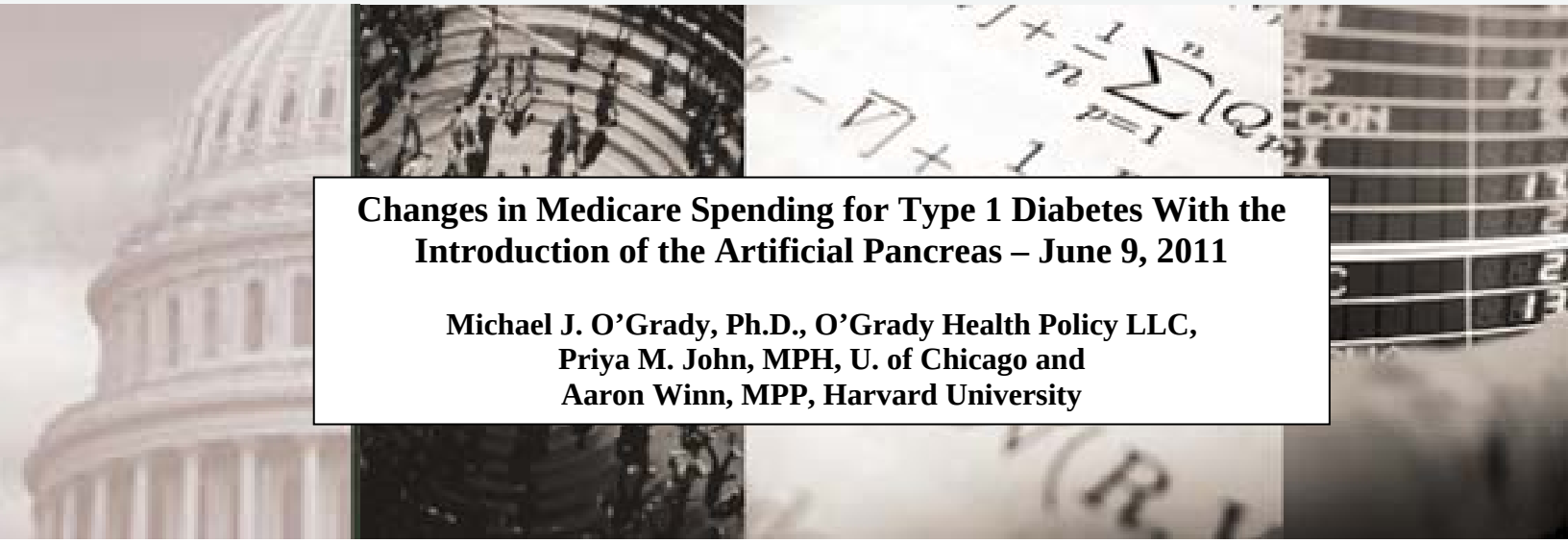
O'GRADY HEALTH POLICY LLC



Changes in Medicare Spending for Type 1 Diabetes With the Introduction of the Artificial Pancreas – June 9, 2011

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Study Summary:

The technologies to improve the management of diabetes have advanced significantly over the last few decades, most notably with the introduction of the insulin pump and the continuous glucose monitor (CGM). Clinical trials have long demonstrated that the tighter the management of glucose levels the greater the probability of avoiding devastating and costly complications later in life.[1] These two technologies provide the patient with unparalleled control over the management of their glucose levels compared to the usual therapy of insulin shots and self-glucose monitoring.[2]

These two technologies are now being joined and enhanced in the form of an artificial pancreas, whereby an insulin pump and CGM will work together automatically to achieve even tighter glucose control. The current study takes those early results[3] and models their implications over time. The model estimates both the clinical improvements that can be expected given the tighter glucose control, as well as the changes in long term spending to treat complications, complications that could now be avoided by the use of the artificial pancreas.

The population with type 1 diabetes ages 30 to 60 was modeled over a 25 year period. The progression of the disease and the complications associated with diabetes was estimated using

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[1] The Diabetes Control and Complications Trial Research Group. Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. JAMA 1996;276:1409-15.

[2] "Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes," The New England Journal of Medicine 2008; 359. September 8, 2008. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group.

[3] Kowalski AJ. *Can we really close the loop and how soon? Accelerating the availability of an artificial pancreas: a roadmap to better diabetes outcomes.* Diabetes Technol Ther. Jun 2009;11 Suppl 1:S113-119.
El-Khatib FH, Russell SJ, Nathan DM, Sutherlin RG, Damiano ER. *A bihormonal closed-loop artificial pancreas for type 1 diabetes.* Sci Transl Med. 2010 Apr 14;2(27):27ra27.
Hovorka R, Allen JM, Elleri D, et al. *Manual closed-loop insulin delivery in children and adolescents with type 1 diabetes: a phase 2 randomised crossover trial.* Lancet. Feb 27;375(9716):743-751.

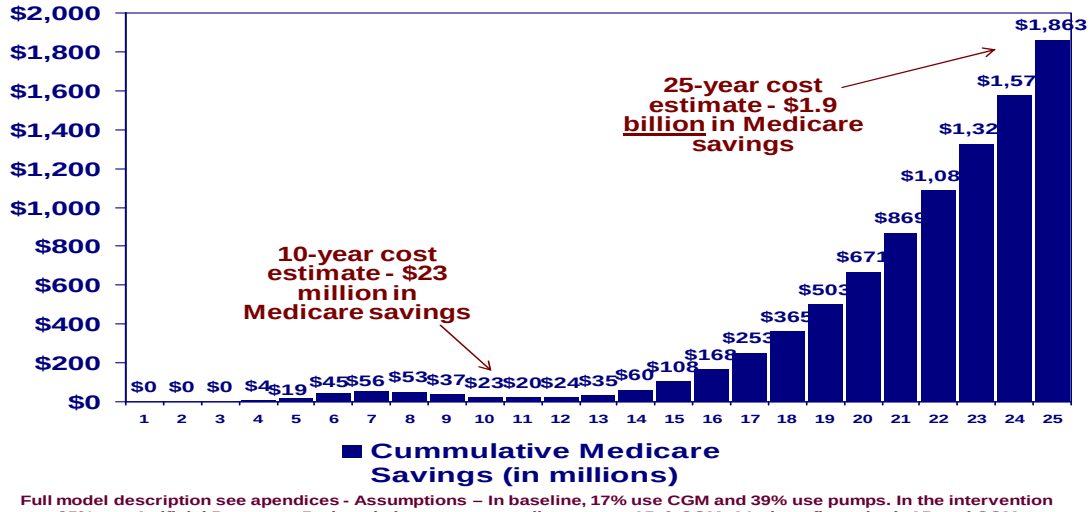
NIH and other clinical trial results. The progression of the disease was modeled both with and without the use of the artificial pancreas. Spending was simulated including the costs of providing the artificial pancreas and the spending associated with diabetes care and diabetes complications.

The focus of this analysis is on Medicare spending. In diabetes care, Medicare is often at a disadvantage compared to other payers. A lack of investment in care to prevent diabetes complications results in higher spending by Medicare, not the insurer who covered the patient during their pre-Medicare years. The artificial pancreas has the reverse dynamic. Investments made during the pre-Medicare years yield savings to the Medicare program.

The model results indicate that as time goes by the savings associated with avoiding costly complications starts to build. By the ten-year mark, the equivalent of a CBO ten year budget estimate, the savings to Medicare equal $23 million. As this cohort of people ages, the savings grow significantly, as major complications are avoided. By the 25-year mark, the savings (reduced Medicare spending) reaches $1.9 billion.[4]

Due to the nature of diabetes and the significant spending on complications that occurs in the later years, a new technology that can significantly slow or stop the progression of diabetes complications has the potential to deliver significant clinical improvements, while simultaneously reducing spending on complications.

Figure 1:
Medicare Savings by Introducing the Artificial Pancreas for the Type 1 Diabetes Population Ages 30-60



Full model description see apendices - Assumptions – In baseline, 17% use CGM and 39% use pumps. In the intervention arm 85% use Artificial Pancreas. Reduced glucometer spending among AP & CGM. A1c benefits to both AP and CGM use

[4] These estimates are presented in undiscounted dollars to be consistent with both CBO and the CMS Office of the Actuary estimates. In more academic analyses, estimates are often presented in discounted dollars to reflect that greater value of money in the current period, over the same amount in the future. The discounted estimates are $22 million after ten years and $1.0 billion after 25 years.

Figure 1 displays estimates for the type 1 diabetes population between 30 and 60 years old. The patterns of spending and saving differ somewhat between the younger and older members of this group. Given the way diabetes progresses over time (the natural history of the disease), the sooner a patient is able to achieve and maintain tight glucose control, the greater the probability of avoiding complication.

Conclusions:

Due to the nature of diabetes and the significant spending on complications that occurs in the later years, a new technology that can significantly slow or stop the progression of diabetes complications has the potential to deliver significant clinical improvements, while simultaneously reducing spending on complications. The early clinical results associated with the new artificial pancreas are strong indicators that the artificial pancreas is just such a rare new technology.