The Growing Burden of Diabetes Mellitus in the US Elderly Population

Frank A. Sloan, PhD; M. Angelyn Bethel, MD; David Ruiz Jr, BS; Alisa H. Shea, MPH; Mark N. Feinglos, MD

Background: The prevalence of diabetes mellitus is growing worldwide. Consequently, there has been increased emphasis on primary and secondary prevention of diabetes. To our knowledge, whether there have been actual improvements in outcomes in the last decade or so has not been documented in a nationally representative sample.

Methods: We undertook this study to examine trends in rates of occurrence of diabetes and its complications in persons older than 65 years in the United States. National longitudinal analysis of Medicare claims and other Medicare program data for persons first diagnosed as having diabetes during 1994 (n=33 164), 1999 (n=31 722), or 2003 (n=40 058) were compared with 2 control groups of persons of approximately equal sample size who were not diagnosed as having diabetes, alternatively during 1994, 1999, or 2003 or for the entire period from 1994 to 1999 or from 1999 to 2004. The main outcome measures were death and complications of diabetes including cardiovascular, cerebrovascular, ophthalmic, renal, and lower extremity events.

Results: The annual incidence of diabetes increased by 23% between 1994-1995 and 2003-2004, and prevalence increased by 62%. The mortality rate after diagnosis in persons having diagnosed diabetes decreased by 8.3% compared with that in the control groups. Complication rates among persons diagnosed as having diabetes generally increased or stayed the same compared with those in the control groups during 1994 to 2004 except for ophthalmic diseases associated with diabetes. Rates for some major complications were high; for example, the rate for congestive heart failure in the diabetes group during 1999 to 2004 was 475 per 1000 persons. In some cases, most notably renal events, including the most serious complications, there were increases in prevalence in both the diabetes and control groups.

Conclusion: The burden of financing and providing medical care for persons older than 65 in the United States having a diagnosis of diabetes is growing rapidly as a result of increased incidence and, especially, prevalence of diagnosed diabetes, decreased mortality, and overall lack of improvement in rates of complications in persons having diagnosed diabetes.

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The prevalence of diabetes mellitus is increasing, in part because of population aging, but also in younger persons. The high disease burden reflects high rates of microvascular and macrovascular complications from diabetes and premature death.

See Invited Commentary at end of article

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Methods

Data

Data for 1991 to 2004 were obtained from national Medicare 5% claims files for inpatient, outpatient, Part B, and durable medical equipment containing data on service dates, diagnosis (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM]), and...
procedures (Current Procedural Terminology). Durable medical equipment claims contained Healthcare Common Procedure Coding System codes used to identify beneficiaries using low-vision aides and dialysis equipment. Other Medicare administrative data provided information on demographics and dates of death of sample persons. Data were linked by a unique identifier, permitting construction of longitudinal, person-specific data.

### SAMPLE SELECTION

Individuals were classified as having diabetes on the basis of having at least 2 Part B or at least 1 inpatient claim with a diabetes diagnosis code (ICD-9-CM, 250.xx). We selected 3 distinct cohorts of persons having a new diagnosis of diabetes in 1994, 1999, and 2003, hereinafter called “diabetes cohorts.” We searched all claims in the database from January 1, 1991, and for cohort years 1994, 1999, and 2003 (Table 1). We eliminated individuals having a diagnosis of diabetes before the cohort year. We then limited each cohort sample to persons older than 65 years for at least 6 months before the person’s first diabetes diagnosis and younger than 96 years as of December 31 of the cohort year. We also excluded individuals not surviving through July 1 of the cohort year and not enrolled for 6 months or more of that year in a Medicare health maintenance organization (HMO) (Table 1). There was no overlap of individuals among the cohorts.

Individuals in the 1994 and 1999 diabetes cohorts were followed up from enrollment in the cohort through December 31, 1999, and December 31, 2004, respectively. The 2003 cohort was followed up from the date of first diagnosis in 2003 through December 31, 2003.

Not all outcomes are unique to diabetes. Recognizing that persons not having a diagnosis of diabetes may have experienced similar adverse outcomes, we used 2 sets of control groups for the 1994 and 1999 diabetes cohorts and 1 control group for the 2003 diabetes cohort. The first control cohorts, control group A, consisted of 3 random samples of 200,000 persons each not having a diagnosis of diabetes from January 1, 1991, through December 31 of their respective cohort years (Table 1). After eliminating persons not satisfying age, survival, and HMO criteria, the control samples included 118,657 persons in 1994, 142,088 in 1999, and 122,069 in 2003. We then randomly sampled within-race/ethnicity categories from these populations so that the racial/ethnic mix and analysis sample sizes for each control group cohort matched the corresponding diabetes cohort (Table 1).

Although no persons in the control group A cohorts had a diabetes diagnosis through their cohort start years, some were subsequently diagnosed as having diabetes. Thus, we also selected control group B, subsamples of their respective control group A cohorts not having a diagnosis of diabetes through December 31 of the fifth year after the cohort year (Table 1). No control group B cohort was created for 2003 control group A because our data did not extend beyond December 31, 2004.

### OUTCOMES CLASSIFICATION

We examined mortality rates and cardiovascular, cerebrovascular, renal, ophthalmologic, and lower extremity adverse outcomes commonly associated with diabetes using ICD-9-CM and Current Procedural Terminology codes (Table 2). All outcomes were identified from diagnosis codes except for low visual acuity and end-stage renal disease (ESRD), which were identified from both durable medical equipment and ICD-9-CM codes.

### STATISTICAL ANALYSIS

Adverse outcomes were considered incident on the date the diagnosis or procedure code first was entered on a claim, and remained prevalent until death or through December 31 of a cohort’s final study year. We computed 3 rates of adverse outcomes, as follows: first-year incidence, with beneficiaries followed up from enrollment in the cohort to December 31 of the same year; 6-year prevalence, with prevalence rates based on diagnoses received from enrollment in cohorts through year 6 in persons still alive; and 6-year cumulative incidence, with rates based

### Table 1. Construction Process of Analysis Sample

<table>
<thead>
<tr>
<th>Year/No. of Persons Enrolled in Medicare 5%</th>
<th>No. of Persons With DM</th>
<th>With DM Before July 1 of Cohort Year</th>
<th>Older Than 65 Years Before</th>
<th>Died Before July 1, 6 Months in HMO, or Resided in US Territory in Cohort Start Year</th>
<th>Final Samples for Diabetes Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994/1 529 074</td>
<td>324 479</td>
<td>278 107</td>
<td>11 551</td>
<td>1657</td>
<td>33 164</td>
</tr>
<tr>
<td>1999/1 398 441</td>
<td>51 444</td>
<td>503 298</td>
<td>14 184</td>
<td>2240</td>
<td>31 722</td>
</tr>
<tr>
<td>2003/1 530 374</td>
<td>785 291</td>
<td>722 431</td>
<td>20 632</td>
<td>2170</td>
<td>40 058</td>
</tr>
</tbody>
</table>

Abbreviations: DM, diabetes mellitus; HMO, health maintenance organization; NA, data not available.

For Control Group A

<table>
<thead>
<tr>
<th>Year/No. of Persons Enrolled in Medicare 5%</th>
<th>No. of Randomly Selected Persons Without DM Before July 1 or Younger Than 95 Years by December 31 of Cohort Year</th>
<th>Died Before July 1, 6 Months in HMO, or Resided in US Territory in Cohort Start Year</th>
<th>DM Diagnosed During Study</th>
<th>Final Samples For Control Group A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994/1 529 074</td>
<td>200 000</td>
<td>39 788</td>
<td>41 555</td>
<td>4974</td>
</tr>
<tr>
<td>1999/1 398 441</td>
<td>200 000</td>
<td>35 325</td>
<td>22 587</td>
<td>6178</td>
</tr>
<tr>
<td>2003/1 530 374</td>
<td>200 000</td>
<td>43 799</td>
<td>34 132</td>
<td>NA</td>
</tr>
</tbody>
</table>

For Control Group B
Dependent variables in the logit analysis were changed relative to persons not having a diagnosis of diabetes. Rates of adverse outcomes showed results from the logit analysis of changes during 1 year; few of these changes were statistically significant.

Table 2. Diagnoses and Outcomes Codes Used to Identify Complications of Diabetes-Related Cardiovascular Disease: Diagnoses and Outcomes

<table>
<thead>
<tr>
<th>Diagnoses and Outcomes</th>
<th>International Classification of Diseases, Ninth Revision, Clinical Modification and Current Procedural Terminology Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular disease</td>
<td>Ischemic heart disease: 411.xx, 414.xx Angina: 413.x Congestive heart failure: 428.0, 428.1, 428.9, 428.2x, 428.3x, 428.4x, 398.91, 402.01, 402.11, 402.91, 404.01, 404.11, 404.91</td>
</tr>
<tr>
<td></td>
<td>Myocardial infarction: 410.x, 412.x Carotid artery stenosis or occlusion: 433.xx, 434.xx</td>
</tr>
<tr>
<td></td>
<td>Ophthalmic disease: Low visual acuity or blindness: 369.xx, V2392, V2600, V2610, V2615</td>
</tr>
<tr>
<td></td>
<td>Renal disease: Proteinuria: 791.x Nephrotic syndrome: 581.8 Chronic renal failure: 404.12, 404.13, 404.92, 404.93, 403.01, 403.11, 403.91, 586, 585</td>
</tr>
<tr>
<td></td>
<td>Ophthalmic disease: Background retinopathy: 362.01 Proliferative retinopathy: 362.02</td>
</tr>
<tr>
<td></td>
<td>Low visual acuity or blindness: 369.xx, 92392, V2600, V2610, V2615</td>
</tr>
<tr>
<td></td>
<td>Lower extremity complications: Claudication: 440.21, 440.22, 443.9 Paresthesia: 782 Pain in feet: 729.5 Diabetic amyotrophy: 358.1</td>
</tr>
<tr>
<td></td>
<td>Mononeuropathy: 355.8, 355.9 Polyneuropathy: 357.2 Cellulitis: 681.xx, 682.xx Neurogenic arthropathy: 713.5</td>
</tr>
<tr>
<td></td>
<td>Charcot foot: 94 Ulcer: 707.1-707.9 Arterial occlusion: 440.23, 440.24 Osteomyelitis: 730.0, 730.1, 731.8</td>
</tr>
<tr>
<td></td>
<td>Gangrene: 040.0, 250.7, 440.24, 785.4 Debridement: 86.28, 11000, 11011, 11040-11042</td>
</tr>
<tr>
<td></td>
<td>Amputation: 84.1x, 27290, 27295, 27590-27592, 27594-27596, 27598, 27880-27882, 27884, 27886, 27888, 28800, 28805, 28810, 28820, 28825</td>
</tr>
</tbody>
</table>

RESULTS

The total number of persons in the sample decreased slightly from 1994 to 1999 but increased from 1999 to 2003 (Table 3), primarily reflecting US population changes and the peak popularity of Medicare HMOs. Incidence and prevalence of diagnosed diabetes increased from 1994 to 2003. First-year incidence rose by 23% (2.2%-2.7% annually). Prevalence rates increased by 62% (15.3%-24.8%).

There were no important demographic changes in the diabetes and control groups except for race/ethnicity (Table 4). Given demographic similarities and the lack of other meaningful differences between control group A and control group B cohorts, we report results only for control group B.

Death rates during the first year after having a diabetes diagnosis were unchanged across cohorts (44, 43, and 44 per 1000 persons for the 1994, 1999, and 2003 diabetes cohorts, respectively) (Table 5). In control group B, death rates were significantly lower and declined between 1999 and 2003 cohorts (26, 26, and 19 per 1000 persons). During 6 years of follow-up, 349 per 1000 persons in the 1994 diabetes cohort died. Overall mortality in the 1999 cohort was lower (332 per 1000 persons), a small downward trend. Although the 6-year mortality rates for the control group B cohorts were much lower than for the diabetes cohorts, there was no significant change between the 1994 and 1999 cohorts.

Many adverse outcomes were diagnosed within the first year in each of the cohorts with diabetes, and during the remaining 5 years, complication rates continued to increase. Thus, most persons with diabetes experienced at least 1 adverse outcome by the end of year 6. Cumulative incidence of any adverse outcome by the end of year 6.

Table 3 lists the most common diagnoses within each category of complications (eg, cardiovascular disease [CVD]). Within cardiovascular complications, congestive heart failure (CHF) and myocardial infarction (MI) were most common. Almost half of the persons in the 1994 and 1999 diabetes cohorts still living at year 6 received a diagnosis of CHF. Cumulative incidence of CHF
in the diabetes cohorts increased by 4.4% between 1994 and 1999, indicating that substantially more persons died of CHF in the 1999 cohort vs the 1994 cohort. The pattern was similar for MI. However, 6-year prevalence of stroke among survivors declined, but there was no significant change in cumulative incidence of stroke, indicating that although stroke remained a major cause of death, among persons surviving through year 6, fewer had a stroke during 1999 to 2004.

For renal complications, there were substantial increases in rates of chronic renal failure and ESRD among persons receiving a diagnosis of diabetes in year 1, 6-year prevalence, and 6-year cumulative incidence. For lower extremity complications, although 6-year prevalence increased, rates of serious complications including amputation, debridement, gangrene, and ulcer remained stable or decreased.

The Figure shows changes in outcomes in persons having a diagnosis of diabetes relative to their corresponding control group B cohorts. Odds ratios (ORs), with 95% confidence intervals (CIs), show changes in the probability of an outcome between the 1994 and 1999 cohorts relative to changes for the control group B cohorts. There was an increase in the frequency of peripheral vascular disease and of stroke (OR, 1.07; 95% CI, 1.01-1.13) and cumulative incidence (OR, 1.07; 95% CI, 1.02-1.12) of CVD among persons with diabetes increased relative to the controls. Cumulative incidence of lower extremity complications among those with diabetes rose comparatively (OR, 1.08; 95% CI, 1.03-1.13), but there was no statistically significant change in 6-year rates or rates of the most serious lower extremity complications. Six-year prevalence (OR, 0.92; 95% CI, 0.87-0.98) of cerebrovascular disease and of stroke (OR, 0.91; 95% CI, 0.84-0.98) decreased, as did cumulative incidence. For renal disease, there were no statistically significant differences in 6-year prevalence or cumulative rates among persons with diabetes relative to controls; however, rates of severe complications, chronic renal failure, and ESRD increased appreciably for both diabetes and control groups. Ophthalmic disease in the diabetes groups decreased relative to that in control groups in 6-year prevalence (OR, 0.80; 95% CI, 0.73-0.88) and cumulative incidence (OR, 0.81; 95% CI, 0.73-0.88). For most conditions (Figure), there was no statistically significant change in outcomes between persons with diabetes and control groups for the 1994 and 1999 cohorts. There was an increase in the frequency of persons with at least 1 claim because of hemoglobin A1c (462-538 per 1000 persons; P < .001) and lipid cholesterol (569-621 per 1000 persons; P < .001) tests between the 1994 and 1999 diabetes cohorts.
The burden of diabetes among the US elderly increased from 1994 to 2004. Incidence and, particularly, prevalence of diagnosed diabetes increased. The mortality rate in persons having a diagnosis of diabetes declined by 8.3% relative to that in control groups. While increased longevity is a favorable outcome, it will add to the burden of care. While changes in 6-year prevalence rates of complications were mixed, when accounting for all persons in the 6-year study (cumulative incidence), most complications increased over time. Combined, these factors impose a direct financial burden of care and resources committed to diabetes and its complications.

New criteria for diagnosing diabetes were introduced in 1997,12,13 lowering the fasting glucose threshold for diagnosis from 140 mg/dL to 126 mg/dL (to convert to millimoles per liter, multiply by 0.055). This change led to diagnosis of diabetes at an earlier stage in the disease process.14 Earlier diagnosis and treatment of diabetes might be expected to improve mortality and lower complication rates, even without a change in rates of disease progression; however, we found that there was little relative improvement in diabetes outcomes between the 1994 and 1999 cohorts. There was no change in 1-year mortality across the 3 cohorts despite the change in diabetes diagnostic criteria. We expected the 1999 diabetes cohort, diagnosed using the newer criteria, to be younger. The age difference, however, between the 1994 and 1999 cohorts was trivial.

Table 5. Rate of Adverse Outcomes per 1000 Persons

Table:<br>Condition | Year 1 | | | Year 6 | | | Cumulative Incidence | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | I n gnost ICU 1968 (NO. 2) | JAN 28, 2008 | WWW.ARCHINTERNMED.COM | 196 | ©2008 American Medical Association. All rights reserved. | Downloaded From:  on 10/17/2018
diabetic and nondiabetic cohorts. In the diabetic cohort, after 6 years of diagnosed diabetes, nearly 9 of 10 individuals experienced at least 1 adverse outcome. Approximately 40% were diagnosed as having CHF vs 20% for the control groups. Similarly, rates of MI in the diabetic cohort were nearly twice that for the control groups. We observed no statistically significant improvements in cumulative incidence for either CHF or MI. Therefore, despite the general focus on cardiovascular prevention and aggressive preventive recommendations for patients with diabetes, no clear effect on cardiovascular event rates was noted.

Fox et al.11 reported a 50% reduction in incident cardiovascular events among adults aged 45 to 64 years with diabetes for 1950 to 1995 using data from the Framingham Heart Study. In our study, cumulative incidence of CVD increased during 6 years after a diagnosis of diabetes. In contrast to the findings of Fox et al.,4 persons diagnosed as having diabetes after age 65 years in our study did not experience reduced CVD rates. Some, but probably not all, of the increase in overall adverse cardiovascular outcomes we observed could be the result of increased usage and sensitivity of diagnostic testing.15

Year-6 stroke rates in patients with diabetes showed a favorable trend compared with unchanged rates in the control groups. However, cumulative incidence of stroke in the group with diabetes was similar between cohorts, compared with increased rates of stroke in the control groups, indicating increased incidence of death owing to stroke in the diabetic group.

A striking study finding is the marked increase in renal disease including renal failure and ESRD in both diabetes and control groups. Increased rates have been reported previously.16-18 The growth rate for ESRD in the United States and worldwide has been far higher than for diabetes.19-22 However, during this same period, vigilance for renal disease increased, exemplified by the recommendation for yearly screening with microalbumin testing. Increased use and complexity of services provided to Medicare beneficiaries during this time have been documented,23,24 including increases in diagnostic testing.19

The frequency of diagnosis of diabetes-related renal disease within 1 year of diagnosis of diabetes rose dramatically with each progressive cohort, doubling by 2003. However, these changes occurred in both persons with and without diabetes, with no significant difference in the trends for renal disease between groups. Reasons for the increase in chronic kidney disease are not well understood.25,26

The prevalence of all lower extremity complications in the first year rose in successive cohorts in persons with and without diabetes. A major contributor to these trends is coding for foot pain.27 In contrast, frequency of limb-threatening conditions such as amputation, debridement, and gangrene remained stable. Indeed, while most patients had evidence of lower extremity complications after 6 years of follow-up, the prevalence of serious complications including gangrene and amputation significantly decreased between the 2 cohorts. Trends in gangrene and amputation were not significantly different between the diabetic and nondiabetic cohorts, perhaps indicating advancements in medical therapy that enabled avoidance of surgical intervention.

Among several important strengths of this study are its national and longitudinal features, its use of control groups, and its analysis of multiple, diverse outcomes. Our findings demonstrate the risk of generalizing about overall outcomes by examining a specific outcome. For example, ophthalmic complications decreased while lower extremity complications increased during 1994 to 2004.

We acknowledge several study limitations. First, diagnosis of diabetes and adverse outcomes was based on data from Medicare claims. Claims data were designed for administrative not research purposes. Medicare claims

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data are highly specific in identifying persons with diabetes and its complications, but such data are insensitive; they often fail to capture diabetes when it is present. While a beneficiary may have had a diagnosis of diabetes before 1991, construction of our cohort samples required, at minimum, a 3-year review period before a cohort year. Having multiple years of data on beneficiaries helped improve diabetes identification sensitivity. Second, outcomes can only be ascertained if patients are seen by a physician. Failure to visit physicians at recommended intervals may lead to underestimation of complication rates. Low rates of adherence to diabetes guidelines have been documented. Third, although a 5-year follow-up after initial diagnosis of diabetes represents an improvement over most previous studies, longer follow-up may have revealed different trends. Fourth, we excluded enrollees in Medicare HMOs. On average, enrollees in such plans tend to be healthier than those remaining in fee-for-service. Fifth, we lacked information on cause of death. Given the lack of significant reductions in cardiovascular event rates, the 8.3% reduction in mortality rate in the diabetic population is somewhat surprising. We have not clearly identified sources of death other than CVD to explain this finding. Although the second limitation may lead to an underestimation of true rates of diabetes and their adverse effects, the fourth limitation may lead to overstatement.

Overall, our findings emphasize the overwhelming burden of diabetes, including the near 90% prevalence of an adverse outcome and many serious and resource-consuming outcomes such as CHF, MI, and stroke. Although other studies have shown improvements with time in surrogate markers for diabetes complications, such as lowering low-density lipoprotein cholesterol concentration and hemoglobin A1c level reduction, these findings come primarily from National Health and Nutrition Examination Surveys (NHANES). Although NHANES is nationally representative, it does not focus on the elderly. To our knowledge, our study is the first to demonstrate that improvements in surrogate markers may not translate into reduction in adverse events. With population aging and increased incidence of diabetes, demand for medical care will almost surely increase, both for general monitoring of diabetes and for treating its sequelae. For Medicare, the message is that the increased burden of diabetes will contribute to increased budgetary pressures in the future.

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Drafting of the manuscript: Sloan, Bethel, Ruiz, Shea, and Feinglos.
Critical revision of the manuscript for important intellectual content: Sloan, Bethel, Ruiz, and Feinglos.
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Study supervision: Sloan.

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REFERENCES

Throughout the world, chronic diseases are becoming the dominant health challenges. Among these chronic diseases, diabetes mellitus, usually type 2, is everywhere. Indeed, the concern about diabetes is so great that the United Nations has declared the condition a potential threat to society. Excessive weight and physical inactivity have a major role, along with the “rectangularization of the demographic profile,” that is, fewer youth and more people older than 60 years with a greater likelihood of diabetes associated with older age. In a previous study, Bethel et al documented the excess complications and mortality in persons older than 65 years with diabetes compared with a control group without diabetes.

Sloan and colleagues further describe the effect of complications associated with the increasing diabetes incidence and prevalence observed in the aging population in the United States. While the mortality rate after diabetes diagnosis decreased about 8% relative to a control group, in general, there was little evidence of fewer serious diabetes complications compared with a comparable control group with time; we do not seem to be making great progress in preventing complications in these elderly diabetes cohorts. Sloan and colleagues rightly describe the effect of this phenomenon on health systems and potentially on the economy. Taken to the extreme, there will soon be too many patients with diabetes to be individually treated and not enough money to pay for it all! Given these possibilities, primary prevention programs must be put in place before the diabetes of advancing age becomes a reality. We know they can work in controlled settings, so the evidence is already there. The real challenge is to translate the study results successfully throughout the world. We are not good at it and have much to learn about how to implement these types of programs. But unless we become good, what Sloan and colleagues describe and worry about will come true!

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