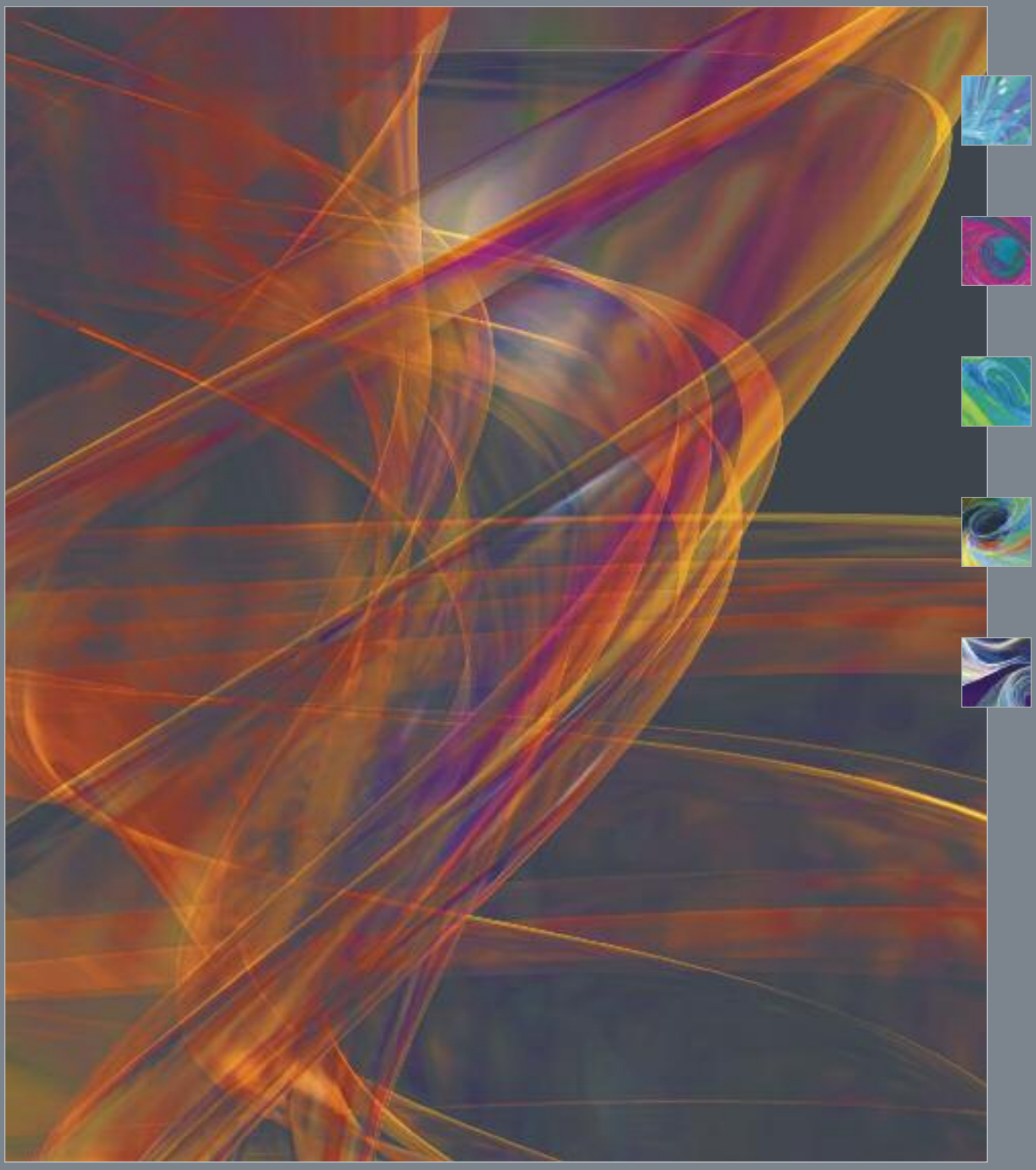
Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book®: Diabetes



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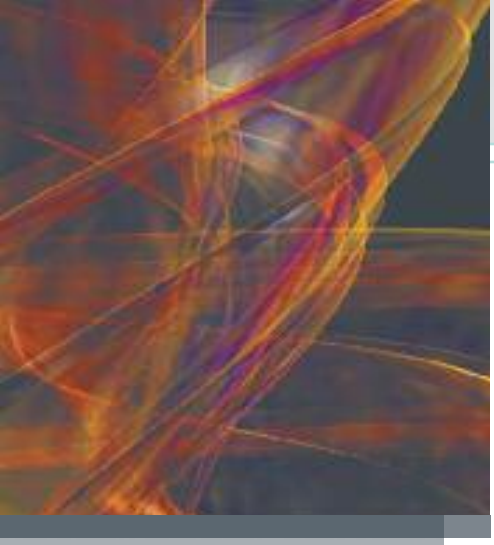

Preface

Americans are living longer than ever before. Unfortunately, for too many people those added years are not always experienced in good health. Chronic disability that can accompany aging accounts for 85% of all health care spending in the U.S., which will escalate as the population grows older with each passing day.

Trillions of tax dollars and consumer spending are at stake in the debate over reforming the financing of U.S. health care. What is too often missing from the current debate is the critical need for scientific and medical advances with the potential to blunt future cost increases posed by increasing encounters with chronic diseases such as diabetes. Reforms to increase access and reduce costs for health care need not and should not undermine the continuous process of innovation that promises newer and better therapies and more effective health and preventive care in the future.

In order to promote pro-innovation policies, the not-for-profit Alliance for Aging Research publishes *The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation. The Silver Book* is a unique almanac of nearly 2,000 compelling statistics and eye-opening facts that spotlight the mounting burden of chronic disease and the promise of innovation in mitigating that burden. While much of this information is usually buried in dense reports and technical studies, *The Silver Book* extracts key findings and brings the well-referenced information to the fingertips of those shaping policy.

The first volume of *The Silver Book* was launched in 2006 and has quickly become a trusted resource. We are pleased to introduce the latest volume in this important collection, *The Silver Book®: Diabetes*, which paints a comprehensive picture of the burden of diabetes (**Information pertaining specifically to the older population is noted in silver type**). All data are thoroughly referenced to validate original sources. This information is also available and continuously updated at www.silverbook.org, along with data on other chronic diseases including cancer, cardiovascular disease, neurological disease, osteoporosis, and vision loss.

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The Silver Book®: Diabetes





Introduction

While there have been advances in recent years in prevention, diagnosis and treatment, diabetes continues to be a major health threat for at least 28 million Americans. The biggest concerns for individuals with the disease are its many complications and co-morbidities. These complications can cause vision loss, heart disease, stroke, and other debilitating medical conditions.

In addition to age, race/ethnicity and socio-economic status (SES) play a large role in increasing risk for diabetes. Non-Hispanic Blacks and Latino Americans are at a much greater risk for developing type 2 diabetes than the general population. Access to care becomes a large burden to those living in poverty. Not only should innovative steps be taken to prevent or eliminate the disease, but to decrease the diabetes disparity gap. Intervention strategies are being developed to immediately ease the complications seen by high-risk groups.

Many studies have led scientists and health care professionals to realize the importance of diabetes management. Even modest steps yield enormous results in the health of individuals and reducing costs associated with the disease. One study, consisting of a 60 minute initial assessment and 12 hours of group education on nutrition and self-management, lowered the number of individuals experiencing coronary heart disease events by 12% over 10 years. This is a significant accomplishment for only 13 hours of education. While scientists are working hard to find a way to prevent diabetes, management interventions can help ease the burden on those currently diagnosed.

In 2007, type 2 diabetes alone cost our nation $159.5 billion in direct and indirect health care expenses. These costs are fairly conservative, not taking into account costs associated with unpaid caregiving and complications resulting from undiagnosed diabetes. Innovation in metabolic research is bringing hope for major advances and breakthroughs against diabetes, but it is still critical that we ensure support for research and incentives for innovation are a top national priority. These costs, both in human and economic terms, will surely continue to rise if new diagnosis and prevention strategies are not developed.

Daniel Perry
President & CEO
Alliance for Aging Research

Alliance FOR AGING RESEARCH
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The Human and Economic Burden

Cost of Diabetes

The cost of diabetes is difficult to assess with precision because of the number of undiagnosed Americans and the rippling effect the disease has on other health conditions. Diabetes slowly erodes productivity and independence, and the health consequences are difficult to reverse. More than 60% of non-traumatic lower-limb amputations occur in Americans who have diabetes. This one consequence of diabetes by itself can quickly rob an individual of high functioning and quality of life.

Diabetes poses a huge burden on individuals, families and the economy. Indirectly, the disease can lead to a host of complications that factor into the total cost. Kidney failure, diabetic retinopathy, nervous system damage, heart disease and stroke are only a few of the many complications of diabetes. Because diabetes is the leading cause of kidney failure, a breakthrough in diabetes prevention or treatment would directly affect the prevalence of that condition. This is the case for many other diabetes complications.

Advancing age is a significant risk factor for diabetes. In fact, about 63% of Americans are diagnosed with diabetes between ages 55 and 74. Because of the many adverse health consequences, not only are the direct costs a burden, but when the indirect costs of other health problems caused by diabetes are added, the economic burden of the disease escalates dramatically. For example, in 2007 $27 billion was spent in direct care for diabetes, but $58 billion was spent to treat diabetes-related chronic complications.

Unless new and better means are discovered and deployed to manage diabetes and its complications, the costs associated will rise with the growing number of Americans diagnosed. Investments towards better care must be maintained and increased in diabetes research to support the hope that such discoveries will relieve a major health challenge to the U.S. While awareness has increased regarding the burden of diabetes and its health complications, funding for research and development has not kept pace. Unless research advances are well financed and rewarded, the personal and public costs of diabetes will continue to burden the nation.

Prevalence and Incidence of Diabetes

- Diabetes was the 7th leading cause of death in 2006, based on the 72,507 death certificates that listed it as the underlying cause of death. However, it is likely that diabetes is underreported as a cause of death. Studies show that only 35-40% of decedents with diabetes had it listed anywhere on the death certificate, and only 10-15% had it listed as the underlying cause of death.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- In 2005-2006, 28 million Americans—13% of the population aged 20 or older—had diabetes; approximately 40% was undiagnosed.

  Cowie et al. 2009, *Full Accounting of Diabetes and Pre-Diabetes in the U.S. Population*

- 17.5 million Americans had diabetes in 2007, compared to 12.1 million in 2002.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- 12 million American men age 20 and older—11.2% of all men in this age group—have diabetes.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- 11.5 million American women age 20 and older—10.2% of all women in this age group—have diabetes.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

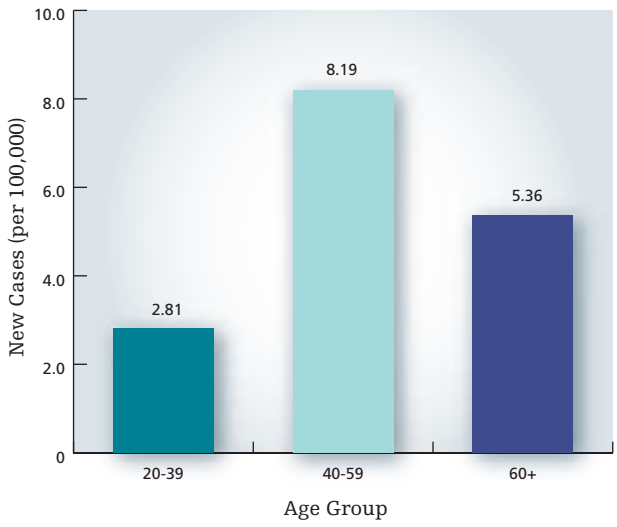
- For Americans born in 2000, their lifetime risk of developing diabetes is about 32.8% for males and 38.5% for females.

  Narayan et al. 2003, *Lifetime Risk for Diabetes Mellitus in the United States*

- Type 1 diabetes accounts for an estimated 5.7% (1.0 million) of the 17.5 million people with diagnosed diabetes.

  Dall et al. 2009, *Distinguishing the Economic Costs Associated with Type 1 and Type 2 Diabetes*

- Estimated Number of New Cases of Diagnosed Diabetes in People Aged 20 Years and Older, By Age Group, United States, 2007



Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Type 2 diabetes mellitus affects more than 7% of adults in the US and leads to substantial personal and economic burden.

  Crandall et al. 2008, *The Prevention of Type 2 Diabetes*

- An estimated 57 million adults had prediabetes in 2007.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

Age—A Major Risk Factor

- In 2007, 12.2 million (23.1%) Americans age 60 and older had diabetes.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- In 2004, 31.3 million Medicare beneficiaries living in the community had diabetes.

  Adler 2008, *Diabetes in the Medicare Aged Population, 2004*

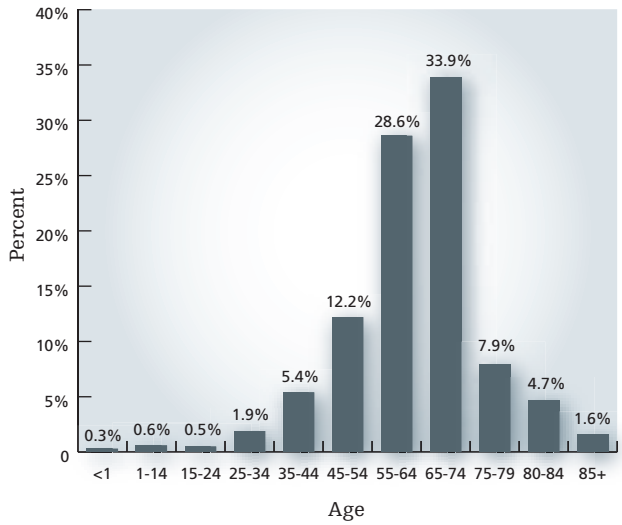
- From 2003-2006, 10.6% of Americans age 40-59 had diabetes. The percentage more than doubled to 22.9% for those aged 60 and over.

  National Center for Health Statistics 2008, *Health, United States, 2008*

- In 2005-2006, prevalence of diagnosed diabetes in Americans increased with age and peaked at age 60–74 years—with 17.6% of this population diagnosed.

  Cowie et al. 2009, *Full Accounting of Diabetes and Pre-Diabetes in the U.S. Population*

- Percent Distribution of Age at First Diagnosis With Diabetes: 2004



Adler 2008, *Diabetes in the Medicare Aged Population, 2004*

The Burden of Diabetes

The Human Burden

- Diabetes is the leading cause of kidney failure; in 2005, it accounted for 44% of new end-stage renal disease cases.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Approximately 60% to 70% of people with diabetes have mild to severe forms of nervous system damage causing impaired sensation or pain in the extremities, slowed digestion, carpal tunnel syndrome, and other nerve problems. Almost 30% of people with diabetes 40 years and older have impaired sensation in their feet.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Americans age 60 and older who have diabetes are 2-3 times more likely to report an inability to walk ¼ of a mile, climb stairs, do housework, or use a mobility aid compared with persons without diabetes in the same age group.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Of Medicare fee-for-service patients with chronic conditions, more are treated for diabetes than any other condition (24.3%).

  Schneider et al. 2009, *Prevalence of Multiple Chronic Conditions in the United States' Medicare Population*

- Heart disease death rates in adults with diabetes are 2 to 4 times higher than in adults without diabetes.

  Centers for Disease Control and Prevention 2008, National Diabetes Fact Sheet

- The risk of stroke is 2 to 4 times higher in people with diabetes than in those without the disease.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- In 2003-2004, about 75% of all adults with self-reported diabetes took prescription medications for hypertension or had blood pressure greater than or equal to 130/80 mmHG.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- The average number of diabetes medications used per patient increased from 1.14 in 1994 to 1.63 in 2007.

  Alexander et al. 2008, *National Trends in Treatment of Type 2 Diabetes Mellitus, 1994-2007*

- Diabetes is the leading cause of new cases of blindness in adults 20-74 years old.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness every year.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Diabetic retinopathy often causes vision loss and blindness during working age years, resulting in more disability and person-years of vision lost per case than other eye diseases.

  Kempen et al. 2004, *The Prevalence of Diabetic Retinopathy Among Adults in the United States*

- Patients with a long duration of type 2 diabetes were found to have a lower total brain volume and gray and white matter volume than those without the disease.

  Saczynski et al. 2009, *Glycemic Status and Brain Injury in Older Individuals*

- More than 60% of non-traumatic lower-limb amputations occur in people with diabetes.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Due to the combined burdens of diabetes and its complications, individuals at age 60 who are diagnosed with diabetes have a reduction in life expectancy and quality-of-life years of 7.3 and 11.1 years, respectively, for men, and 9.5 and 13.8 years for women.

  Gambert & Pinkstaff 2006, *Emerging Epidemic: Diabetes in Older Adults*

- The estimated number of physician office visits for treated diabetes increased from 25 million in 1994 to 36 million in 2007.

  Alexander et al. 2008, *National Trends in Treatment of Type 2 Diabetes Mellitus, 1994-2007*

- Approximately 40.7 million of the 186 million hospital inpatient days in 2007 were the direct result of diabetes, and 24.3 million more were due to other conditions attributed to diabetes.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- In 2004, heart disease was noted on 68% of diabetes-related death certificates among Americans aged 65 and older.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

The Economic Burden

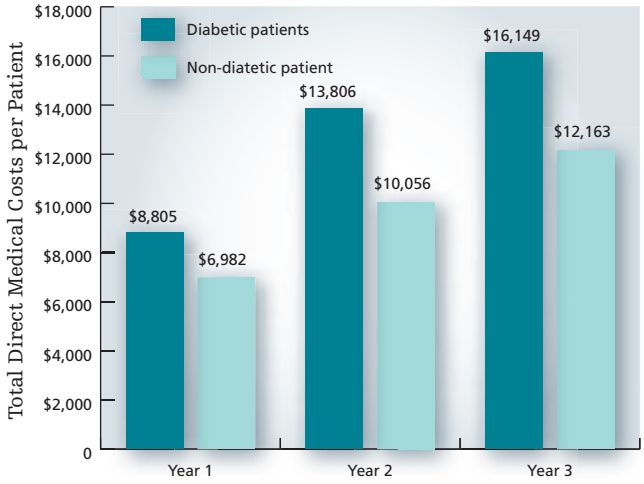
- On average, Americans with diagnosed diabetes have medical expenditures that are approximately 2 times higher than what expenditures would be in the absence of diabetes.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The annual direct medical costs (including outpatient, inpatient, and prescription drug services) for Americans age 40 and older with diabetic retinopathy is $493 million.

  Rein et al. 2006, *The Economic Burden of Major Adult Visual Disorders in that United States*

- Patients with diabetes that are hospitalized for a cardiovascular event incur higher costs for cardiovascular care than their non-diabetic counterparts over 3 years. Compared to patients without diabetes, patients with diabetes had higher mean total direct medical costs per patient for cardiovascular events during follow-up years.



Straka et al. 2009, *Incremental Cardiovascular Costs and Resource Use Associated with Diabetes*

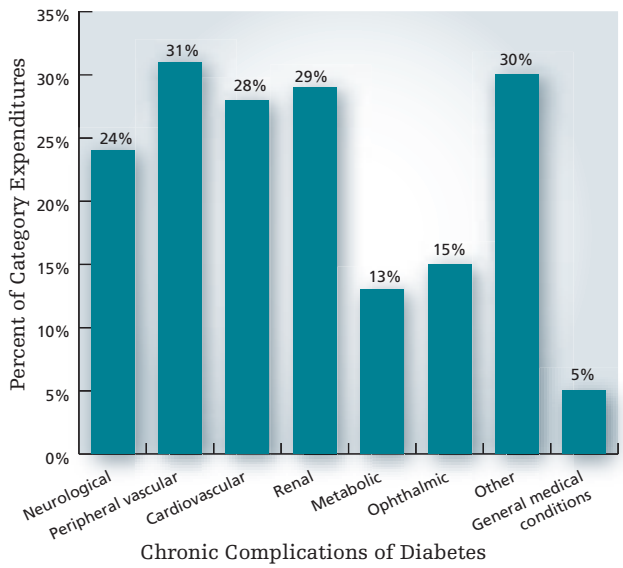
- In 2007, type 1 diabetes cost approximately $14.9 billion (direct medical costs, $10.5 billion; indirect $4.4 billion), while type 2 cost $159.5 billion (direct medical costs, $105.7 billion; indirect $53.8 billion).

  Dall et al. 2009, *Distinguishing the Economic Costs Associated with Type 1 and Type 2 Diabetes*

- Three-year (1993-1995) estimates of medical care charges for patients with diabetes ranged from $10,439 for those without comorbid conditions to $44,417 for those with heart disease and hypertension.

  Gilmer et al. 1997, *The Cost to Health Plans of Poor Glycemic Control*

- Percent of Category Expenditures Associated with Diabetes



American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- Medicare beneficiaries with diabetic macular edema (DME) had 31% higher 1-year costs and 29% higher 3-year costs compared to diabetic Medicare beneficiaries without DME.

  Shea et al. 2008, *Resource Use and Costs Associated with Diabetic Macular Edema in Elderly Persons*

- Health Care Expenditures Attributed to Diabetes in the U.S. by Age Group and Type of Service, 2007 (in Millions of Dollars)

Cost component	Age (years)			Total*
	<45	45–64	≥65	
Hospital inpatient	$4,551	$18,447	$35,346	$58,344
Nursing/residential facility	$166	$1,527	$5,793	$7,486
Physician's office	$1,113	$3,982	$4,802	$9,897
Emergency department	$1,047	$1,384	$1,438	$3,870
Hospital outpatient	$645	$1,312	$1,028	$2,985
Home health	0	$1,823	$3,763	$5,586
Podiatry	$14	$58	$202	$273
Insulin	$788	$1,564	$1,381	$3,733
Diabetic supplies	$217	$859	$707	$1,783
Oral agents	$967	$4,163	$3,456	$8,586
Retail prescriptions	$1,099	$5,161	$6,432	$12,692
Other equipment and supplies	$77	$448	$365	$890

* Numbers do not necessarily sum to totals because of rounding.

American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The total estimated cost of diabetes in 2007 is $174 billion—$116 billion in medical expenditures and $58 billion in reduced productivity.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- Medical costs attributed to diabetes include $27 billion in direct care, $58 billion in treating diabetes-related chronic complications, and $31 billion in excess general medical costs.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The largest components of medical expenditures attributed to diabetes are hospital inpatient care (50% of total cost), diabetes medication and supplies (12%), prescriptions to treat diabetes complications (11%), and physician office visits (9%).

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- Americans with diagnosed diabetes incur average expenditures of $11,744 per year—of which $6,649 is attributed to diabetes.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- Approximately 1 in 5 health care dollars in the U.S. is spent caring for someone with diagnosed diabetes, while 1 in 10 health care dollars is attributed to diabetes.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- In 2007, unemployment from a diabetes-related disability costs $7.9 billion.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- Reduced productivity while at work due to diabetes cost the U.S. $20 billion in 2007.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The cost of lost productivity from premature mortality due to diabetes was $26.9 billion in 2007.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The number of workdays absent because of diabetes in 2007 is approximately 15 million, costing the nation $2.6 billion.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The national burden of diabetes is likely to exceed $174 billion because it omits the social cost of intangibles such as pain and suffering, care provided by unpaid caregivers, excess medical costs associated with undiagnosed diabetes, and other health care expenditures categories omitted from this study.

  American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

- The average cost per diabetes prescription increased from $56 in 2001 to $76 in 2007.

  Alexander et al. 2008, *National Trends in Treatment of Type 2 Diabetes Mellitus, 1994-2007*

- Diabetes drug expenditures rose from $6.7 billion in 2001 to $12.5 billion in 2007.

  Alexander et al. 2008, *National Trends in Treatment of Type 2 Diabetes Mellitus, 1994-2007*

- Annual Productivity Loss Per Person with Diabetes by Cause, 2007

Age	Absenteeism	Presenteeism	Reduced productivity for those not in labor force	Unemployment from disability	Premature mortality
Male					
18–34	22	1,458	17	936	3,366
35–44	99	2,883	10	728	4,476
45–54	493	2,688	72	652	4,468
55–59	360	2,196	109	315	3,081
60–64	181	1,517	131	806	1,822
65–69	86	721	—	274	569
70+	45	378	—	146	284
Female					
18–34	50	844	21	743	1,095
35–44	47	1,378	14	1,216	1,456
45–54	240	1,310	70	449	1,388
55–59	179	1,093	90	491	994
60–64	72	604	80	492	642
65–69	27	228	—	448	140
70+	17	140	—	74	116

American Diabetes Association 2008, *Economic Costs of Diabetes in the U.S. in 2007*

The Future Cost of Diabetes

The Future Human Cost

- By 2050, it is projected that 48.3 million Americans will have diagnosed diabetes.

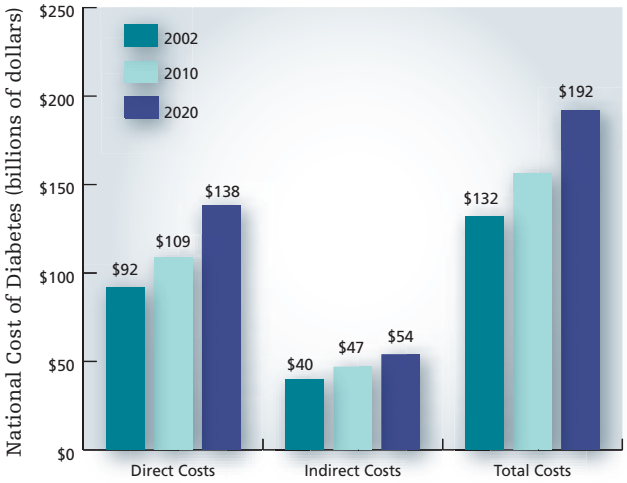
  Narayan et al. 2006, *Impact of Recent Increase in Incidence on Future Diabetes Burden*

- The number of Americans age 75 and older with diabetes is projected to increase 449% (2.87 million to 15.81 million) from 2005 to 2050—the biggest percent increase in any age group.

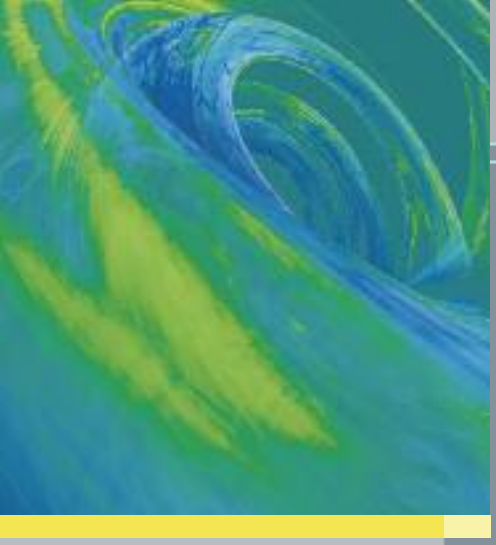
  Narayan et al. 2006, *Impact of Recent Increase in Incidence on Future Diabetes Burden*

The Future Economic Cost

- Projected Impact of Changing Demographic Characteristics on the National Cost of Diabetes: 2002–2020 (in 2002 billions of dollars)



American Diabetes Association 2003, *Economic Costs of Diabetes in the U.S. in 2002*



Standards of Care

Diabetes Management

The medical costs for Americans diagnosed with diabetes are two times higher than those who do not have the disease. These costs could be eliminated with a cure, but can also be greatly reduced through early diagnosis and management of the disease. One employer participating in a pharmaceutical care services program estimated a total increase in productivity valued at $18,000 annually because of the reduced number of sick days taken by employees who had diabetes. These management programs cover a wide range of care, not only based on pharmaceutical management, but nutritional and educational interventions as well. One of the encouraging messages from these studies is the relatively short period of time it takes to see positive results in reducing complications and therefore reducing costs.

Blood glucose control is essential to keeping diabetes and its complications under control. Education regarding self-monitoring can make it easier for individuals to keep track of their blood glucose levels on a daily basis. One glucose management study showed that for every 1% decrease in A1c, there is approximately a $820 savings per year per person. Blood glucose control can potentially be added to other diabetes management programs to increase the effectiveness of the intervention.

Continuing care and disease management are crucial for those diagnosed with diabetes because of the risk of complications. The American Diabetes Association has developed recommendations for clinicians, patients, and others involved in diabetes care to identify steps to mitigate the negative effects of this disease. The American Diabetes Association's full report can be found at http://care.diabetesjournals.org/content/32/Supplement_1/S13.full, and a summary regarding diabetes management can be found on the following page.

In order to provide relief to the millions of Americans with diabetes, techniques are being tested to encourage early diagnosis, and improve access to care and management strategies. These studies have shown that management can reduce the number of complications associated with diabetes, therefore increasing the number of years patients can stay healthy and independent, and decrease the cost strain on the nation's health care system.

This table summarizes ADA's Standards of Care regarding management of diabetes and its complications. Evidence for the benefits of these management techniques and strategies for improving diabetes care can be found in the full report.

Diabetes Self-Management Education (DSME)	DSME is an essential part of care. Care should be given according to national standards and changed as needed. Self-management behavior change should be monitored as part of care. DSME should include emotional well-being education.
Self-Monitoring of Blood Glucose (SMBG)	Results of SMBG can be useful in preventing hypoglycemia and adjusting medications, medical nutrition therapy, and physical activity. The frequency and timing of SMBG should be dictated by the particular needs and goals of the patients. Lowering A1C to at or below 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes. Less stringent A1C goals than the general goal of <7% may be appropriate for some patients.
Pharmacologic Therapy	The ADA and the European Association for the Study of Diabetes recently published an update to their consensus statement on the approach to management of hyperglycemia in individuals with type 2 diabetes. Medications not included in the study because of less glucose-lowering effectiveness, limited clinical data, and/or relative expense, still may be appropriate for some patients. For a list of currently approved diabetes medications, see http://ndep.nih.gov/media/Drug_tables_supplement.pdf.
Medical Nutrition Therapy	MNT is an integral component of diabetes prevention, management, and self-management education. A full review regarding nutrition in preventing and controlling diabetes and its complications can be found in the ADA's "Nutrition Recommendations and Interventions for Diabetes." Because of the complexity of nutrition issues, it is recommended that a registered dietitian provide MNT.
Physical Activity	It is recommended that people with diabetes should perform at least 150 min/week of moderate aerobic physical activity. People with type 2 diabetes should be encouraged to perform resistance training three times per week in the absence of contraindications. High-risk patients should increase the intensity and duration of their activity slowly.
Prevention and Management of Diabetes Complications	Cardiovascular disease management is crucial because it is the major cause of morbidity and mortality for individuals with diabetes and the largest contributor to the direct and indirect costs of diabetes. Diagnosis and management of nephropathy, retinopathy, neuropathy, and foot conditions is recommended.

The Human Value

- In a community pharmacy health management program called the Diabetes Ten City Challenge, in which 573 patients with diabetes participated, eye examination rates increased from 57% to 81% and foot exam rates increased from 34% to 74% between the initial visit and the end of the evaluation period.

  Fera et al. 2009, *Diabetes Ten City Challenge*

- Improvements in key clinical measures over an average of 14.8 months in a community pharmacy health management program called the Diabetes Ten City Challenge, in which 573 patients with diabetes participated.

	Start of Program	14.8 Months After
Glycosylated Hemoglobin	7.5%	7.1%
Low-density Lipoprotein Cholesterol	98 mg/dL	94 mg/dL
Systolic Blood Pressure	133 mm Hg	130 mm Hg

  Fera et al. 2009, *Diabetes Ten City Challenge*

- During the first year of a community pharmacy services program in 2003 which included 256 diabetes patients who used scheduled consultations, clinical goal setting, monitoring, and collaborative drug therapy management with physicians and referrals to diabetes educators, patient satisfaction with overall diabetes care improved from 57% to 87% in the first six months.

  Garrett and Bluml 2005, *Patient Self-Management Program for Diabetes*

- Participants in a diabetes self-management education program for Medicaid recipients, consisting of a 60 minute initial individual assessment of needs, followed by 12 hours of group education on nutrition and self-management, were estimated to have 12% fewer coronary heart disease events and 15% fewer microvascular disease events over 10 years.

  Balamurugan et al. 2006, *Diabetes Self-management Education Program for Medicaid Recipients*

- A diabetes self-management education program for Medicaid recipients, consisting of a 60 minute initial individual assessment of needs, followed by 12 hours of group education on nutrition and self-management, resulted in participants having fewer hospital admissions, emergency department visits and outpatient visits over 1 year.

  Balamurugan et al. 2006, *Diabetes Self-management Education Program for Medicaid Recipients*

- For diabetes patients aged 55 and older, medical nutrition therapy was found to reduce the use of hospital services by 9.5% and physicians services by 23.5%.

  Sheils et al. 1999, *The Estimated Costs and Savings of Medical Nutrition Therapy*

- Blood pressure control reduces the risk of heart disease or stroke among Americans with diabetes by 33-50%. Generally, for every 10 mm Hg reduction in systolic blood pressure, the risk of diabetic complications is reduced by 12%.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Blood pressure control in type 2 diabetes patients with high blood pressure leads to reductions in all diabetes complications by 24%, deaths due to diabetes by 32%, strokes by 44%, heart failure by 56%, and all microvascular complications (eye, nerve and kidney disease) by 37%.

  MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- Studies in the United States and abroad show that improved glycemic control benefits individuals with type 1 and 2 diabetes. Generally, every percentage point drop in A1c blood test results can reduce the risk of microvascular (eye, kidney, nerve diseases) complications by 40%.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

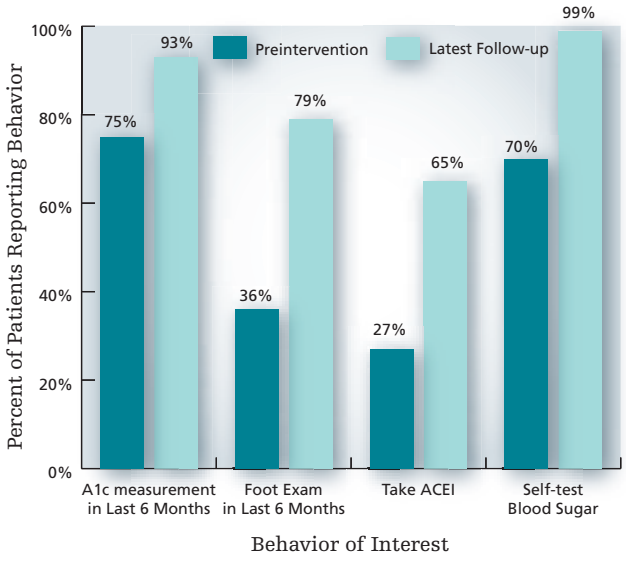
- In a community-based pharmaceutical care services program for 194 participants in 2001, mean A1c decreased at follow-ups, with more than 50% of patients demonstrating improvements at each interval (each year for 1-5 years).

  Cranor et al. 2003, *The Asheville Project*

- Improving the control of LDL cholesterol can reduce cardiovascular complications in those with diabetes by 20-50%.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Patient reported behaviors over time, in 2001, for 194 participants in a community-based pharmaceutical care services program for patients with diabetes.



Cranor et al. 2003, *The Asheville Project*

- Diabetes that is uncontrolled can lead to biochemical imbalances that can cause acute life-threatening events such as diabetic ketoacidosis and hyperosmolar coma.

Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Comprehensive foot care programs for patients with diabetes can reduce amputation rates by as much as 45-85%.

Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

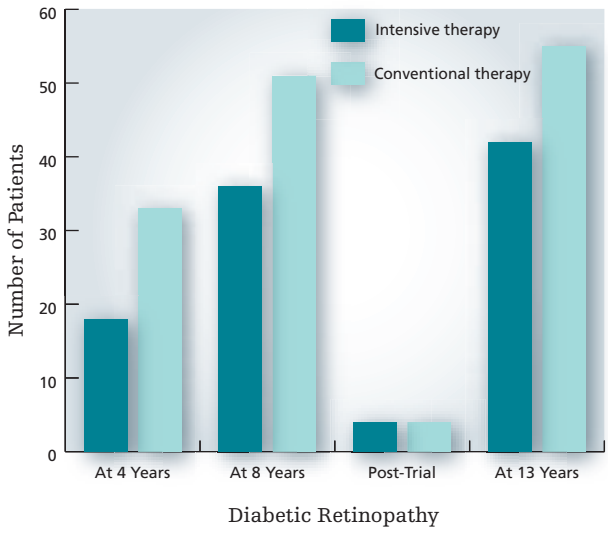
- When cholesterol is lowered with statin therapy, the risk of coronary events is reduced by 25% in type 2 diabetes patients.

MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- Control of blood glucose levels leads to reductions in risks for any diabetes-related complication by 12%, any diabetes-related death by 10%, and all microvascular complications (eye, nerve, and kidney disease) by 25%.

MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- In a trial with 160 participants who had type 2 diabetes, intensive intervention with multiple drug combinations and behavior modification benefited patients with respect to vascular complications and on rates of death from any cause and cardiovascular causes. One example, shown in the graph below, shows the progression of diabetic retinopathy in the two groups at 4, 8 and 13 year intervals.



Gaede et al. 2008, *Effect of a Multifactorial Intervention on Mortality in Type 2 Diabetes*

The Economic Value

- A statin initiation intervention aimed at Medicare Part D prescription drug plan subscribers with diabetes or coronary artery disease was successful in increasing statin use among this group of members at high risk for cardiovascular events. The estimated coronary event cost avoidance was $12,323 per 220 members who received the intervention.

  Stockl et al. 2008, *Effect of an Intervention to Increase Statin Use in Medicare Members Who Qualified for a Medication Therapy Management Program*

- An evaluation of the Diabetes Prevention Program lifestyle intervention found that providing this intervention at age 50 could prevent 37% of new cases of diabetes before age 65. If Medicare paid up to $2,136 in intervention costs over the 15-year period before participants reached age 65, it could recover those costs in the form of future medical costs avoided beginning at age 65.

  Ackermann et al. 2006, *An Evaluation of Cost Sharing to Finance a Diet and Physical Activity Intervention to Prevent Diabetes*

- In a community pharmacy health management program called the Diabetes Ten City Challenge, in which 573 patients with diabetes participated, the average total healthcare costs per patient per year were reduced by 7.2% ($1,079) compared to projected costs.

  Fera et al. 2009, *Diabetes Ten City Challenge*

- A diabetes self-management education program for Medicaid recipients, consisting of a 60 minute initial individual assessment of needs, followed by 12 hours of group education on nutrition and self-management, saved each participant approximately $415 over 3 years.

  Balamurugan et al. 2006, *Diabetes Self-management Education Program for Medicaid Recipients*

- Evaluation of a Cooperative Extension Service diabetes education program showed improved nutrition knowledge, anthropometric measures and glucose control. These improvements reduced medical costs by approximately $94,010 for the 62 participants.

  Christensen et al. 2004, *Cost Savings and Clinical Effectiveness of an Extension Service Diabetes Program*

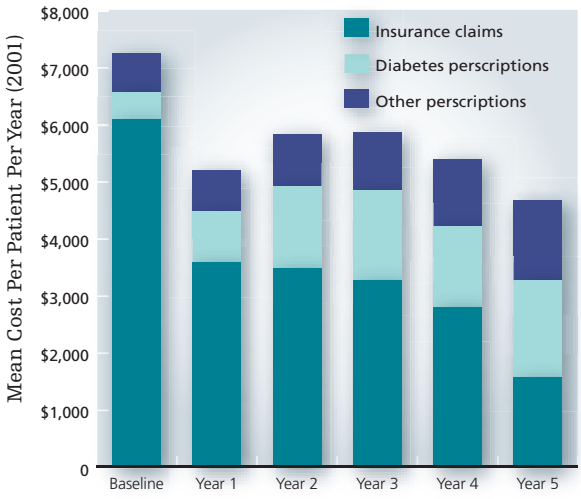
- In a study investigating the effectiveness of diabetes management services from clinical pharmacists on patients, based on an estimated savings of $820 for each 1% decrease in A1c, the reduction in hemoglobin A1c saved about $59,040 over 1 year for the 191 participants.

  Ragucci et al. 2005, *Effectiveness of Pharmacist-Administered Diabetes Mellitus Education and Management Services*

- During the first year of a community pharmacy services program in 2003 which included 256 diabetes patients who used scheduled consultations, clinical goal setting, monitoring, and collaborative drug therapy management with physicians and referrals to diabetes educators, the total average health care costs per patient were $918 lower than projected for the first year of enrollment.

  Garrett and Bluml 2005, *Patient Self-Management Program for Diabetes*

- Average direct medical costs over time, in 2001, for 194 participants in a community-based pharmaceutical care services program for patients with diabetes.

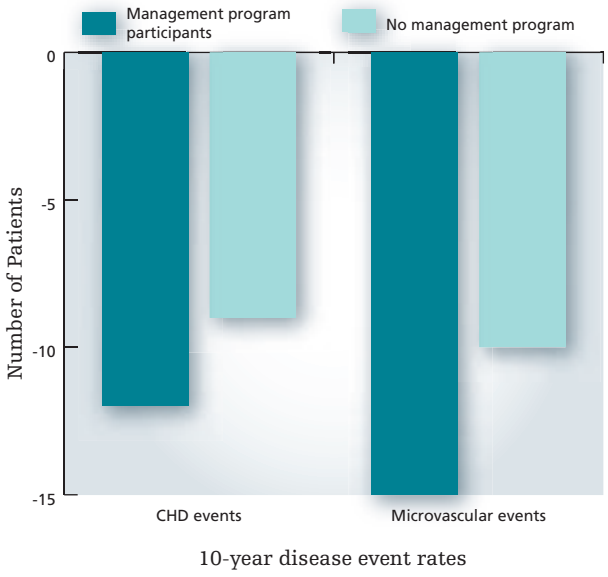


Cranor et al. 2003, *The Asheville Project*

- In a community-based pharmaceutical care services program for 194 participants in 2001, days of sick time decreased at each interval (each year for 1-5 years) for one employer, with estimated increases in productivity estimated at $18,000 annually.

  Cranor et al. 2003, *The Asheville Project*

- Projected change in 3-year diabetes-related costs and 10-year disease event rates among Medicaid recipients participating in a diabetes self-management education program consisting of a 60 minute initial individual assessment of needs, followed by 12 hours of group education on nutrition and self-management.



  Balamurugan et al. 2006, *Diabetes Self-management Education Program for Medicaid Recipients*

- The initiation of insulin therapy in the management of type 2 diabetes involves an approximate 10% increase in total health care expenditures initially, although this is offset by the consistent and substantial 40% decrease in subsequent total health care expenditures 9 months following insulin initiation.

  Rosenblum & Kane 2003, *Analysis of Cost and Utilization of Health Care Services Before and After Initiation of Insulin Therapy in Patients with Type 2 Diabetes Mellitus*

Investing in Science

Innovative Medical Research

As the number of Americans age 65 and older increases at an accelerated rate after 2011, the goal of ameliorating the effects of diabetes becomes critical to easing a looming financial and human burden on society. Even with recent advancements, the cost of this disease, both to individuals and the economy, is rapidly increasing. As the threat of diabetes increases in U.S. communities, Americans should urge public policy officials to commit sufficient health care resources to tame the threat and reduce its impact on our people.

Current research shows real potential in managing, delaying and preventing diabetes. The success of scientific breakthroughs is evident—diabetes death rates declined by about 4% just from 2006 to 2007. In addition to the decreased diagnosis rate, investment in diabetes research also saves precious health care dollars. Based on Medicare claims data, every dollar spent on the treatment of type 2 diabetes produced health gains valued at $1.49. This proves that new treatments and prevention strategies will reduce the human and financial burden of diabetes.

Progress in research providing better prevention, treatment, and management options for diabetes will produce health gains that far outweigh the initial financial investments. As the national debate over health care costs continues, we need to appreciate the positive financial and human impact that medical innovation will have on diabetes. Short-sighted tactics to reduce health care spending are tempting to pursue, especially in stringent budgetary times. However, too often such gambits have a devastating impact on early-stage investments in medical innovation, while short-circuiting the remarkable returns that can come from medical investments. This closer look at diabetes confirms that point.

The Human Value

- A study by the Diabetes Prevention Program found that the use of the drug metformin by high-risk patients reduced the risk of development of type 2 diabetes by 31%.

  National Institute of Diabetes and Digestive Kidney Diseases 2008, *Diabetes Prevention Program*

- Detection and treatment of diabetic eye disease with laser therapy can reduce development of severe vision loss by an estimated 50% to 60%.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- The Diabetes Prevention Program, a large prevention study of people at high risk for diabetes, showed that lifestyle intervention reduced development of diabetes by 58% during a 3-year period. The reduction was even greater among adults aged 60 years and older at 71%.

  Centers for Disease Control and Prevention 2008, *National Diabetes Fact Sheet*

- Due to innovation as well as other factors, the death rate in the U.S. from diabetes decreased by 3.9% in 2007 from 2006.

  Xu et al. 2009, *Deaths: Preliminary data for 2007*

The Economic Value

- Based on a study of claims data for Medicare patients, every additional dollar spent on the overall treatment of type 2 diabetes has produced health gains valued at $1.49.

  MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- Every additional dollar spent on screening and treating diabetic eye disease in type 2 diabetics on insulin has produced health gains valued at $36.

  MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- Every additional dollar spent on statin therapy for diabetes patients who also suffer from high cholesterol has produced health gains valued at $3.

  MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- Every additional dollar spent on intensive blood glucose control in newly diagnosed type 2 diabetic patients has produced health gains valued at $3.77.

  MEDTAP International, Inc. 2004, *The Value of Investment in Health Care*

- The U.S. could save up to $2.5 billion in hospital costs with appropriate primary care for diabetes complications. Much of these savings would come from Medicare with preventable hospital costs of $1.3 billion, and Medicaid with preventable hospital costs of $386 million.

  Agency for Healthcare Research and Quality 2005, *Economic and Health Costs of Diabetes*

The Future Value

- There are currently 183 medicines in development for diabetes or related conditions.

  PhRMA 2009, *Medicines in Development for Diabetes*

- One medicine has shown in clinical trials to significantly improve long-term glycemic control and targets the dysfunction of cells in the pancreas that causes high sugar levels in type 2 diabetes.

  PhRMA 2009, *Medicines in Development for Diabetes*

- A medicine that addresses the underlying cause of type 2 diabetes by modulating genes responsible for insulin sensitization is now in development.

  PhRMA 2009, *Medicines in Development for Diabetes*

- A medicine is now in development that stimulates the release of insulin only when glucose levels become too high and by inhibiting appetite in patients with type 2 diabetes.

  PhRMA 2009, *Medicines in Development for Diabetes*

- Widespread use of diabetes prevention drugs that enhance insulin sensitivity could result in a 50% prevention of type 2 diabetes over a 10 to 15 year period.

  Shekelle et al. 2005, *Identifying Potential Health Care Innovations for the Future Elderly*

Conclusion

The Silver Book®: Diabetes volume projects a growing human and economic burden of diabetes in America and makes a strong case for the value of innovation in reducing that burden. We fully expect this volume to join *The Silver Book* collection as an invaluable tool for encouraging policy formulation that invests in medical research and innovation. If breakthroughs are not made soon, the number of Americans diagnosed with diabetes could double by 2050. If this comes to pass it would add an intolerable burden on American families and the U.S. health care system.

Sound public policy should strive for cost containment strategies that assure high quality health care that is patient-centered, values-driven, knowledge-intense, innovation-rich, and prevention-oriented. We must have sound long-range plans for deploying research and medical innovation to reduce the burdens imposed by diabetes. Historically, investments that produce new medical innovations have paid for themselves many times over through decreased medical expenses and increased human productivity. Medical innovation will be essential to containing the costs of health care as the Baby Boom generation grows older. Research and discovery, properly applied to health care and prevention, will be essential to avoid an unacceptably high toll of diabetes.

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