 diabetes had a stroke.

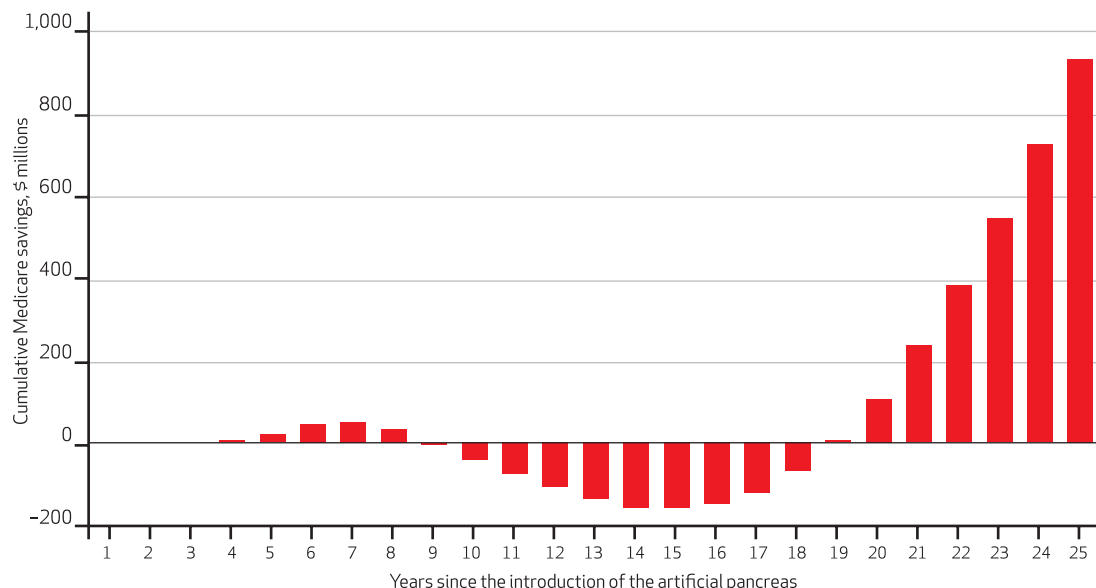
The model also captured the spending associated with providing the artificial pancreas to patients and any additional spending associated with the potentially longer life enjoyed by patients equipped with the artificial pancreas. A detailed description of the model's inputs and simulation assumptions is available in the online Appendix.<sup>17</sup>

## Study Results

We estimated that total Medicare spending would decrease greatly if the program covered the cost of an artificial pancreas along with ongoing supplies (Exhibit 1). With type 1 diabetes, hypoglycemia—glucose levels below those of

**EXHIBIT 1**

**Estimated Medicare Savings By Introducing Coverage Of The Artificial Pancreas For Beneficiaries Ages 30–60 With Type 1 Diabetes**



**SOURCE** Authors' modeling. **NOTES** We assumed that 85 percent of Medicare beneficiaries used the artificial pancreas once it was introduced, at year 1. We assumed that 17 percent of the beneficiaries who did not use the artificial pancreas used continuous glucose monitors and 39 percent used insulin pumps. For a full description of the model, see the online Appendix (Note 17 in text).

people without diabetes—can lead to seizures and even death. Avoiding episodes of hypoglycemia reduces short-term spending by avoiding emergency medical treatment. Hyperglycemia—glucose levels higher than 150 percent of the level of a person without diabetes—can lead to long-term complications such as stroke, heart disease, blindness, end-stage renal (kidney) disease, and amputation, all of which involve long-term costs.

Better glucose control helps avoid both types of problems and their associated costs. However, most of the savings in our modeling resulted from avoiding or delaying the long-term complications associated with poor glucose control.

After a number of years, the cumulative savings associated with avoiding costly complications through the use of an artificial pancreas start to build (Exhibit 1). By the ten-year mark, the traditional Congressional Budget Office window for cost estimates, Medicare's cumulative spending has increased by \$44 million, compared to what it would be without the adoption of the artificial pancreas. By the twenty-five-year mark, however, Medicare's cumulative savings are \$937 million.

Because complications of type 1 diabetes often take more than ten years to appear, we believe that using a twenty-five-year window is a more accurate way to assess the impact of the artificial

pancreas. That window captures the full dynamics of costs and offsetting savings that result from reductions in complications.

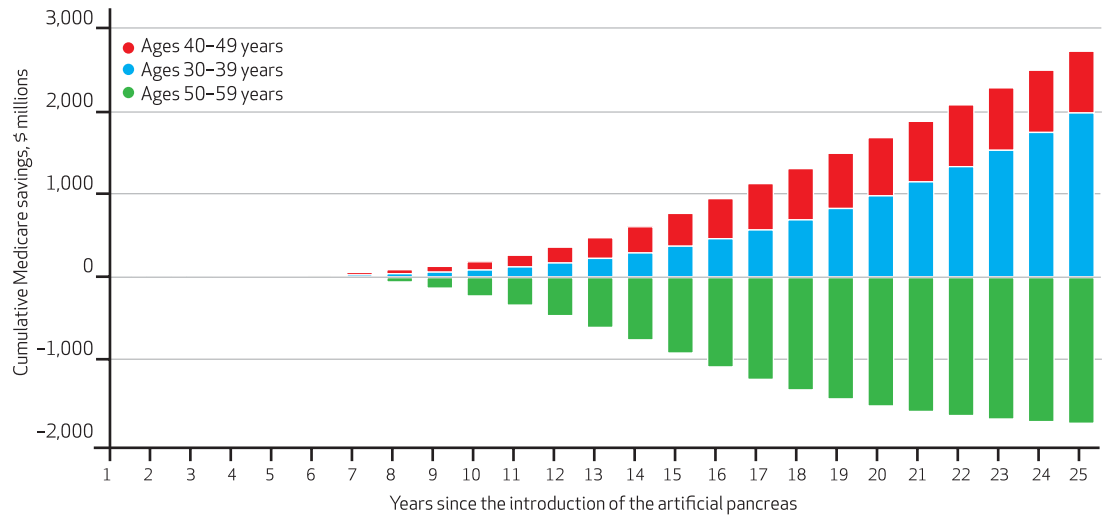
The patterns of spending and saving differ somewhat between the younger and older subgroups of beneficiaries (Exhibit 2). Given the way diabetes progresses over time, the sooner a patient is able to achieve and maintain good glucose control, the greater his or her chances of avoiding—or at least delaying—complications. For example, a patient with diabetes and good control might still develop a condition like congestive heart failure, but that would probably happen when the patient was in his or her eighties (when people without diabetes typically develop congestive heart failure), rather than in his or her sixties (the typical age for people with diabetes today).

Although the results of our simulation are compelling, the current clinical results do not reflect how technology improves over time. One of the hopes for both the continuous glucose monitor and the artificial pancreas is that they will allow patients to reduce the use of test strips, which add substantially to the cost of diabetes care.

To test the sensitivity of costs to the number of test strips used, our model decreased the number of test strips for subjects when they transitioned to the artificial pancreas or continuous glucose

EXHIBIT 2

Estimated Medicare Savings By Introducing Coverage Of The Artificial Pancreas For Beneficiaries With Type 1 Diabetes, By Age Group



**SOURCE** Authors' modeling. **NOTES** We assumed that 85 percent of Medicare beneficiaries used the artificial pancreas once it was introduced, at year 1. We assumed that 17 percent of the beneficiaries who did not use the artificial pancreas used continuous glucose monitors and 39 percent used insulin pumps. For a full description of the model, see the online Appendix (Note 17 in text).

monitoring. Exhibit 3 shows the Medicare savings that could result if the number of test strips used by patients was reduced by 75 percent or 50 percent from the baseline case of 2,008 test strips per patient per year. It is clear that the number of strips used has a large impact on the overall cost of diabetes care.

Exhibit 4 shows the results of a scenario in which the simulated population of Medicare beneficiaries received only half of the improvement in glucose control that we modeled earlier (Exhibit 1). In this scenario, more complications occurred, and more of them occurred earlier in the patient's life. The complications were not as numerous as in the current situation, without an artificial pancreas, but more plentiful than would occur if the results from clinical trials were fully generalizable to all Medicare beneficiaries.

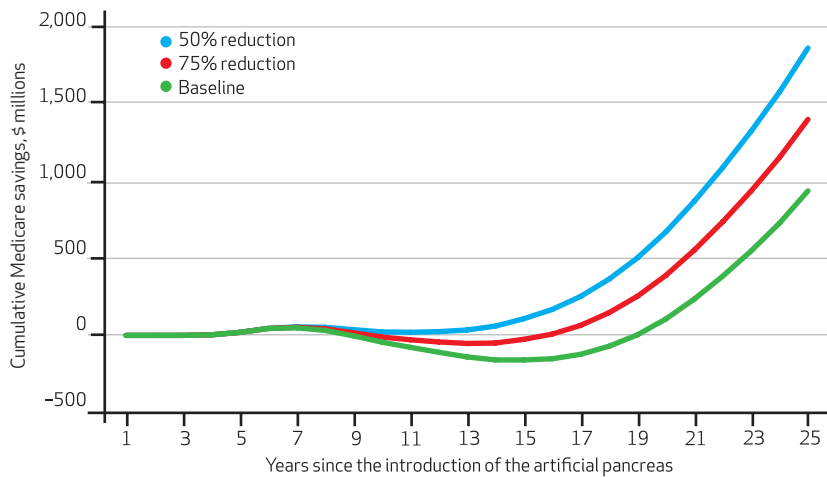
By the ten-year mark, Medicare's cumulative spending increased by \$76 million, compared to the increase of \$44 million shown in Exhibit 1. By the twenty-five-year mark, Medicare's cumulative savings were \$357 million, compared to \$937 million in Exhibit 1.

We performed additional sensitivity analyses estimating Medicare savings under multiple scenarios. These scenarios included variations in the simulated population's rate of adoption of the artificial pancreas and use of the insulin pump and continuous glucose monitoring; costs of the artificial pancreas; and the effect of its use on patients' HbA1c levels. Under all of the scenarios, use of the artificial pancreas resulted in cost savings to Medicare at the twenty-five-year mark (see the online Appendix for a detailed diagram depicting these analyses).<sup>17</sup>

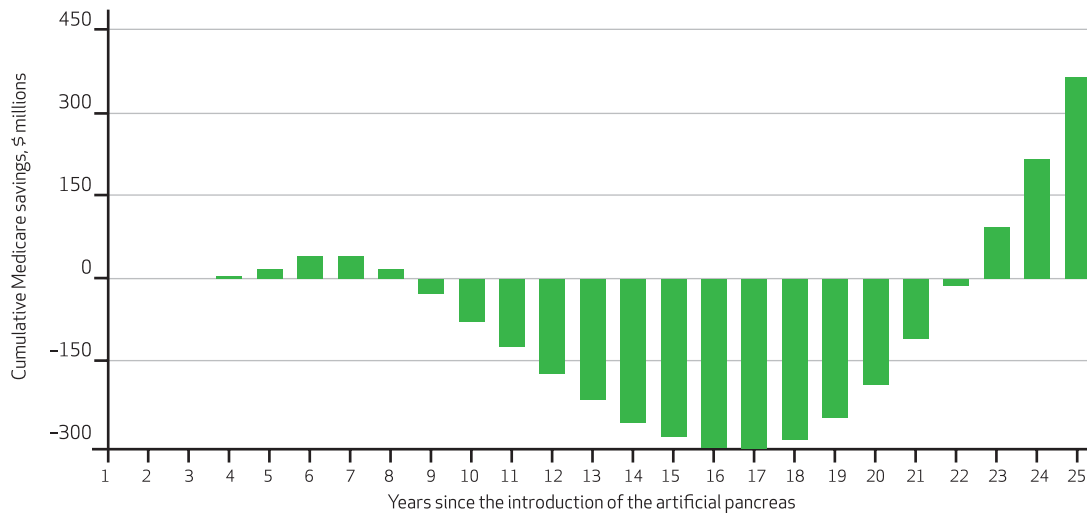
There are limitations to this study. The major limitation is that the results are based on early studies with relatively small sample sizes and

EXHIBIT 3

Estimated Medicare Savings By Introducing Coverage Of The Artificial Pancreas For Beneficiaries Ages 30-60 With Type 1 Diabetes, By Differing Test Strip Usage



**SOURCE** Authors' modeling. **NOTES** Baseline usage of test strips is 2,008 per patient per year; 75 percent of that usage is 1,506 strips, and 50 percent is 1,004 strips.

**EXHIBIT 4****Estimated Medicare Savings By Introducing Coverage Of The Artificial Pancreas For Beneficiaries Ages 30–60 With Type 1 Diabetes, Assuming Only Half Of The Clinical Benefit**

**SOURCE** Authors' modeling. **NOTE** This scenario assumes only half of the improvement in glucose control shown in the other exhibits.

limited time horizons. Once full clinical trials are complete, we will be in a stronger position to estimate the full effects of the artificial pancreas.

Another limitation, or at least complication, is the existence of strong interactions between input costs—particularly the cost of test strips and the cost associated with how often patients change their continuous glucose monitor's sensors. In our first sensitivity analysis, estimated Medicare savings doubled, from \$0.9 billion to \$1.8 billion. The underlying assumption in this analysis was that the use of test strips would drop as the accuracy of the glucose monitor improved and patients became comfortable with relying more on the artificial pancreas.

### Conclusion

In diabetes care, Medicare is often at a disadvantage compared to other payers. Another insurer's lack of investment in care to prevent diabetes complications in younger patients generally results in higher spending by Medicare in patients' later years. Adoption of the artificial pancreas would have the opposite effect: Investments made before a patient is eligible for Medicare yield savings to the Medicare program. As discussed earlier in this article, major insurers have been willing to cover the use of continuous glucose monitoring—which is very cost-effective though not cost-saving<sup>4</sup>—and we believe they will also be willing to cover the cost of the artificial pancreas.

The results of our model indicate that as time

passes, the savings associated with avoiding costly complications start to build. By the twenty-five-year mark, Medicare would save \$937 million in nominal dollars—or \$461 million in dollars discounted to take into account the time value of money. As this cohort of people ages and major complications are avoided, the savings grow.

Saving a little under a billion dollars might not seem particularly important for Medicare's long-term financial viability. However, it should be kept in mind that these savings are accruing over a relatively small subpopulation of beneficiaries. The clinical results we simulated were for people with type 1 diabetes, although the vast majority of Medicare beneficiaries with diabetes have type 2.

As noted above, currently, the artificial pancreas is intended for people with type 1 diabetes. However, it is not uncommon to try a treatment first on the type 1 population and introduce it later to the type 2 population. An example is insulin therapy. If the artificial pancreas proves effective in both the type 1 and type 2 populations, the Medicare savings will be much more than estimated here.

Because of the nature of diabetes and the substantial spending on complications that occurs in patients' later years, a new technology that can slow or stop the progression of diabetes complications has the potential to deliver clinical improvements, while simultaneously reducing spending on expensive complications. The early clinical results associated with the new artificial

pancreas are strong indicators that it will do just that.

In this study we looked at the potential reductions in Medicare spending that could result from use of the artificial pancreas. The results

of this analysis support conducting a more comprehensive trial to assess the long-term impact of the artificial pancreas on glucose levels and the technology's related costs. ■

This article was adapted in part from analysis conducted by the authors for the Juvenile Diabetes Research Foundation. Additionally, a version of

this article was presented at AcademyHealth in Orlando, Florida, June 2012. The authors thank Elbert Huang and two anonymous reviewers for their

thoughtful comments. The views expressed are those of the authors and do not necessarily reflect the views of others.

## NOTES

- 1 Authors' analysis, using the definition of *diabetes* used by the Centers for Medicare and Medicaid Services to risk-adjust Medicare Advantage payments. CMS.gov. Risk adjustment [Internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; [last modified 2012 Apr 25; cited 2012 Jul 5]. Available from: [http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk\\_adjustment.html](http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk_adjustment.html)
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- 12 Our analysis of the 2008 fee-for-service Medicare claims with a diagnosis code for diabetes (see Note 1) indicated that 912,280 fee-for-service beneficiaries received services with the *International Classification of Diseases*, Ninth Revision (ICD-9), code 25001 (for "Diabetes Mellitus without mention of complication, Type I (juvenile type), not stated as uncontrolled") and 215,740 fee-for-service beneficiaries received services with the ICD-9 code 25003 (for "Diabetes Mellitus without mention of complication, Type I (juvenile type), uncontrolled"). Given that the same patient might be coded as uncontrolled at one point in the year and controlled at another, we hesitated to simply add the two numbers together. If the only claim with one of these codes was for screening the patient, we did not count the beneficiary as having diabetes.
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- 17 To access the Appendix, click on the Appendix link in the box to the right of the article online.



## ABOUT THE AUTHORS: MICHAEL J. O'GRADY, PRIYA JOHN & AARON WINN



**Michael J. O'Grady** is a senior fellow at NORC at the University of Chicago.

In this month's *Health Affairs*, Michael O'Grady and coauthors describe their modeling of the clinical and budgetary impact of technologies known as the "artificial pancreas," and the potential to save money for Medicare from better outcomes for diabetes patients. The authors conclude that if Medicare covered the cost of an artificial pancreas at a relatively early point in the life of a patient with diabetes, the reduction in complications would save Medicare \$937 million in nominal dollars after twenty-five years. The authors recommend that these results be tested in a more comprehensive trial that would assess the long-term impact on patients and costs.

O'Grady is president of the West Health Policy Center where he is responsible for establishing the center's programs; activities; operations; Washington, D.C. presence; and its reputation. The center's main activities include conducting independent, nonpartisan research and analysis; convening and educating stakeholders; and advancing practical and actionable health

policy. It is part of a larger initiative, including the West Wireless Health Institute and West Health Investment Fund, created by Gary and Mary West to lower the cost of health care.

From 2003 to 2005 O'Grady was the assistant secretary for planning and evaluation at the Department of Health and Human Services, where he directed both policy development and policy research. Prior to joining the department, O'Grady served as the senior health economist on the majority staff of the Joint Economic Committee of Congress. Previously, he held senior staff positions at the Senate Finance Committee, the Bipartisan Commission for the Future of Medicare, the Medicare Payment Advisory Commission, and the Congressional Research Service at the Library of Congress. He received his doctorate in political science from the University of Rochester.



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