National Changing Diabetes Program, Federal Scoring Project: Phase II Report

The Use of Epidemiological Modeling for Projecting Diabetes Incidence and Spending Under Alternative Policies - *August 22, 2008*

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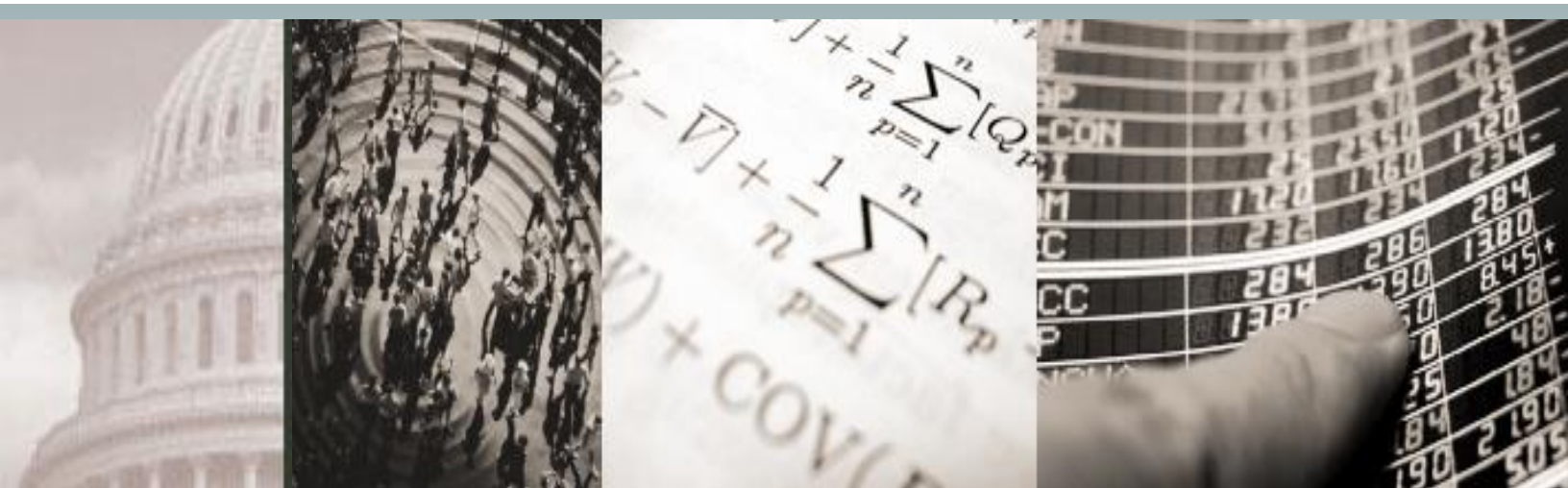


Phase II[1]

1. Introduction

As we discussed in Phase I of this project, common and chronic diseases such as diabetes, heart disease, and cancer drive much of health care spending today and are likely to continue to do so in the future. However, neither the Congressional Budget Office (CBO) nor the Centers for Medicare and Medicaid Services (CMS) makes extensive use of disease-based modeling to inform its projections of federal health spending.

We believe that both scoring agencies should consider changing their current practice in this regard. In particular, when appropriate, they should consider adding cost-estimating approaches that more explicitly incorporate projections of expected disease burden in the future and the expected health care spending as a result. Such modeling is likely to provide insights into the challenges we will face in the future in a manner that current projection approaches do not.

We present here one such model -- the Diabetes Population Cost Model (DPCM). We used work already in the public domain to build this robust model for estimating the incidence and costs of caring for patients with diabetes. This model marks the first time that the already existing input data are being used explicitly to project the impact of changing disease burden on federal program spending into the future.[2]

Our model's results suggest that explicitly taking into account the natural history of diabetes and the impact of diabetes treatments can refine current governmental forecasts of future costs attributable to diabetes and significantly alter our understanding of the budgetary impact of proposed health care programs. In light of the fact that Medicare already faces staggering increases in costs in the future, it is important to bring to bear existing knowledge and methodology that may improve the accuracy of forecasts of health care costs.

This report is divided into seven sections:

1. Introduction
2. A brief description of the Diabetes Population Cost Model (DPCM), its assumptions, and methodology
3. The estimates of a baseline for diabetes spending over the next 25 years
4. Details of the model

[1] The authors would like to thank the National Changing Diabetes Program and Novo Nordisk. Inc. for their financial support of this work. While they provided significant support and assistance, they did not interfere or impose in any way on the scientific or analytic aspects of this work.

[2] As part of the research and modeling done for this analysis, estimates are made up of the number of people with diabetes, both diagnosed and undiagnosed, as well as the spending directly associate with their diabetes and its complications. While these data differ slightly from other published accounts, the authors explored these differences and found they are related to factors such as using different years survey data and using different age cohorts. While our estimates may differ, our results are not intended to contradict the estimates of other researchers.

5. Description and modeling of possible/hypothetical policy options for diabetes treatment improvement
6. Corresponding changes in the federal budget process that would reinforce the utility of more long-term disease-based modeling
7. Conclusions

2. A Brief Description of the Diabetes Population Cost Model, Its Assumptions, and Methodology

In the coming decades, the United States will continue to face the growing challenge of absorbing the increasing costs of managing chronic diseases common among older individuals. In the case of diabetes-related costs, overall costs will be influenced by the demographic shifts in the population, population-level trends in obesity, the development of new diabetes-related treatments and diagnostic tests, and the dissemination of treatments and tests.

In light of the sheer magnitude of current costs associated with diabetes, it is critical for policymakers to understand how these costs will change over the next decades and how new policies potentially may alter these trends in costs. One positive development is that both Senator McCain and Senator Obama have strong commitments in these areas. Policymakers already are keenly interested in developing and pursuing policies that can prevent the expected rise in disease burden and head-off expensive public commitments to care for the chronically ill

As we have found previously, current cost estimating practices may not be well-suited for examining questions related to chronic disease cost trends. At present, federal bodies charged with estimating the future costs of health care do not utilize epidemiological models of chronic disease incidence and chronic disease-related complications. The possible avenues for improved estimating presented in this report should be explored aggressively to determine if they would add valuable information and thus improve policy.

Highlights of the Diabetes Population Cost Model (DPCM) –

Estimates of the future total healthcare costs for diabetes must account for two cohorts of the population with diabetes: one that is prevalent today and the other that will consist of new cases each year. The incident rates over time will depend on the changing demographic compositions of the population without diabetes and the population not yet diagnosed with diabetes, the rate of progression to diabetes, and the rate of screening. The lifetime costs for each diagnosed cohort of patients will depend on the natural history of diabetes progression and the quality of diabetes care.

Reflecting these two types of cohorts, we designed the DPCM with two major components: a component that models the incidence and prevalence of diabetes in the population, and a component that models the natural history of diabetes progression once diabetes is diagnosed.

The diabetes incidence component models diabetes incidence and prevalence and accounts for the progression rates from non-diabetes to diabetes, the screening rates in the population, the incidence of undiagnosed diabetes, and the incidence of diagnosed diabetes in the population. The inputs for this model component come from publicly available data such as the National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Medical Expenditure Panel Survey (MEPS).

The diabetes progression component is built around prediction models for the development of five major diabetes-related complications.

- Eye disease – retinopathy
- Kidney disease – nephropathy
- Nervous system disease – neuropathy
- Coronary heart disease, and
- Stroke

Transitions to more advanced complication states were assumed to be unidirectional and were based on transition probabilities (the probability that a person will progress from one disease state to the next). These probabilities vary with demographic and clinical characteristics (blood pressure levels, cholesterol levels, glycosylated hemoglobin levels, and duration of diabetes). The progression component follows the structure originally used by the National Institutes of Health (NIH) modeling group.

As with the diabetes incidence modeling, the underlying assumptions used in this model component are from publicly available estimates. In addition, publicly available models for individual complications developed with United Kingdom Prospective Diabetes Study (UKPDS) data form the backbone of the diabetes progression component of the model.

The diabetes progression component accounts for the costs of basic diabetes management as well as the costs of treating various micro and macro-vascular complications. Expected costs over the lifetime of a patient (categorized by gender and race) diagnosed with diabetes at specific ages are calculated based on Monte Carlo simulations -- a random-sampling technique used to approximate the probability of outcomes.

The design of the Diabetes Population Cost Model used in projecting health care expenditures, the underlying assumptions, and the data used are derived from rigorous, peer-reviewed sources representing the best available data in this field. All the aspects of the modeling are intended to be transparent, so that none of the data or calculations has to be taken on faith and so that a future user inside or outside the government could replicate these results.

A description of the model's details is presented after the discussion of the projection results.

3. The Estimates of a Baseline for Diabetes Spending over the Next 25 Years

This model provides the following results:

- Between 2009 and 2034, the number of people with diagnosed and undiagnosed diabetes in the country will increase from 23.7 million to 44.1 million.

- Total spending on caring for patients with diagnosed diabetes is expected to increase, in constant 2007 dollars, from $113 billion in 2009 to $336 billion in 2034.

- The Medicare eligible population with diagnosed and undiagnosed diabetes will increase from 8.2 million in 2009 to 14.6 million by 2034.[3]

- Medicare spending for people with diagnosed diabetes is expected to increase from $45 billion in 2009 to $171 billion in 2034 (again in constant 2007 dollars).

Results

For this analysis we use the Diabetes Population Cost Model to predict the average annual population level costs of living with diabetes, accounting for differences by age, gender, racial group, and major duration of diabetes. No changes in the prevention or treatment of diabetes beyond currently observed care are included in these baseline projections. In effect, these projections represent a "current law" baseline for the incidence and spending attributable to diabetes-specific treatments and complications. All costs are expressed in 2007 dollars. In estimating costs for future years, we applied the cost growth assumptions utilized by the Congressional Budget Office.

Future population size and cost projection for the United States

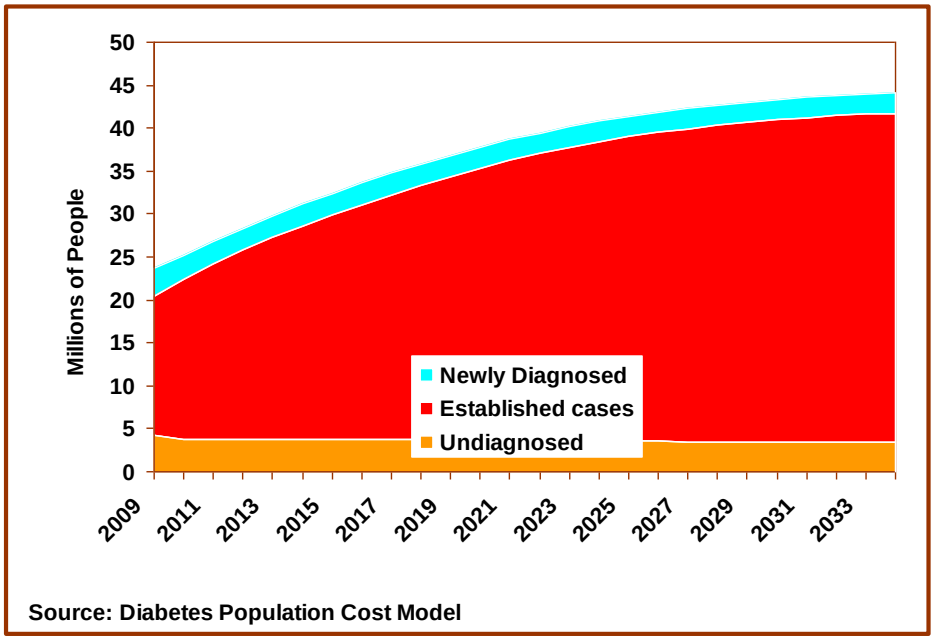
We found that by 2009, 19.5 million people will have diagnosed diabetes and 4.25 million people will have undiagnosed diabetes in the U.S. adult population ages 24 to 85. Figure 1 depicts the estimated change in numbers of cases of newly diagnosed and undiagnosed cases of diabetes in the U.S. over the next 25 years. At the present time, the incidence of people with newly diagnosed diabetes occurs at the rate of about 8 per 1000 people without diagnosed diabetes. This observed rate is in part driven by the subpopulation (or cohort) of people with undiagnosed diabetes. Over the next 12 years, the cohort of people with diabetes is expected to rise. This trend reflects the expected demographic shift that currently is occurring with the aging of the baby boom generation combined with increases in obesity. However, at the same time, the medical system is screening continually for diabetes, including the addition of specific new Medicare

[3] The data we had available could not directly identify Medicare eligible people. Our proxy for Medicare is age 65 and older or End-Stage Renal Disease (ESRD) patients.

benefits for diabetes screening.[4] The combined effect is an increase in the number of diabetes cases and the successful identification of many of these cases by the medical system. This translates into a growing annual cohort of diagnosed incident diabetic cases and a declining cohort of undiagnosed diabetes that stabilizes in size around 3.7 million by 2020.

After 2020, the size of the cohort of people with undiagnosed diabetes is estimated to decline. The annual incident cohort size follows the same pattern.

Figure 1:
Projected Distribution of Newly Diagnosed, Undiagnosed and Established Cases of Diabetes, 2009-2034



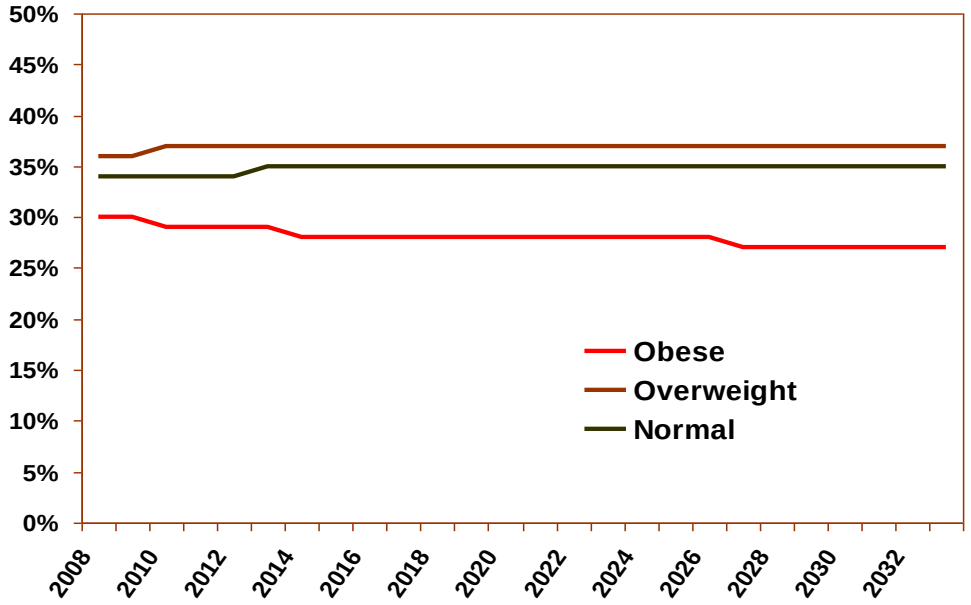
[4] It's important to keep in mind that there are different levels of screening for diabetes. There are very specific screening tests like those covered by the new Medicare benefit. There are also more broadly based metabolic panels that screen patients for a wide range of possible problems, including diabetes. Different researchers using different definitions of what constitutes effective screening will generate different results. These estimates are based on self-reported data from the 2005-2006 NHANES Survey – HHS/CDC. We assume that the observed rates of screening in 2005-2006 (NHANES) will persist in future years.

The Impact of Changes in Obesity

Increases in obesity over the last decade are well documented, as is the correlation between obesity and the risk of Type 2 diabetes.[5] The question for this analysis is: How will obesity rates trend in the future? The increases in rates of obesity observed in the past are in effect included in our baseline. If the obesity rates continue to rise, the incidence of new cases of diabetes will rise. If the trend falls, the incidence of new cases of diabetes will fall.

Figure 2 shows our estimates of changes in percentage of obese, overweight, and normal weight individuals in the population without diabetes. Overall obesity distribution in this population remains fairly stable over time with about 65% of the population being overweight or obese. Although overweight and obese subjects have greater hazards of progression to diabetes (see Figures 11a and 11b), growth in these categories will be small and therefore are not expected to contribute towards the growth in diabetes prevalence. This same leveling of the obesity trend is found in projections produced by the Centers for Disease Control and Prevention (CDC) for the entire U.S. population.[6]

Figure 2:
Projected Distribution of the Obese, Overweight and Normal Weight Populations, Non-Diabetics, 2008-2033



Source: Authors' modeling (projected) based on HHS/CDC/NCHS NHANES data. See also Homer J., Milstein, B., Dietz W., Buchner D., & Majestic E., Obesity Population Dynamics: Exploring Historical Growth and Plausible Futures in the U.S., HHS/CDC.

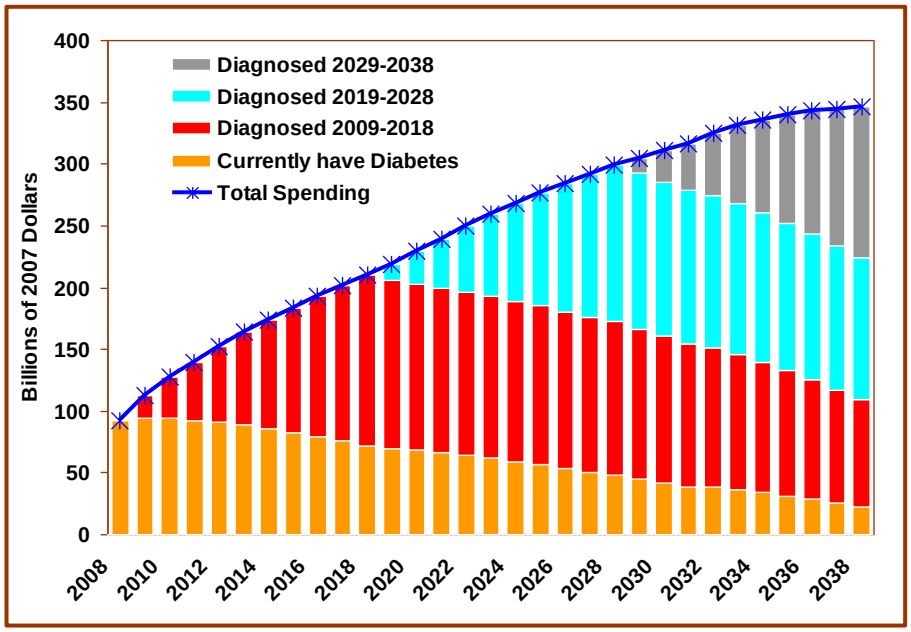
[5] Homer J., Milstein, B., Dietz W., Buchner D., & Majestic E., Obesity Population Dynamics: Exploring Historical Growth and Plausible Futures in the U.S., HHS/CDC.
[6] Ibid.

For the immediate future, the rates of diabetes will reflect the increased obesity trends of the past decade. The result being an increased incidence of new diabetes cases and a parallel increase spending associated with those new cases. As Figure 2 highlights, the projected obesity trend and its impact on diabetes cases and spending are not expected to improve or worsen substantially during the next 25 years.

The Spending Associated with the Direct Care of Diabetes and Its Complications

There are a number of different ways to measure spending related to diabetes. This study looks only at the spending associated with the direct treatment of diabetes and its complications. Other studies look at indirect spending for patients with diabetes and non-medical, quality of life effects, e.g., time lost from work.[7] The American Diabetes Study in particular provides a more comprehensive picture of overall economic impact of the disease.

Figure 3(a):
Projected Direct Spending on Diabetes and Its Complications for Different Cohorts, 2008-2033



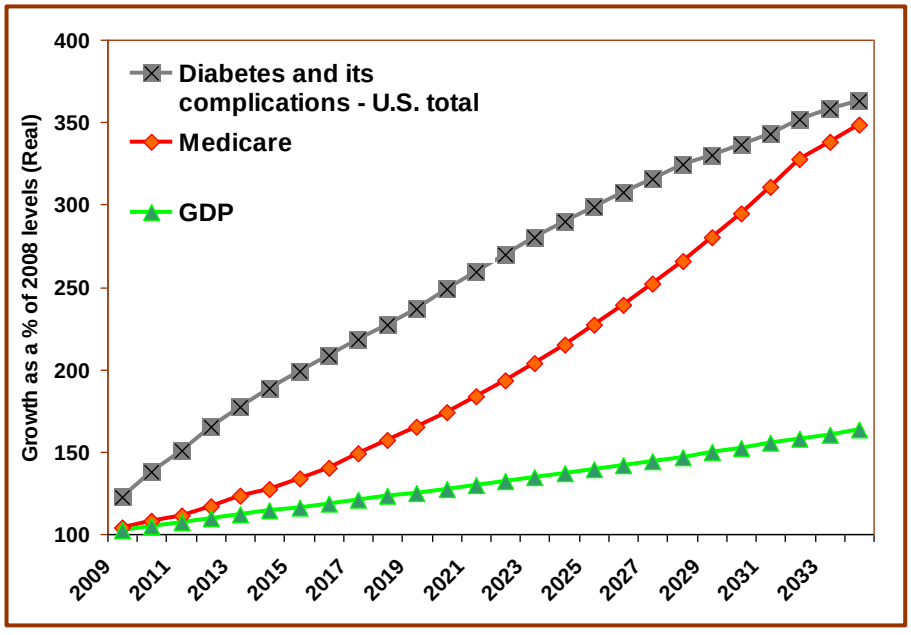
For this analysis we have projected direct spending on diabetes and its complications for the next 25 years. Figure 3a depicts the lifetime spending for both the current and future cohorts of patients with diabetes. The sum of the spending for the cohort that currently

[7] Economic Costs of Diabetes in the U.S. in 2007, American Diabetes Association. Diabetes Care 31:1–20, 2008.

has diabetes (the prevalent cohort) and the spending for the populations expected to be diagnosed during the next 25 years (the incident cohorts) determines the total costs of diabetes in future years. In the next 25 years, annual spending is expected to increase steeply to approximately $336 billion, mainly because of the increasing size of the incident cohorts. The annual costs should stabilize from that point on as the size of the incident cohort plateaus.

The projected real growth in direct spending for diabetes clearly exceeds current growth projections for gross domestic product for the foreseeable future (Figure 3b). Projected real growth in spending for diabetes also exceeds growth projections for Medicare spending in the next two decades but then begins to converge in the third decade.

Figure 3(b):
Projected Real Growth – Direct Spending on Diabetes and Its Complications, Medicare Overall Spending and GDP, 2009-2034



The Medicare Population:

Future Population Size and Cost Projection for People with Diabetes in the Medicare Program

The growth and spending of the Medicare population with diabetes follows many of the same trends found for the overall population with diabetes. In order to obtain estimates for the Medicare population, we modeled the overall population growth and aging over

time as described in the previous section. Therefore, we were able to account for both the Medicare diabetes patients who continue from year to year and the current Medicare non-diabetic patients who will be diagnosed with diabetes during a future year. By modeling these growth trends we can also project the number of patients who enter Medicare every year, and what percentage is likely to be newly diagnosed with diabetes.

Figure 4 illustrates the estimated change in numbers of cases of newly diagnosed and undiagnosed cases of diabetes among people eligible for Medicare during the next 25 years.[8]

For 2009, the model projects 6.5 million Medicare beneficiaries with diagnosed diabetes. During 2009, 0.9 million will be diagnosed, while another 0.9 million will remain undiagnosed. By 2034, the number of people with diagnosed diabetes eligible for Medicare will rise to 14.1 million. However, the size of the annual cohort of people with undiagnosed diabetes will decrease to 440,000 by 2034.

While the patterns in the Medicare population closely track the patterns in the overall population, some differences can be found in the early years. This appears to be a function of the retirement of baby boomers who are more likely to be obese than earlier cohorts and the projected increased screening of the Medicare population

[8] The data we had available could not directly identify Medicare eligible people. Our proxy for Medicare is age 65 and older or End-Stage Renal Disease (ESRD) patients.

Figure 4:
Projected Distribution of Newly Diagnosed, Undiagnosed and Established Medicare Cases of Diabetes, 2009-2034

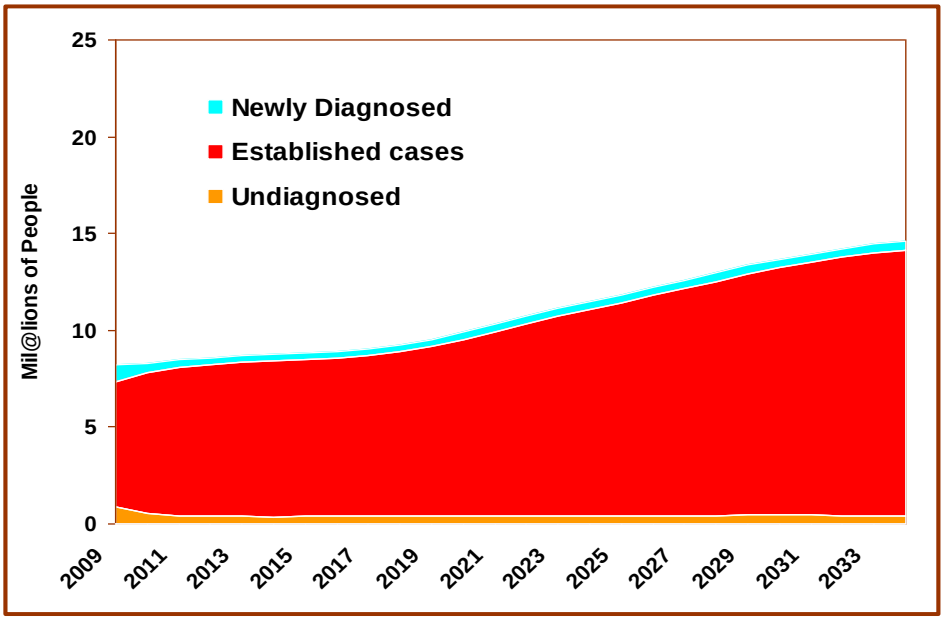
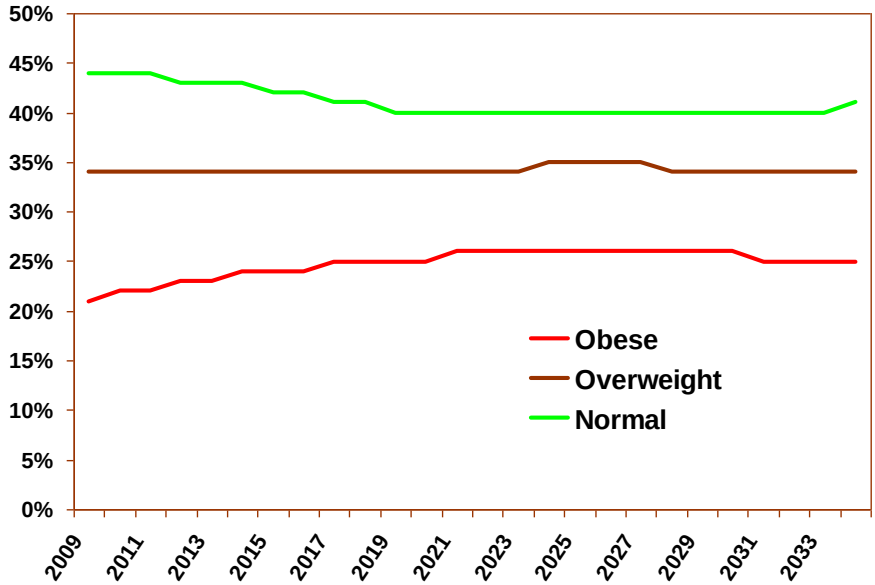


Figure 5:
Projected Distribution of the Obese, Overweight and Normal Weight Medicare Populations, Non-Diabetics, 2009-2034

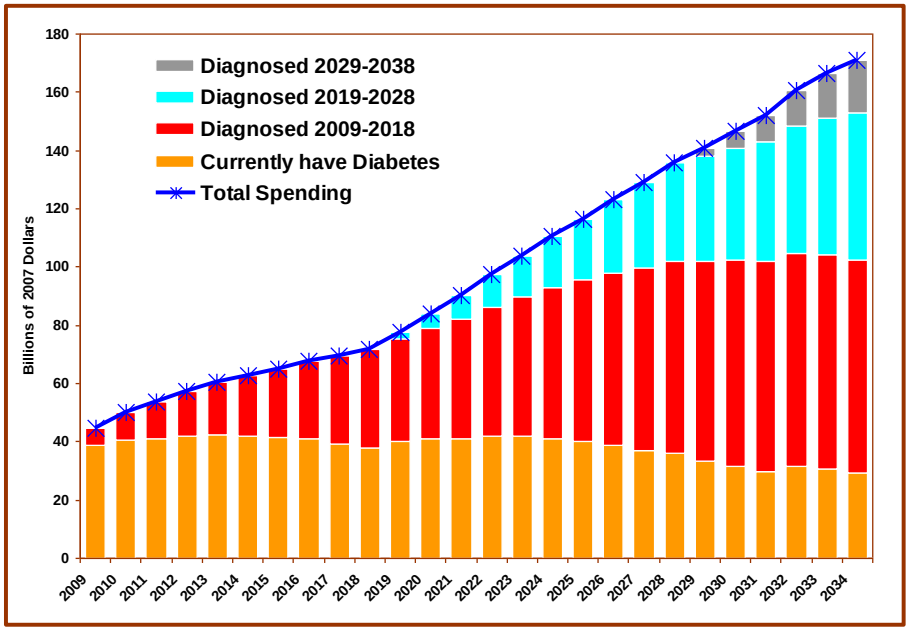


Source: Authors' modeling based on HHS/CDC/NCHS NHANES data. See also Homer J., Milstein, B., Dietz W., Buchner D., & Majestic E., Obesity Population Dynamics: Exploring Historical Growth and Plausible Futures in the U.S., HHS/CDC.

Figure 5 illustrates the distribution of BMI categories -- obese, overweight, and normal weight -- in the Medicare eligible population without diabetes. Similar to the overall population, obesity distribution among this Medicare eligible population without diabetes remains fairly stable, but with a moderate increase over time. In the early years, about 55% of the population is projected to be overweight or obese. By 2020, the obese and overweight categories are projected to account for approximately 60% of the Medicare population. As discussed earlier, a demographic wave of heavier baby boomers is working its way through the population.

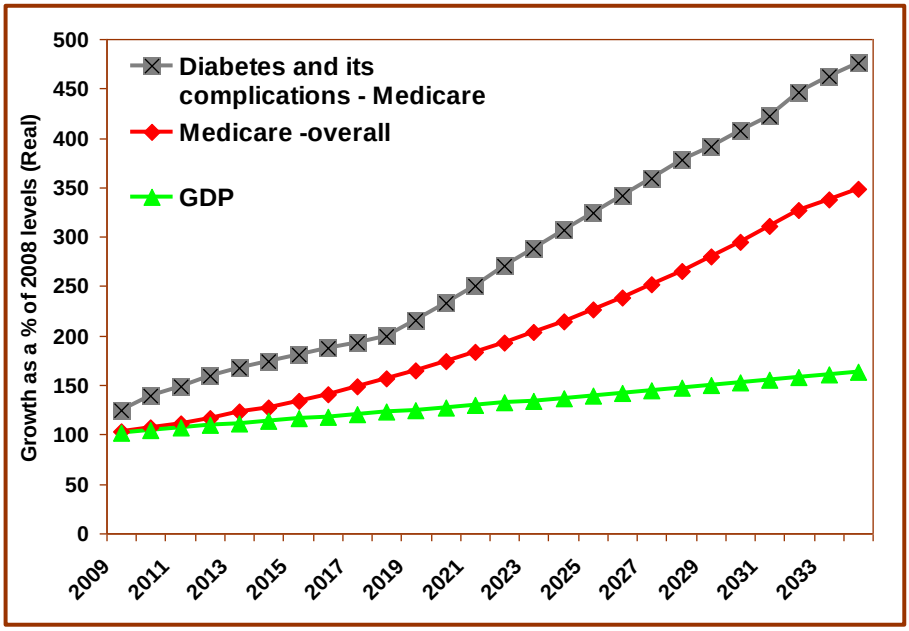
Figure 6a depicts the rise in estimated Medicare spending attributable to diabetes care. Direct spending for diabetes and its complications is projected to be $44.7 billion in 2009. The lifetime spending for this cohort who already has diabetes in 2009 is illustrated in Figure 6 along with the lifetime spending for the incident Medicare cohorts that will develop diabetes after 2009. The annual spending for Medicare eligible people with diabetes will rise to $171 billion by 2034 (in constant 2007 dollars).

Figure 6(a):
Projected Direct Medicare Spending on Diabetes and Its Complications for Different Cohorts, 2009-2034



The projected real growth in Medicare spending for individuals with diabetes clearly exceeds current projections of spending growth by Medicare and for the growth domestic product (Figure 6b).

Figure 6(b):
Projected Real Growth – Medicare Direct Spending on Diabetes and Its Complications, Medicare Overall and GDP, 2009-2034



4. Details of the Model

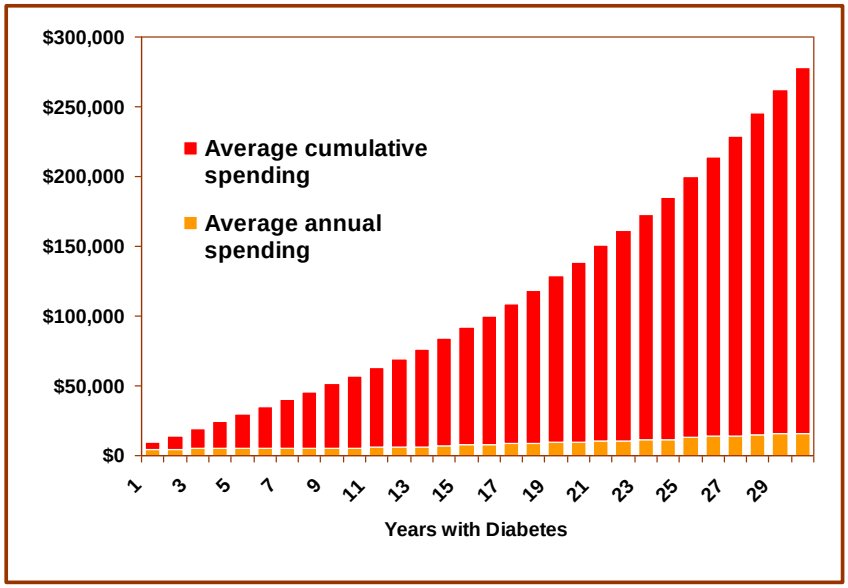
Any attempt to obtain estimates on the future total healthcare costs for diabetes must conceptualize the population with diabetes in two distinct ways. First, there is the population with diabetes that exists today. This population will change constantly over time. New people will be diagnosed with diabetes and added to the population of people with diabetes in America. Other people will die or otherwise leave this subpopulation, e.g., receive pancreas transplants. In effect the incidence of diabetes will change on an annual basis.[9] The size of the subpopulation with diabetes will grow at different rates at different times depending on factors ranging from the rise in obesity to the aging of the baby boomer generation.

A lifecycle approach is the other distinct way to conceptualize the subpopulation of people with diabetes and their associated healthcare spending. Every person's health and health care spending tends to change over time. Newborns and the elderly tend to be more expensive than teenagers and young adults. The progression of diabetes as a disease also has the equivalent of a lifecycle. Complications take time to develop and inflict damage to the eyes, kidneys, circulatory, and nervous systems.

[9] CDC's Division of Diabetes Translation. Incidence of Diabetes in the Population Aged 18-79 Years. http://www.cdc.gov/diabetes/statistics/incidence/. Accessed 4/20/2008.

The lifetime spending for a person with diabetes can be substantial. Figure 7 provides an example of the typical spending patterns of a white middle-aged man with diabetes. The natural history of the disease is well understood and documented, which is one of the key reasons that the type of modeling presented here should be considered as a source of additional cost estimating information for policymakers.

Figure 7:
Average Annual and Cumulative Costs of Diabetes Care for a White Male, 40-50 Years Old at Onset



In our model, we account for two types of cohorts, a prevalent and incident cohort. The prevalent cohort is the population of individuals with diabetes in 2008. It reflects the distribution of different ages and different years with diabetes of the subpopulation in 2008. The second type of cohort is called an incident cohort. This group represents the new people with diabetes entering the diagnosed population after the base year of 2008. The number of people with diabetes in any year is the sum of the population in the previous year (in 2008, it is the prevalence cohort) and the incident cohort, minus deaths from all causes in the previous year's population with diabetes.

To account for the costs of both cohorts, we tracked costs using two time lines: 1) the chronological timeline during which we will report our total costs estimates, and 2) the age timeline for various heterogeneous subgroups within the prevalent and incident cohorts. For example, different patients may start with diabetes at different ages in the same calendar year. Other patients may start at the same age but in different calendar

years. Accounting for such dynamic nature of cost accumulation will produce the most robust evidence on the future projections of healthcare costs for diabetes.

Methods

In this paper, we develop explicit models to address this dynamic nature of cost accumulation.

Figure 8:
Conceptual Model Of Costs Of Diabetes With Prevalent And Future Cohorts Over Time.

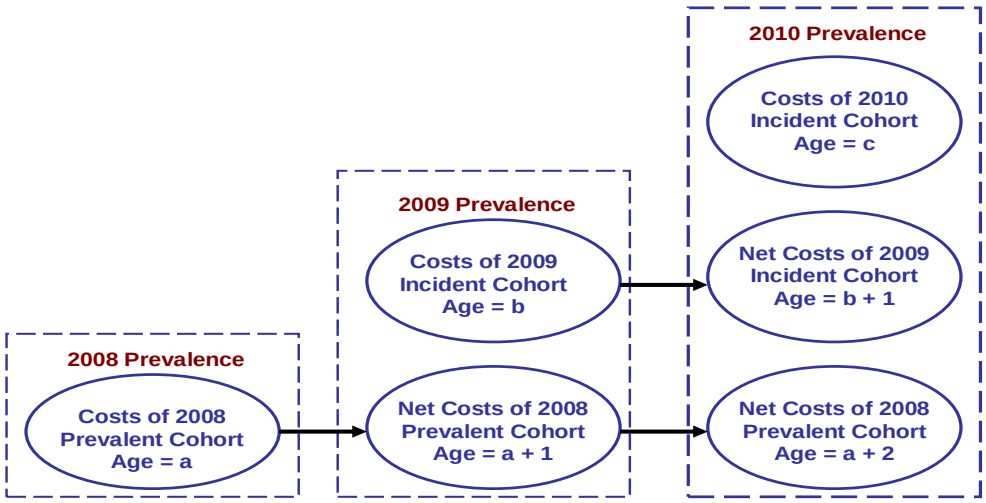


Figure 8 presents the conceptual accounting of costs over time. This involves accounting for all healthcare costs to the prevalent groups of people with diabetes, after the annual incident cohort for that year joins the prevalent cohort (illustrated by a dotted box in Figure 8). Empirically, we account for costs horizontally (as represented by arrows in Figure 8). That is, we take the prevalent cohort of patients in 2008 and lay out their lifetime cost profiles throughout the calendar time starting from 2008. Similarly, we take the incident cohort of patients in 2009 and lay out their lifetime cost profiles throughout the calendar time starting from 2009. We repeat this pattern for future incident cohort of patients. We also account for heterogeneity in terms of patient characteristics for all cohorts.

Next we explain three parts that are central to estimating this accumulation of costs:

1. Defining the prevalent cohort and its heterogeneity
2. The diabetes incidence model
3. The lifetime simulation model for diabetes progression.

1. *Defining the prevalent cohort and its heterogeneity.* -- In our analyses, we assume that the prevalent cohort of adult patients living with diabetes has the demographic and clinical characteristics of adult individuals reporting that they have diabetes in the National Health and Nutrition Examination Surveys (NHANES) (2005-2006). The NHANES is a series of cross-sectional surveys that provides nationally representative information on the nutrition and health status of the U.S. civilian population. The first, second, and third NHANES surveys (NHANES I, II, and III) were collected in 1971-1975, 1976-1980, and 1988-1994, respectively. Since 1999, NHANES has been a continuous survey. Detailed descriptions of the sample design, interview procedures, and physical and lab examinations conducted can be found at http://www.cdc.gov/nchs/nhanes.htm.

   To create the prevalent cohort, we utilized self-report of disease as the method of identifying individuals living with diabetes. We then accounted for the number of subjects in the U.S. population with diagnosed diabetes, undiagnosed diabetes, and no diabetes, categorized by gender, race (whites, blacks, latinos and others) and every age from 24 years to 85 years. Since this cohort consists of subjects with diagnosed diabetes, their lifetime costs are accounted for based on the lifetime simulation model for diabetes progression that we describe below (See Part 3).

2. *The diabetes incidence model.* -- The main purpose of the incidence model is to account for both the evolving number of undiagnosed and diagnosed diabetes in the U.S. population over time. Once new subjects are diagnosed, their lifetime costs are calculated using the cost estimates arising out of the lifetime model of diabetes progression.

   To estimate the incidence of diabetes over time along with the heterogeneity of patient characteristics representing the incidence cohort, we start with the U.S. adult population ages 24 years and above. A fraction of these people already may have diabetes, although they do not know about it yet, i.e. they are undiagnosed. Every year this cohort is supplemented with a new group of people without diabetes who just turned 24 years. Both of these two groups of people transition into those with diagnosed diabetes at a certain rate that is determined by various factors.

Figure 9(a):
A Markov Model Representing the Transitions of the US Population across BMI categories

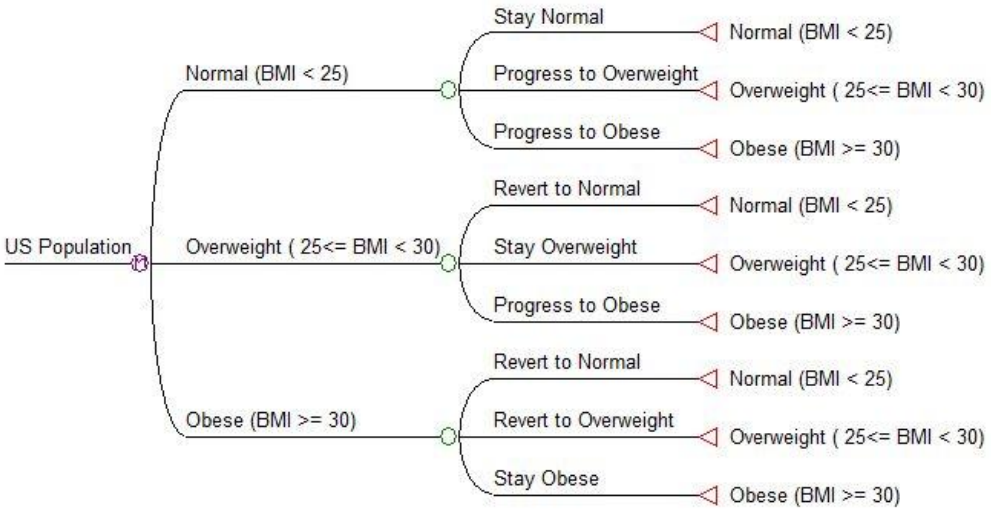
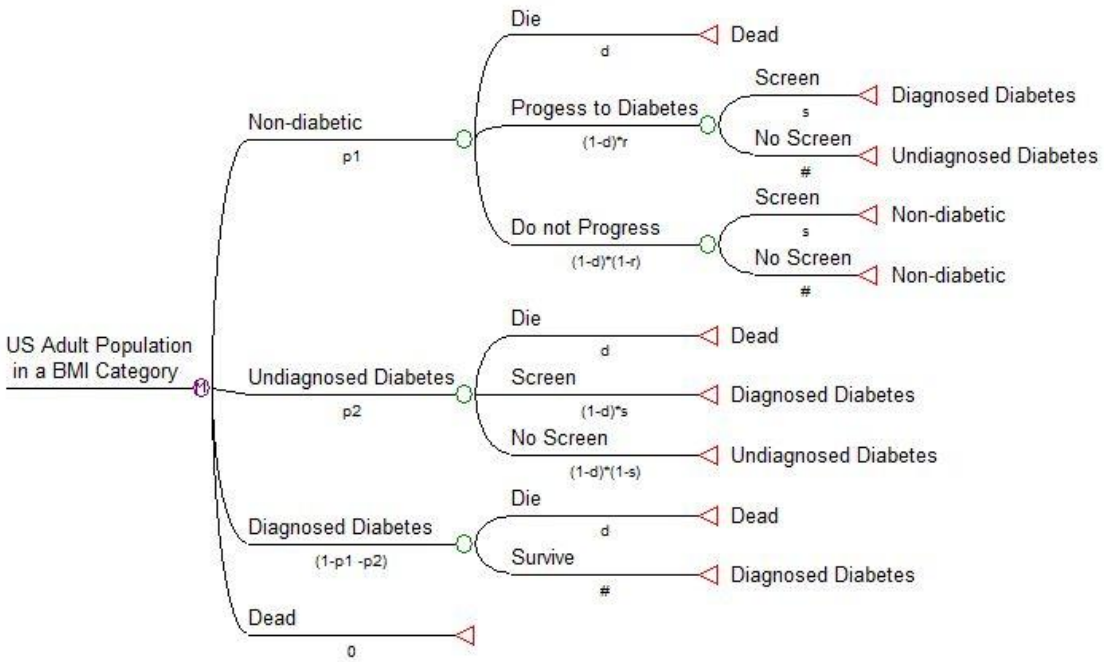


Figure 9(b):
A Markov Model Representing the Transitions of the US Population in a BMI category to Developing Diabetes



Key: d = death rate. r = progression rate. s = screening rate

Figure 9a displays the basic structure of the Markov model[10] that traces the transition of the U.S. population across BMI categories over the age of the subjects. These transition probabilities determine the distribution of BMI categories at any point in time, which in turn affects the transition to diabetes. Figure 9b displays the basic structure of the Markov model that tracks the movement of the population between four main states: 1) no diabetes, 2) undiagnosed diabetes, 3) diagnosed diabetes, and 4) death. It also displays the key transition probabilities driving the results of the model.

A fraction of the population without diabetes, conditional on their survival (death rate is denoted by d and is assumed to be the same for both people with and without diabetes) to the next period, may progress to have diabetes. Annual progression rates are denoted by the parameter *r*. These people transition to become diagnosed or to remain undiagnosed with diabetes depending on whether they are screened. Annual screening rates are denoted by the parameter *s*. Similarly, depending on whether they are screened, those with currently undiagnosed diabetes transition to become diagnosed or remain undiagnosed. (Here we assume that the screening test is perfect, which is mostly true for diabetes detection). As mentioned above, the group with diagnosed diabetes then is removed from this model and fed into the lifetime simulation model described below. The others continue.

Although the model for the incidence of diagnosed diabetes appears simplistic, it captures the basic essence of diabetes progression and behavior. One can make this model more detailed, especially when evaluating interventions on the general population that are designed to curb the incidence of diabetes.

Initial distribution of BMI categories are obtained from NHANES data (2005-2006). Yearly transitions across BMI categories are estimated using the 2004-2005 longitudinal data on the Panel 9 cohort from the Medical Expenditure Panel Survey (MEPS). Estimates of *d* are obtained from published U.S. Life Tables (2004). Estimates of s are obtained from NHANES data (2005-2006). Finally, estimates of r are obtained by fitting the Markov model to published incidence rates from the Centers for Disease Control and Prevention (CDC using National Health Interview Survey).[11] All parameters are allowed to vary by gender and race and smoothed over ages 24 and 85. Estimates of *r* are separately smoothed for age-groups < 45 years, 45-64 years and >64 years due to substantial heterogeneity across these age-ranges.

[10] Markov models are useful when a decision problem involves risk that is continuous over time, when the timing of events is important, and when important events may happen more than once. Markov models assume that a patient is always in one of a finite number of discrete health states, called Markov states. All events are represented as transitions from one state to another. A Markov model may be evaluated by matrix algebra as a cohort simulation or as a Monte Carlo simulation.

[11] (Microsoft Excel 2000, Microsoft, Seattle, WA and @Risk 4.0, Palisades, Inc., Newfield, NY).

Figure 10(a):

Females' Screening Rates by Age and Race/Ethnicity – (NHANES 2005-2006)

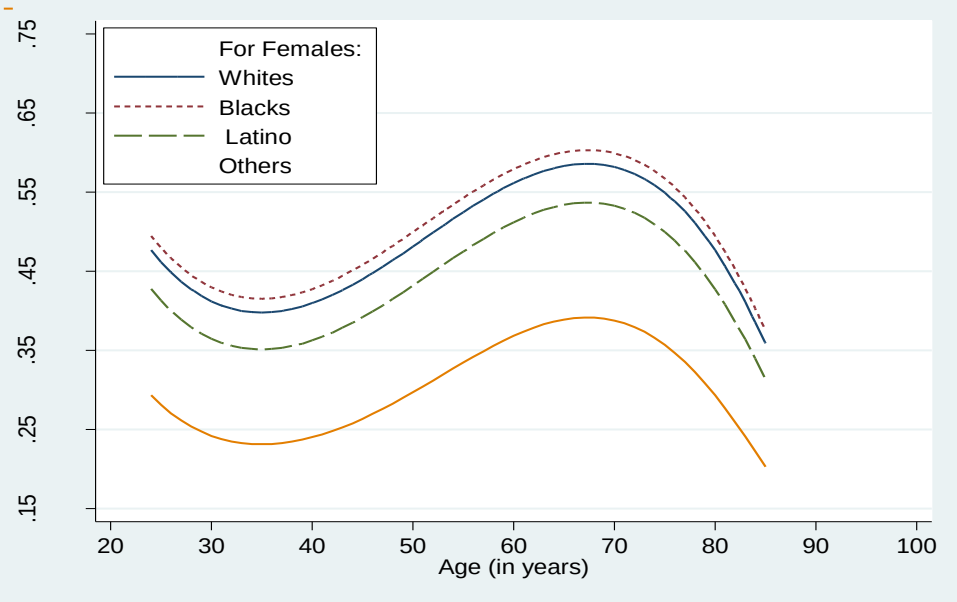
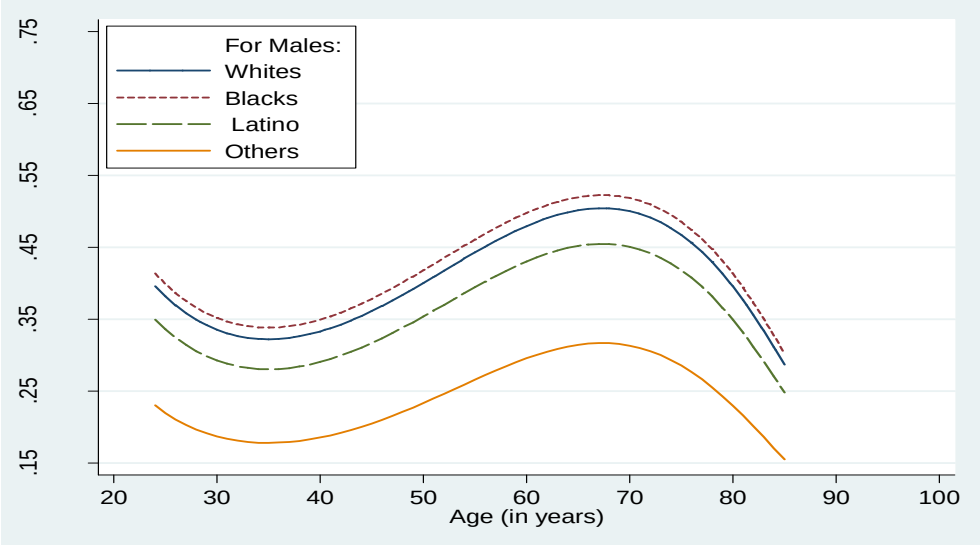


Figure 10(b):

Males' Screening Rates by Age and Race/Ethnicity (NHANES 2005-2006)



Figures10a and 10b illustrate our estimated screening rates over ages, by gender and race groups. Generally, screening rates start off low at younger ages and increases with age until they peak around 70 years of age after which screening rates decline.

Figures 11a and 11b illustrate the age-specific annual hazard of progression to diabetes for people without diabetes for different genders and BMI categories. These progression rates are calculated based on observed incidence of people with diagnosed diabetes and current screening rates. The progression hazards appear to be increasing monotonically with age in all categories and are highest for obese category followed by overweight and normal at all ages.

Figure 11(a):
Females' Estimated Annual Hazard of Progressing to Diabetes over Age by BMI Category

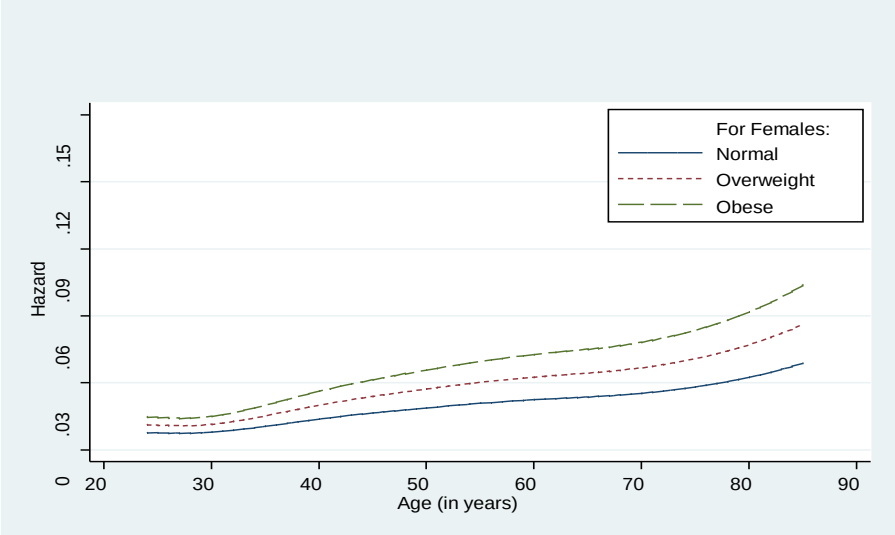
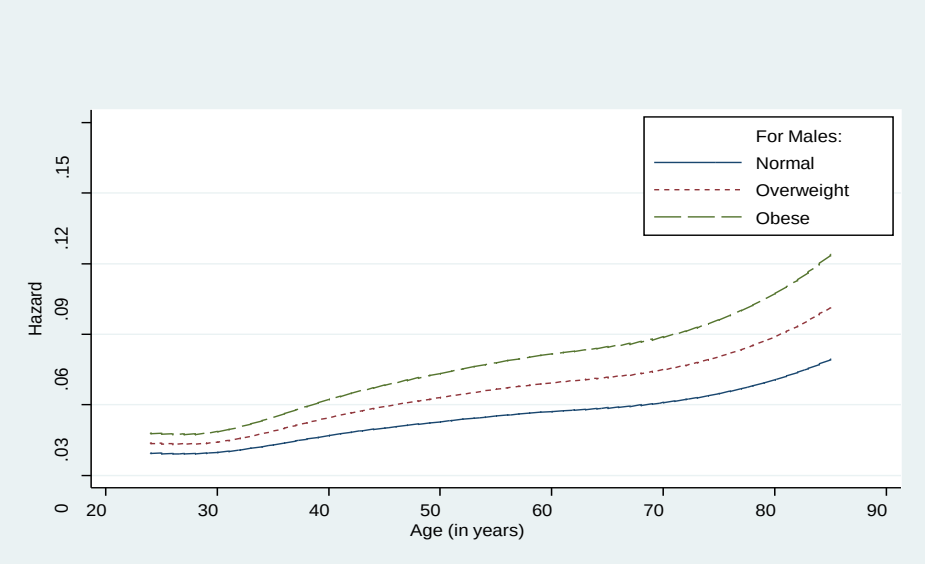


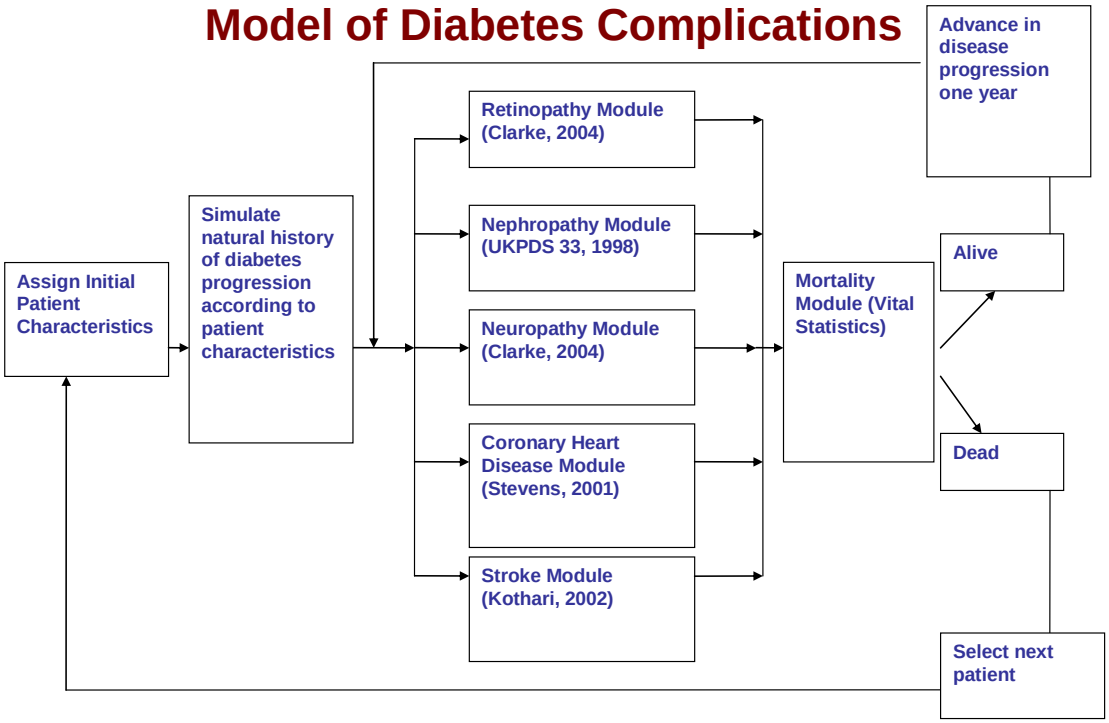
Figure 11(b):
Males' Estimated Annual Hazard of Progressing to Diabetes over Age by BMI Category



3. *The lifetime simulation model of diabetes complications.* -- Within a 1-year cycle length, patients move from one disease state to another or stay in the current disease state until death or age 95. For each specific model setting (e.g., patient age group and race), the model is run 10,000 iterations (each iteration representing a patient life).

Figure 12 displays the design of the model of diabetes complications. The structure of the decision analytic model is presented in this figure. Hypothetical patients move through the model from left to right for each cycle length (one year). Based on initial patient clinical characteristics, patients are subject to the risk of various complications related to diabetes as well as mortality. Patients who survive a given year repeat the cycle until death.

Figure 12.
Model of Diabetes Complications



Data on demographic characteristics (gender and racial) as well as relevant clinical characteristics (blood pressure levels, cholesterol levels, glycosylated hemoglobin levels, and duration of diabetes) are obtained from NHANES and used as data inputs for the simulation models. For each clinical risk factor, we use age, gender, and race specific distributions of these factors within the models.

The diabetes complication models in this analysis are derived from United Kingdom Prospective Diabetes Study (UKPDS) results.[12,13] Prediction models for all major diabetes-related complications have been developed by the UKPDS study group.[14,15] These models have been internally and externally validated with cardiovascular trial data.[16] We could not use the UKPDS prediction model for end-stage renal disease

[12] U.K. Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837-853.

[13] Clarke PM, Gray AM, Briggs A, et al. A model to estimate the lifetime health outcomes of patients with type 2 diabetes: the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model (UKPDS 68). Diabetologia. 2004;47:1747-1759.

[14] Stevens RJ, Kothari V, Adler AI, Stratton IM. The UKPDS risk engine: a model for the risk of coronary heart disease in Type II diabetes (UKPDS 56). Clin Sci (Lond). Dec 2001;101(6):671-679.

[15] Kothari V, Stevens RJ, Adler AI, et al. UKPDS 60: risk of stroke in type 2 diabetes estimated by the UK Prospective Diabetes Study risk engine. Stroke. Jul 2002;33(7):1776-1781.

[16] The Mount Hood 4 Modeling Group. Computer modeling of diabetes and its complications. Diabetes Care. 2007;30(6):1638-1646.

because this model does not include glucose control as a predictor. Instead, we modeled the development of microalbuminuria and proteinuria, which are linked to the intensity of glucose control.[17,18] We used prediction models for these intermediate complications developed using optimization procedures to fit observations from the UKPDS control arm to a functional form used in the original NIH model.[19] For the transition between proteinuria to end-stage renal disease, we used probabilities from an observational study.[20]

For background mortality rates, we used race- and gender-specific background mortality rates reported in U.S. life table statistics from 1999.[21] To calculate background mortality rates for individuals with diabetes, we first subtracted cardiovascular mortality rates for the general population from the overall mortality rates found in life tables. These mortality rates were multiplied by 2.75 as previously done to reflect higher background mortality rates for patients with diabetes.[22] When patients developed specific complications, such as coronary heart disease, stroke, end-stage renal disease, and amputation, we assumed that patients had higher mortality rates attributable to these complications.[23,24,25]

Within the model, we also accounted for the effect of individual medications. The benefits of ACE inhibitors were based on the findings from the Heart Outcomes Prevention Evaluation (HOPE) Study.[26,27] Aspirin was assumed to reduce the probability

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[17] The CDC Diabetes Cost-effectiveness Group. Cost-effectiveness of intensive glycemic control, intensified hypertension control, and serum cholesterol level reduction, for type 2 diabetes. JAMA. 2002;287(19):2542-2551.

[18] Huang ES, Zhang Q, Brown SES, Drum ML, Meltzer DO, Chin MH. The cost-effectiveness of improving diabetes care in U.S. federally-qualified community health centers. Health Serv Res (OnlineEarly Articles). 2007.doi:10.1111/j.1475-6773.2007.00734.x

[19] 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;276:1409-1415.

[20] Humphrey LL, Ballard DJ, Frohnert PP, Chu CP, O'Fallon WM, Palumbo PJ. Chronic renal failure in non-insulin-dependent diabetes mellitus. A population-based study in Rochester, Minnesota. Ann Intern Med. 1989;111(10):788-796.

[21] Andersen R, DeTurk P. National Vital Statistics Report. Hyattesville, Maryland: National Center for Health Statistics; 2002. 50 (6).

[22] Eastman RC, Javitt JC, Herman WH, et al. Model of complications of NIDDM: I. Model construction and assumptions. Diabetes Care. 1997;20(5):725-734.

[23] Hunink MGM, Goldman L, Tosteson ANA, et al. The recent decline in mortality from coronary heart disease, 1980-1990. JAMA. 1997;277(7):535-542.

[24] Petty GW, Brown Jr. RD, Whisnant JP, Sicks JD, O'Fallon WM, Wiebers DO. Survival and recurrence after first cerebral infarction: a population-based study in Rochester, Minnesota, 1975-1989. Neurology. 1998;50:208-216.

[25] U.S. Renal Data System. USRDS 1994 Annual Data Report: Appendix D17. Bethesda, MD: National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 1994.

[26] Heart Outcomes Prevention Evaluation Study Investigators. Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. Lancet. 1999;355:253-259.

[27] Rosen AB, Hamel MB, Weinstein MC, Cutler DM, Fendrick AM, Vijan S. Cost-effectiveness of full Medicare coverage of angiotensin-converting enzyme inhibitors for beneficiaries with diabetes. Ann Intern Med. Jul 19 2005;143(2):89-99.

of coronary heart disease, but to increase the probability of gastrointestinal bleed.[28,29] We assumed that the joint effect of aspirin and an ACE inhibitor on cardiovascular effects was multiplicative. We did not assume that simply the processes of care such as foot examination or routine laboratory tests independently produced any clinical benefits.[30] For example, we assume there was no effect in merely having more A1c's done during the year, if the A1c values did not improve.

Health service utilization and costs inputs -- We assumed that the use of medications reflects the current distribution of use of insulin, oral agents, insulin plus oral agents, and diet therapy as observed in national studies of diabetes care.[31] The distribution of use of different oral glucose lowering agents was assumed to be the observed distribution in national studies.[32] The dosing of insulin was assumed to be 65 units per day. The use of ACE inhibitors and aspirin therapy were based on recent national reports of diabetes care.[33] The frequency of office visits and laboratory tests were assumed to be those observed in a recent national study.

We estimated the costs of drugs based on the average type and frequency of drug prescriptions, dosage of medications, and wholesale drug prices.[34] The annual costs of microvascular[35,36] and cardiovascular complications[37] were obtained from recent studies in the literature.

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[28] Hansson L, Zanchetti A, Carruthers SG, et al. Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. HOT Study Group. Lancet. 1998;351(9118):1755-1762.

[29] American Diabetes Association. Aspirin therapy in diabetes. Diabetes Care. 2004;27(Supp. 1):S72-S73.

[30] Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005;293(2):217-228.

[31] Saydah SH, Fradkin JE, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. JAMA. 2004;291(3):335-342.

[32] Cohen FJ, Neslusan CA, Conklin JE, Song X. Recent antihyperglycemic prescribing trends for U.S. privately insured patients with type 2 diabetes. Diabetes Care. 2003;26(6):1847-1851.

[33] Saaddine JB, Cadwell B, Gregg EW, et al. Improvements in diabetes processes of care and intermediate outcomes: United States, 1988-2002. Ann Intern Med. Apr 4 2006;144(7):465-474.

[34] 2004 Drug Topics Red Book. Montvale, NJ: Medical Economics Company, Inc.; 2004.

[35] Boulware LE, Jaar BG, Tarver-Carr ME, Brancati FL, Powe NR. Screening for proteinuria in US adults: a cost-effectiveness analysis. JAMA. 2003;290(23):3101-3114.

[36] Gordois A, Suffman P, Shearer A, Oglesby A, Tobian JA. The health care costs of diabetic peripheral neuropathy in the U.S. Diabetes Care. 2003;26(6):1790-1795.

[37] Rosen AB, Hamel MB, Weinstein MC, Cutler DM, Fendrick AM, Vijan S. Cost-effectiveness of full Medicare coverage of angiotensin-converting enzyme inhibitors for beneficiaries with diabetes. Ann Intern Med. Jul 19 2005;143 (2):89-99.
Nichol G, Valenzuela T, Roe D, Clark L, Huszti E, Wells GA. Cost effectiveness of defibrillation by targeted responders in public settings. Circulation. 2003;108:697-703.
Van Alem AP, Dijkgraaf MGW, Tijssen JGP, Koster RW. Health system costs of out-of-hospital cardiac arrest in relation to time to shock. Circulation. 2004;110:1967-1973.
Brandle M, Zhou H, Smith BRK, et al. The direct medical cost of type 2 diabetes. Diabetes Care. 2003;26(8):2300-2304.
Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. Am Heart J. 1999;138(3 Part 1):430-436.
Cundiff DK. Coronary artery bypass grafting: reassessing efficacy, safety, and cost. Medscape General Medicine. 2002;4(2):7.

For this analysis we used the complication model to predict the average annual costs of living with diabetes by different ages, genders, racial groups, and major durations of diabetes. All costs are expressed in 2007 dollars.

5. Description and modeling of possible/hypothetical policy option for diabetes treatment improvement.

One of the primary goals of this project is to illustrate the potential for epidemiologically-based simulation models to inform the federal budget estimating process for health care programs. In order to do this, we modeled an example of a hypothetical diabetes policy intervention to help illustrate the insight that the Diabetes Population Cost Model can provide in estimating the cost consequences of adopting different policies. The policy intervention is a diabetes quality improvement intervention that is designed to intensify the treatment of individuals with prevalent and incident diabetes. This is a program that would be quite similar to current disease management programs that are currently being piloted by CMS. The assumptions made for the costs, effects, and populations of interest are described below.

For each of the policy simulations, we compared 1) the baseline total costs of diabetes care, 2) added program costs, and 3) the revised overall costs incorporating program costs and program clinical benefits. The difference between the combination of cost categories 1+2 and cost category 3 represents the cost offset of the hypothetical intervention. These costs were compared for a 10-year and 25-year budget window.

Diabetes Quality Improvement Intervention

For the diabetes quality improvement intervention, we assumed that the program was a diabetes disease management program with services provided by nurses or diabetes educators outside of routine care.[38] In these programs, nurses or diabetes educators typically take on the role of population management, which includes monitoring of risk factor levels and recommending intensification of medications when necessary.

We assumed that the annual program costs for this program for each patient enrolled would be $424 based on an estimate of costs from prior studies of diabetes quality improvement programs.[39,40] With the program in place, the costs of diabetes care related

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Hlatky MA, Boothroyd DB, Melsop KA, et al. Medical costs and quality of life 10 to 12 years after randomization to angioplasty or bypass surgery for multivessel coronary artery disease. Circulation. 2004;110:1960-1966.

[38] Chodosh J, Morton SC, Mojica W, et al. Meta-analysis: chronic disease self-management programs for older adults. Ann Intern Med. 2005;143:427-438.

[39] Huang ES, Brown SE, Zhang JX, et al. The cost consequences of improving diabetes care: the community health center experience. Jt Comm J Qual Patient Saf. Mar 2008;34(3):138-146.

[40] Sidorov J, Shull R, Tomcavage J, Girolami S, Lawton N, Harris R. Does diabetes disease management save money and improve outcomes? A report of simultaneous short-term savings and quality improvement associated with a health maintenance organization-sponsored disease management program among patients fulfilling health employer data and information set criteria. Diabetes Care. Apr 2002;25(4):684-689.

to preventive medications and routine testing would increase by $600 annually based on a micro-costing exercise.[41]

After reviewing the scientific literature on the effects of such programs, the quality improvement program was assumed to lead to multiple improvements in diabetes care given the current clinical insight that diabetes care is not limited to glucose control but encompasses optimal cardiovascular prevention. We assumed that the hypothetical program would bring about an average reduction in glycosylated hemoglobin (A1c) of 0.81%[42] and an average reduction in systolic blood pressure of 5 mm Hg.[43] These two estimates are based on a meta-analysis of existing trials of chronic disease management programs (26 glucose lowering trials and 13 blood pressure lowering trials). We also assumed that there would be a reduction in total cholesterol of 20 mg/dl, a 10% absolute increase in ACE inhibitor utilization (50% to 60%), and a 10% absolute increase in aspirin utilization (45% to 55%) based on the experience of the Health Disparities Collaborative, a four-year observational study of a quality improvement program in federally-qualified community health centers.[44,45]

We assumed that the program would enroll individuals with existing diabetes in a pre-Medicare age range (41-64). With each subsequent year, 60,000 individuals who had existing diabetes and aged into the program or who developed new-onset diabetes in this age range also would be enrolled in the program. With each enrolled patient, we assumed that the diabetes improvement program would continue to follow the patients for the rest of their lives. We also assumed that the adherence to the program would persist over the lifetime of patients and affect their long-term risk of blindness, renal failure, lower extremity amputation, and coronary heart disease. We know that the actual adherence to such a program in real-world practice will not be one-hundred percent. Lower adherence would lessen the effectiveness of the program but also would lessen the costs of the program with subject dropout.

The results displayed in Table 1 are illustrative. Table 1 divides the treatment population into different age cohorts to illustrate the relative costs of different subpopulations. The size of the program budget and the number of people treated can be adjusted up or down based on available funding and other policy considerations. We selected the size of the treatment group based on an assumption that the budget for such a program would be unlikely to exceed $20 billion in gross spending over 25 years, or about $0.8 billion per year, on average, in 2007 dollars. For most of the age cohorts this translated into 60,000 randomly selected participants entering the program in each of the 25 years modeled.

Table 1 illustrates a number of findings:

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[41] Crivera C, Suh DC, Huang ES, et al. The incremental costs of recommended therapy versus real world therapy in type 2 diabetes patients. Curr Med Res Opin. Nov 2006;22(11):2301-2311.
[42] Chodosh, et al., op. cit.
[43] Ibid.
[44] Huang ES, Zhang Q, Brown SES, Drum ML, Meltzer DO, Chin MH. The cost-effectiveness of improving diabetes care in U.S. federally-qualified community health centers. Health Serv Res (Online Early Articles). 2007.doi:10.1111/j.1475-6773.2007.00734.x
[45] Chin MH, et al. Medical Care 2007; 45(12): 1135.

- The younger the subpopulation in the program, the greater the clinical benefits from treatment improvement, which translate into larger offsets against program costs.
- As shown in Table 1, for most age groups, the treatment improvement program will not reduce overall healthcare spending, but will generate a cost offset which acts to minimize the net program costs. The cost offset is generated by long-term reductions in the major complications of diabetes including blindness, kidney failure, lower extremity amputations, and coronary heart disease.
- A program that included a range of cohorts could use the savings from the younger cohorts to partially subsidize the costs of older cohorts.

The relationship between age and effectiveness of the program is consistent with prior studies of the long-term projected clinical effectiveness of diabetes treatments.[7] These results provide policy makers a range of options in designing an actual program. By adjusting the combination of eligibility age and total program size policymakers can adjust the program to meet budget constraints or other policy considerations.

The results in Table 1 are based on a budget window of 25 years, which enlarges program costs but also captures long-term cost offsets of improvements in diabetes care. Table 2 displays results for the same improvement program analysis using a traditional 10-year budget window. In the 10-year budget window, there is no subgroup of patients with any cost savings from the intervention program. The cost offsets in the 10-year window are proportionally smaller than those in the 25-year window. For example, in the 10-year window, the cost offset for 41-50 year old enrollees was $2.1 billion, $3.6 billion in gross spending minus $1.5 billion in net spending. This means that 58% of program costs were offset by reduced spending on diabetes and its complication. In the 25-year window, the cost offset for the same age group was $17 billion which represented an offset of 89% of program costs.

In a more general sense, this policy simulation illustrates the potential for epidemiologically-based simulation models to inform the federal budget estimating process. It demonstrates the power this kind of modeling can bring to the debate on how to move forward in combating chronic illnesses like diabetes. The estimators can provide policymakers with better, more refined measures of the actual outcomes of different policy options. This kind of modeling provide the estimators with the tools necessary to finally be able to address the question how a proposed policy change will affect long-term health care spending. It also allows the policymakers to see the interactions between different cohorts of possible beneficiaries so that they can refine policy to maximize its cost effectiveness.

Table 1 - Diabetes Quality Improvement Intervention - 25-year (2009 – 2033) Effects

ENTRY AGE RANGE	Number of patients with diabetes entering treatment program each year	25-year total costs Without improvement program (Baseline)	25-year costs of Improvement program (gross spending)	25-year total costs with improvement program*	25-year costs of Improvement program (net spending)
24-30 year old	60,000	$167 billion	$21 billion	$161 billion	-$6 billion
31-40 year old	60,000	$145 billion	$20 billion	$145 billion	$0 billion
41-50 year old	60,000	$134 billion	$19 billion	$136 billion	$2 billion
51-60 year old	80,000	$153 billion	$21 billion	$159 billion	$6 billion
61-64 year old	100,000	$160 billion	$21 billion	$165 billion	$5 billion
24-40 year old	60,000	$151 billion	$21 billion	$148 billion	-$3 billion
41-64 year old	70,000	$137 billion	$19 billion	$141 billion	$4 billion

* Includes program costs. Dollar amounts in 2007 US $.

Table 2 - Diabetes Quality Improvement Intervention - 10-year (2009 – 2018) Effects

ENTRY AGE RANGE	Number of patients with diabetes entering treatment program each year	10-year total costs Without improvement program (Baseline)	10-year costs of Improvement program (gross spending)	10-year total costs with improvement program*	10-year costs of Improvement program (net spending)
24-30 year old	60,000	$21.0 billion	$3.7 billion	$22.1 billion	$1.2 billion
31-40 year old	60,000	$20.2 billion	$3.7 billion	$22.0 billion	$1.9 billion
41-50 year old	60,000	$20.7 billion	$3.6 billion	$22.1 billion	$1.5 billion
51-60 year old	80,000	$28.0 billion	$4.5 billion	$29.4 billion	$1.4 billion
61-64 year old	100,000	$34.9 billion	$5.1 billion	$36.5 billion	$1.6 billion
24-40 year old	60,000	$20.4 billion	$3.7 billion	$22.1 billion	$1.7 billion
41-64 year old	70,000	$24.4 billion	$4.0 billion	$25.9 billion	$1.4 billion

* Includes program costs. Dollar amounts in 2007 US $.

One of the policy challenges is how to design a program to effectively implement a diabetes quality improvement intervention like the one modeled above. It is clear that the younger the patient at the time of the intervention the greater the reduction in future complications and therefore future spending. This means that a traditional Medicare based approach would yield good, but not optimal results for either the patients or taxpayers. A better approach might target the younger cohorts reaching them before they reach 65 or become disabled.

There are a number of different design options available to policymakers. One example/option might use the Centers for Disease Control and Prevention (CDC) in partnership with state public health agencies and employers. This approach would not require an expansion of the Medicare entitlement and would allow policymakers to expand or contract the size of the program based on need and availability of funding. One advantage the designers would have is that many of the benefits needed for this intervention are already covered under most public and private insurance plans. Federal standards and financial underwriting might be matched with state implementation programs that partner with employers to encourage diabetic patients to join the intervention. States would be in a position to innovate based on their own population with diabetes, as long as they met federal standards. Employers might be encouraged to modify cost-sharing rules for patients with diabetes participating in the intervention to remove any disincentives for patients to obtain the combination of tests and treatments the intervention promotes.

This is only one example of the type of policy changes that could be used to implement the type of interventions modeled above. Policy makers and policy designers have a number of different parameters that can be balanced to optimize the positive outcomes of a program like this, while recognizing the realities of financing and political viability.

6. Corresponding changes in the federal budget process

In Phase I of this study we reviewed the federal budget process and its relationship to health spending projections, particularly as those projections related to efforts to prevent disease and avoid expensive care for complications arising from such diseases. In this section we explore how projections like those provided by the Diabetes Population Cost Model might be accompanied by changes in current federal scorekeeping practices to improve policymaking.

Professional cost estimators maintain a healthy skepticism regarding calls to alter the federal budget process, and rightfully so. In particular, the current congressional process is intended to support fiscal discipline in an environment that is inherently inclined to move in the opposite direction for political reasons. It is easier for elected leaders to agree to more spending and lower revenue than to vote to restrain spending and impose tax increases.

Moreover, it is not at all uncommon for proponents of more federal spending on particular programs to argue that such spending is necessary to achieve a later financial return. More funding for export promotion programs will create jobs and higher revenue; investments in the tax administration system will produce higher levels of revenue collection; more research and development funding will increase product development and economic growth; and the like. These types of arguments for increased spending are only successful with the professional estimators if the evidence is persuasive to a wide audience of neutral parties, particularly academic scholars.

As a result, the bar for making exceptions to the normal processes for cost estimating and enforcing budgetary decisions is set high among the professional staff at CBO and CMS, a stance that seems appropriate given the role they have in the overall process.[46]

Nonetheless, in the area of health care policy, it is clear that examining the implications of policies beyond ten years would, under certain circumstances, generate additional insights into current trends and how those trends might be affected by policy.

First, as is demonstrated in the DPCM, in the case of diabetes, it can take several years for some illnesses to progress from initial diagnosis to costly health care consequences. However, the current congressional budget process generally looks no further into the future than ten years. Indeed, current law only requires CBO and the Administration to provide budgetary estimates covering a five-year period, although recent congressional rules and historical practice have pushed the normal budgetary timeframe out somewhat.

We believe that for baseline and policy projections for certain health conditions, such as diabetes, even a ten-year window is too short to fully capture the health outcome and cost implications of various alternative scenarios. The risk factors for developing diabetes can be seen and measured many years before the disease has fully progressed, as shown in the output of the DPCM and certainly long before the costs associated with complications occur. These long time horizons for the natural history of the disease necessitate long-term thinking in terms of health care policy as well.

Second, policymakers need to focus their attention on the long-term cost problems in health care anyway. As the CBO Director, Comptroller General of the United States, and many others have stated, the most important threat to the nation's economic strength over the long run is the coming explosion in governmental health care spending in the Medicare and Medicaid programs. But today's budget process, particularly in Congress, remains focused on health costs within the ten-year budget window, which really does not provide a full perspective on the problem. Congress should be examining all manner of policy options aimed at reducing the cost pressures in 2020 and 2030.

[46] The Office of Management and Budget (OMB) is the agency responsible for overseeing all budgetary estimates transmitted by the President to Congress. However, in actual practice, OMB plays more of an oversight role, reviewing the estimates and modeling assumptions produced by the agencies. This is particularly true for estimates associated with complex programs, such as Medicare and Medicaid. Consequently, for the health care programs, CMS is the critical agency in the Executive Branch in terms of producing cost estimates and building models for cost projections. For a more lengthy explanation of the roles of the different agencies in the estimating process, see the Phase I report of this project.

We recommend that in certain cases, CBO and CMS should produce cost estimates for legislation covering a twenty-five year period instead of just ten years. While this would not be necessary for the vast majority of cost estimates produced by either agency, it would greatly add to the information base when Congress is considering health legislation with implications for the treatment of a small number of costly chronic illnesses.

To build consensus support for implementation of this new procedure, a joint task force, with members appointed by both the Executive Branch and the leaders in Congress, should be charged with establishing the circumstances under which such longer-term estimates would be required from the cost estimating agencies. These criteria should be based on ensuring such estimates are produced only when legislation would have a significant impact on the treatment or prevention of a costly and prevalent chronic illness for which a credible epidemiological model is readily available.

To allow these longer term estimates to be useful in the budget process, Congress could consider modifying a provision included in the 2008 Congressional Budget Resolution. In Section 204 of that resolution, Congress, for the first time, incorporated CBO's growing capacity for long-term cost estimating into the official budget process, albeit in a one-sided direction of simply preventing new long-term costs from easily passing in at least one chamber. The Senate established a new procedural hurdle against legislation that would increase the federal budget deficit by more than $5 million in any of the four decade increments beyond the normal ten-year budget horizon. If CBO found that legislation did in fact increase the deficit by more than the de minimis amount, any Senator could raise a "point of order" against the bill, which would prevent its consideration by the full Senate. That point of order could, like other budget enforcement mechanisms, be "waived," but only with the support of at least 60 Senators.[47]

Of course, this point of order is intended to prevent costly legislation from being enacted, even if such costs are not apparent within the normal ten-year window. Nonetheless, it provides an important precedent for using CBO estimates to enforce budgetary issues over longer time periods.

We believe Congress should consider building on the long-term cost estimating implicit in this provision as follows:

- The current pay-as you-go rules would continue to operate as they do now, which generally set up hurdles against legislation that would increase entitlement spending or cut taxes without also providing offsetting savings or new taxes within the ten-year window.

[47] Conference Report on the Concurrent Resolution on the Budget for Fiscal Year 2008, U.S. House of Representatives, Report 110-153, May 2007, p. 14.

- However, for legislation addressing a selected number of chronic conditions that would be best estimated using improved, long-term modeling approaches, CBO could be asked to provide twenty-five year cost estimates for legislation with a potential large impact on disease burden and budgetary costs. As mentioned, chronic conditions that might fall into this exceptional process would be limited to those for which credible long-term, epidemiological modeling is available and that are expected to have large costs and high numbers of beneficiaries suffering from the condition.

- The twenty-five year cost estimates provided by an approach then could be factored into the process for assessing the procedural hurdles faced by such legislation in a number of different ways. For instance, one approach would be to establish an average, inflation-adjusted cost for the full 25 years and apply such an estimate to the costs within the ten-year paygo point of order. This would effectively spread out over the full 25 years the offsetting reduction in costs that, in the context of diabetes, is otherwise only fully in view in the final 15 years of a cost estimate.

- CBO could provide a discounted estimate of the cost of the effort within the ten year window, reflecting the magnitude of the moderation as well as the probability that it would persist for the entire, longer-term period.

- For this adjustment to go into effect, it would be important to have broad-based agreement among the scorekeeping community. If the CMS actuary confirmed CBO's assessment, then the House or Senate Budget Committee Chairman could employ the alternative estimate.

One of the challenges associated with capturing savings from prevention efforts flows from Medicare's current design. The program generally pays at least a portion of the bill for whatever health services the enrollees use, with no questions asked. Consequently, in the past, efforts to reduce spending in a part of the program (such as inpatient hospital care) by increasing utilization of less expensive services in another part of the program (such as home health), have not been successful because there was no easy way to ensure reduced pressure for hospitalization could be realized and captured by the program. In the end, hospital use continued at its traditional rate, and home health care use increased rapidly as well.

This dilemma may well be raised and discussed in the context of treatment improvement efforts for chronic illnesses. Some budgetary experts might observe that given Medicare's current design, it would be difficult to ensure that improved health outcomes would translate into reduced use of services, given the tendency for demand to fill up whatever supply exists.

One potential way to address this dilemma is to give participants a stronger financial incentive to capture potential savings from treatment improvement. Currently, there is great interest in examining ways to put physicians in charge of overseeing care for those

with expensive chronic illnesses. Congress and CMS should pursue new studies of approaches to care which combine improved financial incentives for providers' management of chronic illnesses with treatment improvement regimes, such as those modeled in this study, which have the potential to reduce the need for expensive care due to complications. These kinds of studies need to be pursued with some care to avoid discouraging the necessary use of services.

7. Conclusions:

The burden of common and chronic diseases like diabetes will grow in the coming decades and have significant impacts on both the lives of Americans and the financial viability of programs like Medicare. It is crucial to provide policymakers with the best, most scientific information available as they wrestle with these difficult issues. This study has sought to raise this issue, provide recommendations for improving the information base, and stimulate discussion among policymakers and analysts.

In sum, this study makes the following points:

1. Cost-estimating agencies should carefully examine whether policymaking would be improved by augmenting current practices with disease-focused approaches to cost-estimating methodologies for certain conditions that are costly and can be modeled credibly based on current understanding of risk factors and disease progression.

2. Diabetes, specifically, can be modeled for disease burden and costs to the government over the next 25 years.

3. This model for diabetes burden and costs shows that certain, well-targeted prevention efforts could significantly improve health outcomes and reduce the costs of some costly complications later.

4. The federal budget process can be augmented to better incorporate this new modeling information into decision-making.

None of the work presented here is intended to replace current methodologies; rather, it is intended as an enhancement to the current set of tools that estimators use to better inform policymakers in the future.

We believe we have provided a new set of tools for policymakers and the estimators who help inform the policy debate. We have illustrated the potential for epidemiologically-based simulation models to better inform the federal budget estimating process. As shown by the results presented here, this kind of modeling can bring important information to the policy debate, including the health outcome implications of alternative policy scenarios.