PROJECTING THE FUTURE DIABETES POPULATION SIZE AND RELATED COSTS FOR THE U.S.

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OBJECTIVE — We developed a novel population-level model for projecting future direct spending on diabetes. The model can be used in the federal budget process to estimate the costs implications of alternative policies.

RESEARCH DESIGN AND METHODS — We constructed a Markov model simulating individuals’ movement across different BMI categories, the incidence of diabetes and screening, and the natural history of diabetes and its complications over the next 25 years. Prevalence and incidence of obesity and diabetes and the direct spending on diabetes care and complications are projected. The study population is 24- to 85-year-old patients characterized by the Centers for Disease Control and Prevention’s National Health and Nutrition Examination Survey and National Health Interview Survey.

RESULTS — Between 2009 and 2034, the number of people with diagnosed and undiagnosed diabetes will increase from 23.7 million to 44.1 million. The obesity distribution in the population without diabetes will remain stable over time with ~65% of individuals of the population being overweight or obese. During the same period, annual diabetes-related spending is expected to increase from $113 billion to $336 billion (2007 dollars). For the Medicare-eligible population, the diabetes population is expected to rise from 8.2 million in 2009 to 14.6 million in 2034; associated spending is estimated to rise from $45 billion to $171 billion.

CONCLUSIONS — The diabetes population and the related costs are expected to at least double in the next 25 years. Without significant changes in public or private strategies, this population and cost growth are expected to add a significant strain to an overburdened health care system.

The high cost of caring for individuals with chronic diseases is one of the most pressing issues in health care in the U.S. today (1). The baby boom generation is aging, and advanced age is accompanied by costly chronic illnesses. As a result, Medicare and other health-related governmental programs will face demographic and epidemiological forces that will challenge their financial viability.

In light of the sheer magnitude of costs associated with diabetes, policymakers and the public need to understand how these costs will change over the next decades and how new policies may alter these trends in costs. 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.

The forecasting effort presented in this article speaks directly to this concern by improving the rigor of the estimates of health outcomes and health care spending associated with future trends in the incidence, prevalence, and progression toward complications. We constructed a model of diabetes costs that accounts for the trends in risk factors for diabetes, the natural history of disease, and the effects of treatments—factors currently not used by government budget analysts. Inclusion of these factors in forecasting models can improve estimates under current trends and policies, and more importantly, forecast the impact of alternative policy scenarios.

Overall costs related to type 2 diabetes will be influenced by the demographic shifts in the population, population-level trends in obesity, the development and dissemination of new diabetes-related treatments, and diagnostic tests. Recent trends in obesity rates and major advances in the understanding of the natural history of diabetes have not been formally incorporated into prior forecasts of the burden of diabetes (2–4). We set out to integrate recent prediction models and epidemiological data for obesity, diabetes incidence, and diabetes complications to forecast the future size of the diabetic population and their related health care costs.

RESEARCH DESIGN AND METHODS — Estimates of future total health care costs for diabetes must take into account two dynamic processes. First, the diabetes population is constantly changing over time. New people are diagnosed and added to the population; contemporaneously, other individuals with existing diabetes die and leave this subpopulation. With the balance of these two processes, the prevalence of diabetes in the total population changes on an annual basis. The pace of change differs over time depending on factors such as the rate of obesity and age of those at risk. For instance, the aging of the large baby boom generation will bring large numbers of new people into age categories that are at higher risk of developing the disease.

Second, costs associated with diabetes tend to follow a natural progression over time. Complications take time to develop and inflict damage to the eyes, kidneys, and circulatory and nervous systems. Therefore, robust projection models must include estimates of the expected natural history of the disease based on alternative levels of disease management.

In developing our forecasting model, we account for two types of cohorts—a
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prevalent and an 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 the incident cohort. This group represents the new people with diabetes entering the diagnosed population each year 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 prevalent 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 timelines: 1) the chronological timeline during which we will report our total cost 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.

We developed explicit models to address this dynamic nature of cost accumulation. Figure 1 presents the conceptual accounting of costs over time. This involves accounting for all health care costs incurred for 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 Fig. 1). Empirically, we account for costs horizontally (as represented by arrows in Fig. 1). 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 cohorts of patients. We also account for heterogeneity in terms of patient characteristics for all cohorts.

There are three components that are central to estimating this accumulation of costs: 1) defining the prevalent cohort and its heterogeneity, 2) the diabetes incidence model, and 3) the lifetime simulation model for diabetes progression.

Defining the prevalent cohort and its heterogeneity
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 Survey (NHANES) (2005–2006). To create the prevalent cohort, we used self-reported disease to identify individuals with diabetes. We then estimated the U.S. population with diagnosed diabetes, undiagnosed diabetes, and no diabetes, categorized by sex, race/ethnicity, and age from 24 to 85 years. Because few clinical trial results include populations under 24 or over 85 years, this age range allows the model to estimate the effects of clinical trial results on the entire study population. Lifetime diabetes-related costs for the prevalent cohort are estimated using the lifetime simulation model for diabetes progression described below.

The diabetes incidence model
The main purpose of the incidence model is to account for new cases of undiagnosed and diagnosed diabetes in the 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.

Appendix Fig. S1A (available in an online appendix at http://care.diabetesjournals.org/cgi/content/full/dc09-0459/DC1) displays the basic structure of the Markov model 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. Online appendix Fig. S1B 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) 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 100% sensitive and specific). 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.

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. 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 (using the National Health Interview Survey) (3). All parameters are allowed to...
vary by sex, race, and ethnicity and smoothed over ages 24–85 years. Estimates of \( r \) are separately smoothed for age-groups <45, 45–64, and >64 years due to substantial heterogeneity across these age ranges.

Age-specific annual hazard of progression to diabetes for people without diabetes for different sexes and BMI categories are calculated based on observed incidence of people with diagnosed diabetes and current screening rates. The progression hazards increase monotonically with age in all categories and are highest for the obese category followed by overweight and normal at all ages.

**Lifetime simulation model of diabetes complications**

Within a 1-year cycle, patients move from one disease state to another or stay in the current disease state until death or age 95 years.

Online appendix Fig. S2 displays the design of the model of diabetes complications. This figure presents the structure of the decision analytic model. Hypothetical patients move through the model from left to right for each cycle length (1 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.

Data on demographic characteristics (sex and race/ethnicity) as well as relevant clinical characteristics (blood pressure levels, cholesterol levels, GHb 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-, sex-, and race/ethnicity-specific distributions of these factors within the models.

The diabetes complication models in this analysis are derived from U.K. Prospective Diabetes Study (UKPDS) results (6). Prediction models for all major diabetes-related complications have been developed by the UKPDS study group (7,8). These models have been internally and externally validated with cardiovascular trial data (9). The UKPDS model does not include glucose control as a predictor, making it unsuitable for evaluating the impact of improved diabetes care on end-stage renal disease. Instead, we modeled the development of microalbuminuria and proteinuria, which are linked to the intensity of glucose control (10). We used prediction models for these intermediate complications using optimization procedures to fit observations from the UKPDS control arm to a functional form used in the original National Institutes of Health model (11). For the transition between proteinuria to end-stage renal disease, we used probabilities from an observational study (12).

For background mortality rates, we used race/ethnicity- and sex-specific background mortality rates reported in U.S. life table statistics from 1999 (13). To calculate background mortality rates for individuals with diabetes, we subtracted cardiovascular mortality rates for the general population from the overall mortality rates found in life tables. We multiplied these rates by 2.75 as previously done to reflect higher background mortality rates for patients with diabetes (11). 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 (14,15).

Within the model, we 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 (16). Aspirin was assumed to reduce the probability of coronary heart disease but to increase the probability of gastrointestinal bleed (17). 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 clinical benefits (18).

**Health service utilization and cost 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 (19). Distribution of use of different oral glucose-lowering agents was assumed to be the observed distribution in national studies (20). Use of ACE inhibitors and aspirin therapy was based on recent national reports of diabetes care (21). Frequency of office visits and laboratory tests was assumed to be that observed in a recent national study (22).

We estimated drug costs based on the average type and frequency of drug prescriptions, dosage of medications, and wholesale drug prices. Annual costs of microvascular and cardiovascular complications were obtained from recent studies in the literature (please see the online appendix Table for details).

For this analysis, we used the complication model to predict the average annual costs of living with diabetes by different ages, sexes, racial groups, and major durations of diabetes. A total of 10,000 Monte-Carlo iterations (each iteration representing a patient life) were used to generate average estimates. All costs are expressed in 2007 USD. In estimating costs for future years, we applied the cost growth assumptions used by the Congressional Budget Office.

**RESULTS** — The results of our model regarding overall population changes in obesity, future population size, and health care spending have been briefly described in a related publication (23). We expand on those results and describe forecasts for the Medicare population.

**Changes in obesity**

Because our model predicts the progression from non-diabetes to diabetes, we estimate changes in percentage of obese, overweight, and normal-weight individuals in the population living without diabetes. Overall obesity distribution in the non-diabetes population remains fairly stable over time, with ~65% of the population being overweight or obese. The percentage categorized as overweight in the non-diabetes population is expected to remain steady at 35% over the time period. The percent categorized as obese is expected to drop slightly from 30% in 2009 to 27% in 2033. This same leveling of the obesity trend is found in projections produced by the Centers for Disease Control and Prevention for the U.S. population (24).

**Future population size for the U.S.**

We found that in 2009, there will be 19.5 million diagnosed and 4.25 million undiagnosed diabetes cases in the population ages 24–85 years. Over the next 12 years, the overall population with diabetes is expected to rise (Fig. 2). Among this population, the distribution of diagnosed and undiagnosed individuals will be shaped by the rate of arrival of new cases and continued screening for diabetes by the medical system. The combined effect is that the cohort of established diagnosed diabetes will grow, while the cohort of undiagnosed diabetes steadily declines and stabilizes at around 3.7 million by 2020. After 2020, the size of the cohort of people with undiagnosed diabetes is esti-
mated to decline. The annual incident cohort size follows the same pattern.

The growth of the Medicare population follows many of the same trends for the overall population with diabetes. For 2009, the model projects 6.5 million Medicare-eligible beneficiaries with prevalent diagnosed diabetes. During 2009, 0.9 million will be newly diagnosed with diabetes, while another 0.9 million will remain undiagnosed. By 2034, the number of individuals with diagnosed diabetes eligible for Medicare will rise to 14.1 million, while the size of the annual cohort with undiagnosed diabetes will decrease to 440,000.

Spending associated with the direct care of diabetes and its complications

For this analysis, we projected direct spending on diabetes and its complications for the next 25 years (Fig. 3). The sum of spending for the cohort that currently 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 (in constant 2007 USD), 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. Similarly, Medicare spending on diabetes care is estimated to rise from $45 billion in 2009 to $171 billion in 2034. Based on these estimates, Medicare spending alone will represent just over 50% of direct spending on diabetes in 2034.

CONCLUSIONS — We project that over the next 25 years, the number of Americans with diagnosed and undiagnosed diabetes will increase from 23.7 million to 44.1 million. During the same time period, annual spending related to diabetes is expected to increase from $113 billion to $336 billion (in constant 2007 USD). These changes are driven more by the size of incoming age cohorts than by changes in obesity and overweight rates. For Medicare, the project growth in diabetes care spending exceeds current projections of spending by Medicare and for the growth domestic product.

Our analysis is distinct from prior efforts to forecast the future size of the diabetes population. Prior studies have accounted for the changing size and age composition of the overall population and assumed fixed age-specific and sex-specific prevalence rates (2,3). More recently, Boyle et al. (4) demonstrated the important impact of changes in the ethnic composition of the population on the projected burden of diabetes. Our study is distinct in its accounting for the evolving nature of the distribution of body weight categories in the population. Our analysis is also unique in its accounting for the natural history of diabetes complications. Both innovations enhance our ability to forecast the future costs attributable to diabetes.

We built this model to improve the budgetary and health outcome information available to federal policymakers. The model provides a rigorous assessment of the future burden of diabetes that accounts for the natural history of the disease and recent advances in treatment. More importantly, the model can also be used to provide estimates of the impact of alternative policy scenarios. Current practices by federal scorekeeping agencies do not approach cost estimating in this manner, nor do they generally provide estimates beyond 10 years. This diabetes model is also meant to serve as an
example of the type of forecasting model that can be used by policymakers when considering policies for other chronic diseases. Such models are appropriate when abundant epidemiological data are available to forecast the natural history of disease incidence and progression, as is the case with type 2 diabetes.

The study has several limitations. First, attempts to forecast future costs and utilization are conditional on current rates of utilization. For example, we have used the most current estimates of screening rates for diabetes from NHANES. However, rates change over time, and future changes may influence our results. Our model also does not account for individuals under 24 years of age who enter the population. This limitation may be particularly relevant for accurately incorporating diabetes prevalence and incidence in the immigrant population, who may experience heterogeneous rates of developing the disease (25). Lastly, during our analysis of transitions across BMI categories, we grouped all individuals who had BMIs ≥30 kg/m². We did this because of a lack of available Medical Expenditure Panel Survey data to model transitions across finer BMI categories. Many of these limitations may lead to more conservative estimates of the future size of the diabetes populations and their costs.

Despite these limitations, our study strongly suggests that diabetes will grow in the coming decades, both in population size and costs, and will have significant impacts on the lives of Americans and the financial viability of programs like Medicare. Forecasting models like this can help policymakers anticipate future burdens of chronic diseases and design targeted policies that fight these diseases in the most effective ways possible, both in terms of clinical effectiveness and cost-effectiveness.

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E.S.H. and A.B. participated in the conception and design of the overall study, formulation of analysis plan, analysis of data, interpretation of findings, and preparation of the manuscript. M.O. and J.C.C. contributed to the overall study conception and design, formulation of analysis plan, interpretation of findings, and critical revision of the manuscript. E.S.H. had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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