



Incidence of diabetic foot ulcer and lower extremity amputation among Medicare beneficiaries, 2006 to 2008

Diabetic Foot Ulcers

Data Points #2

Diabetes mellitus, a metabolic disorder characterized by elevated blood glucose, is a serious and growing problem. More than 23 million people in the United States (U.S.) are believed to have diabetes. It is estimated that by 2025, 300 million people worldwide will have diabetes and by 2030, 360 million people. Thus, by 2030, worldwide prevalence will approach 5 percent.¹⁻⁴

In general, the incidence of nontraumatic lower extremity amputations (LEAs) has been reported to be at least 15 times greater in those with diabetes than with any other concomitant medical illness.^{3;5;6} It has been reported that annually, about 1 to 4 percent of those with diabetes develop a foot ulcer; 10 to 15 percent of those with diabetes will have at least one foot ulcer during their lifetime.⁷

LEA is less common but is an extreme complication associated with diabetes and foot ulcer. In the U.S., nearly 80,000 LEAs are performed on diabetics each year.^{8;9} In 2005, the overall rate of hospital discharge for new LEA was about 4.3 per 1,000 people with diabetes compared with a rate of about 0.3 per 1,000 in the general population.^{4;8;10-13}

In 2003, the Centers for Disease Control and Prevention's (CDC's) National Hospital Discharge Survey (www.cdc.gov/nchs/nhds.htm; data available at www.cdc.gov/diabetes/statistics/hospitalization_national.htm) reported a rate of 8 hospital discharges with a diagnosis of foot ulcer per 1,000 individuals with diabetes ages 65-74. Among patients with diabetes age 75 and over, the rate was 11 per 1,000. These data are limited because they did not include outpatient care or chronic care facilities, may have counted individuals who had venous leg ulcers, and may have counted individuals more than once if they were hospitalized more than once. Using the same dataset, the CDC estimated that the rate of LEA in 2005 was 5.3 to 5.6 per hospital discharge per 1,000 individuals with diabetes. These rates have been shown to exhibit variation by age, gender, race/ethnicity, and Dartmouth Atlas of Health Care Hospital Referral Region (HRR, www.dartmouthatlas.org).¹⁴



In Medicare Parts A and B fee-for-service beneficiaries with diabetes, the incidence of diabetic foot ulcer is about 6.0% and lower extremity amputation about 0.5%.

Among Medicare Parts A and B fee-for-service beneficiaries with diabetes and foot ulcer, the prevalence of microvascular and macrovascular complications is about 46% and 65%, respectively. Further, among those with a lower extremity amputation, the prevalence of microvascular and macrovascular complications is about 46% and 76%, respectively.

The annual mortality rate for Medicare Parts A and B fee-for-service beneficiaries with diabetes who have an incident diabetic foot ulcer is about 11%; for those with an incident lower extremity amputation, about 22%.



People with diabetes often experience several associated medical complications, such as renal disease, cardiac disease, and retinopathy. These complications are often categorized as microvascular (e.g., nephropathy, retinopathy) and macrovascular (e.g., cardiac disease). Many researchers have reported an increased incidence of death among LEA patients. Depending on the study, the 1-year post-LEA mortality rate in people with diabetes is between 10 and 50 percent, and the 5-year mortality rate post-LEA is between 30 and 80 percent.¹⁵⁻¹⁷

This *Data Points* brief explores the incidence of foot ulcer and LEA in Medicare beneficiaries. Incidence is the number of new onsets of an illness in a specified period of time. This is distinct from prevalence, the number of people affected by an illness during a period of time. While both incidence and prevalence are important for public health decisions, the former more clearly describes the impact of a new onset of an illness, can help determine if prevention methods are successful, is useful when trying to determine risk factors for the onset of a new disease, and can be used to help gauge the severity of illness. This *Data Points* also examines microvascular and macrovascular complications associated with diabetes, as well as the death rate among people with diabetic foot ulcer and LEA. Refer to companion briefs for separate discussions of the prevalence of diabetes, foot ulcer, and LEA; and medical utilization and costs associated with foot ulcers and amputation.

FINDINGS

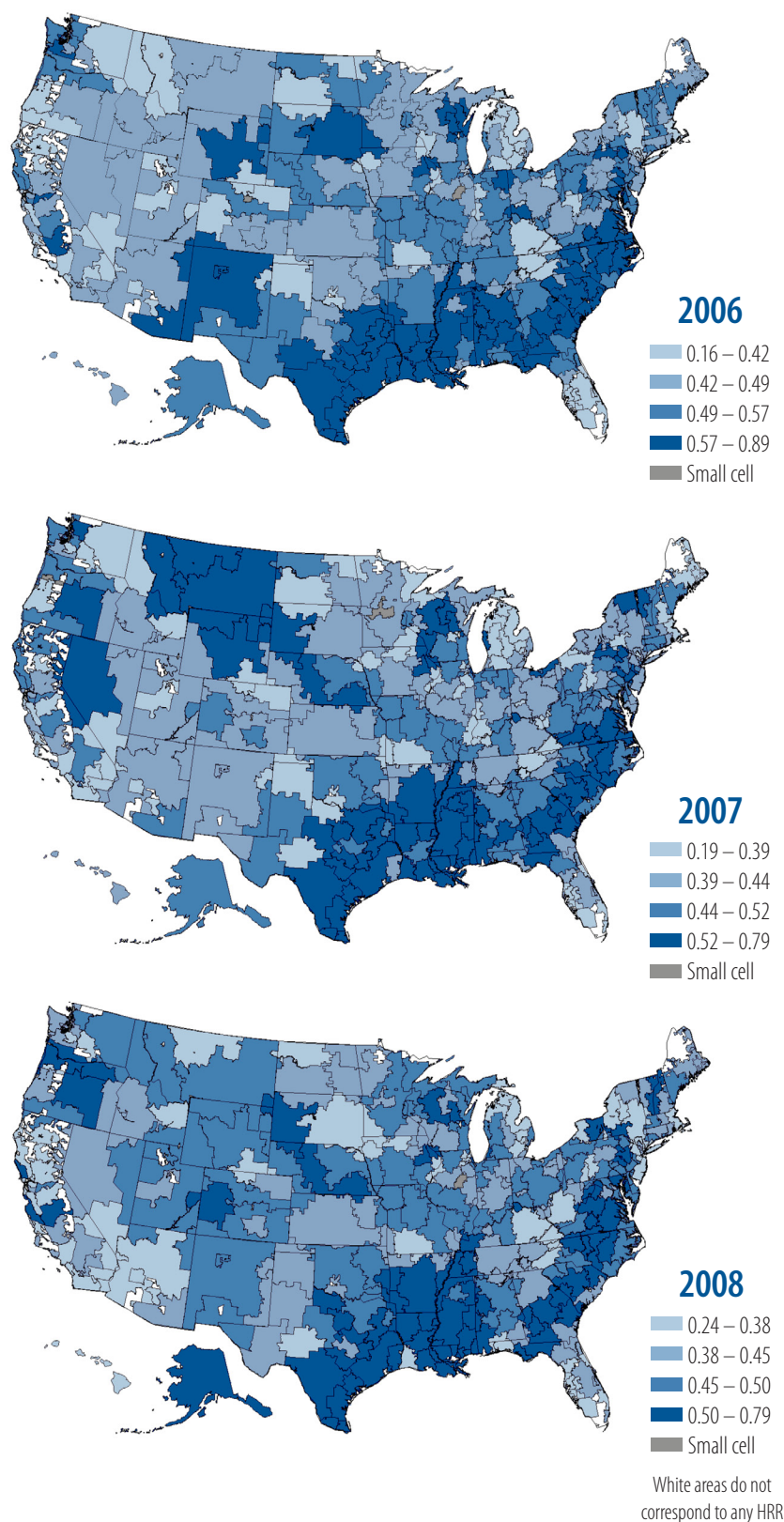
Incidence of Foot Ulcer

Among Medicare beneficiaries continuously enrolled for at least 12 months in Parts A and B fee-for-service (FFS), continuously enrolled for each calendar year of interest (hereafter referred to as the Medicare Parts A and B FFS population; see Data Source section for a comprehensive definition), and with diabetes, the annual incidence of diabetic foot ulcer was 6.0 percent in 2006, 2007, and 2008 (Table 1).

Table 1: Yearly Incidence of Diabetic Foot Ulcer and LEA in Medicare FFS Beneficiaries (Parts A and B), 2006–2008

Variable	Year	Among Medicare FFS Diabetic Population (%)		
		Incidence of Diabetic Foot Ulcer	Incidence of LEA	
Overall	2006	6.0	0.5	
	2007	6.0	0.5	
	2008	6.0	0.4	
Age	Under 45	2006	6.5	0.6
		2007	6.5	0.5
		2008	6.5	0.5
	45 to 54	2006	7.2	0.9
		2007	7.1	0.7
		2008	7.1	0.7
	55 to 64	2006	7.0	0.9
		2007	7.0	0.8
		2008	6.9	0.8
	65 to 74	2006	4.6	0.4
		2007	4.6	0.4
		2008	4.6	0.4
	75 to 84	2006	6.2	0.5
		2007	6.1	0.4
		2008	6.0	0.4
	85 to 94	2006	8.8	0.6
		2007	8.7	0.5
		2008	8.7	0.5
95 and over	2006	11.5	0.5	
	2007	11.4	0.5	
	2008	11.3	0.5	
Gender	Male	2006	6.0	0.6
		2007	6.0	0.6
		2008	6.0	0.6
	Female	2006	6.0	0.4
		2007	6.0	0.4
		2008	5.9	0.3
Race or Ethnicity	White	2006	6.0	0.4
		2007	6.0	0.4
		2008	6.0	0.4
	African American	2006	6.5	0.9
		2007	6.4	0.8
		2008	6.3	0.7
	Asian	2006	3.5	0.2
		2007	3.4	0.2
		2008	3.4	0.2
	Hispanic	2006	6.5	0.6
		2007	6.4	0.5
		2008	6.4	0.5
	American Indian/ Alaska Native	2006	6.9	1.0
		2007	6.8	0.8
		2008	7.0	0.8

Figure 1: Annual incidence of LEA (nonadjusted) per 100 Medicare FFS beneficiaries (Parts A and B) based on Dartmouth Atlas of Health Care Hospital Referral Regions (HRRs), 2006-2008



The incidence of diabetic foot ulcer in the Medicare FFS subpopulation with diabetes and peripheral arterial disease (PAD) was more than two times greater, with incidence rates of 13.5 percent in 2006, 13.2 percent in 2007, and 13.1 percent in 2008. Foot ulcer rates varied by age, gender, race/ethnicity, and geographic location. For example, in 2008, the annual incidence of foot ulcer among those with diabetes was 6.0 percent for males and 5.9 percent for females. The annual incidence of foot ulcer among beneficiaries with diabetes by race in 2008 was white, 6.0 percent; African American, 6.3 percent; Asian, 3.4 percent; Hispanic, 6.4 percent; American Indian/Alaska Native, 7.0 percent; and other, 4.0 percent. Geographic distribution of incident foot ulcer among those with diabetes varied widely based on Dartmouth Atlas of Health Care HRRs. However, the yearly incidence rates varied little from 2006 to 2008.

Incidence of LEA

Among Medicare Parts A and B FFS beneficiaries with diabetes, the annual incidence of LEA was 0.5 percent in 2006 and 2007 and 0.4 percent in 2008 (Table 1). The annual incidence of LEA in the Medicare FFS subpopulation with diabetes and PAD was about four times as high as the incidence in the diabetic Medicare FFS population, with a yearly incidence of 2.1 percent in 2006, 1.9 percent in 2007, and 1.8 percent in 2008. However, incidence appears to be trending down.

Incidence varied by age, gender, race/ethnicity, and geographic location. For example, in 2008, the annual incidence of LEA in the Medicare FFS population with diabetes was 0.6 percent for males and 0.3 percent for females. The annual incidence of LEA among Medicare FFS beneficiaries with diabetes by race was white, 0.4 percent; African American, 0.7 percent; Asian, 0.2 percent; Hispanic, 0.5 percent; American Indian/Alaska Native, 0.8 percent; and other, 0.4 percent. Geographic distribution of incident LEA among those with diabetes varied widely based on the Dartmouth Atlas of Health Care HRRs (Figure 1).

Geographic variation was also affected by gender, age, race/ethnicity, as well as the presence of microvascular complications, macrovascular complications, and obesity (Figure 2, as an example for 2007).

Other factors also affected the incidence rate of LEA. As expected, those with a prevalent foot ulcer were more likely to have an incident LEA. But the annual incidence of LEA among Medicare FFS beneficiaries with a prevalent diabetic foot ulcer trended downward. Incidence was 5.3 percent in 2006, 5.0 percent in 2007, and 4.9 percent in 2008. This finding may be reflected in the rate of osteomyelitis in those with a diabetic foot ulcer, which was 13.2 percent in 2006 and 2007 and 13.6 percent in 2008 and has been shown to be a risk factor for LEA. The annual incidence of amputation among those with a previous incident amputation was 16.7 percent in 2006, 17.5 percent in 2007, and 17.1 percent in 2008.

Individuals with diabetic foot ulcers and LEAs often have other complications associated with diabetes. Among those with diabetic foot ulcers, the prevalence of microvascular complications was 45.8 percent in 2006, 46.7 percent in 2007, and 47.6 percent in 2008. Among those with diabetic foot ulcers, the prevalence of macrovascular complications was 65.9 percent in 2006, 65.4 percent in 2007, and 65.0 percent in 2008.

Mortality

The rate of death among diabetic Medicare FFS beneficiaries with a prevalent diabetic foot ulcer was 12.7 percent in 2006, 12.4 percent in 2007, and 12.3 percent in 2008. The rate of death among diabetic Medicare FFS beneficiaries with an incident diabetic foot ulcer (i.e., a new foot ulcer in the same year, but before their death) was 11.1 percent in 2006, 10.9 percent in 2007 (Table 2), and 10.7 percent in 2008. Mortality after a prevalent LEA was 18.2 percent in 2006, 17.5 percent in 2007, and 17.0 percent in 2008. Mortality after an incident LEA was 23.1 percent in 2006, 21.8 percent in 2007 (Table 2), and 20.6 percent in 2008.

Figure 2: Annual incidence of LEA per 100 Medicare FFS beneficiaries (Parts A and B) Based on Dartmouth Atlas of Health Care Hospital Referral Regions, 2007

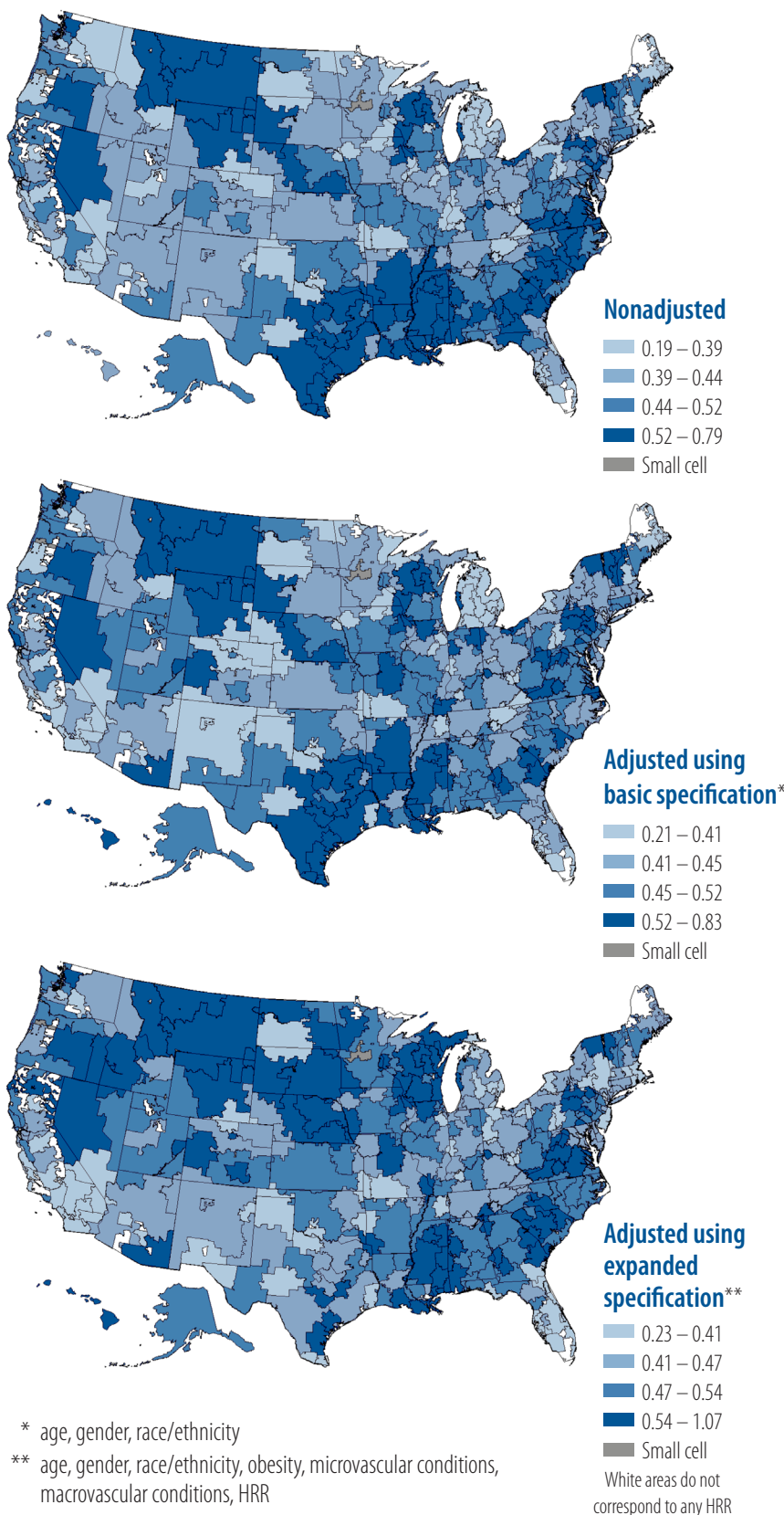


Table 2: Yearly mortality rate (per 100) for diabetes, incident diabetic foot ulcer, and incident LEA, in diabetic Medicare FFS beneficiaries (Parts A and B), 2007

Variable	Mortality Among Diabetic Medicare FFS Population	
	With Incident Foot Ulcer	With Incident LEA
Overall	10.9	21.8
Age	Under 45	7.3
	45 to 54	6.2
	55 to 64	7.4
	65 to 74	11.6
	75 to 84	18.8
	85 to 94	28.5
	95 and over	12.0
Gender	Male	11.4
	Female	10.5
Race or Ethnicity	White	10.5
	African American	13.3
	Asian	10.0
	Hispanic	10.7
	American Indian/ Alaska Native	10.7

DATA SOURCE

Unless otherwise specified, the prevalence and incidence rates in this *Data Points* brief were derived from the Medicare Parts A and B FFS population. Prevalence and incidence was determined separately for 2006, 2007, and 2008. A beneficiary was included in the enrollment population for a given year if he or she had at least a 12-month period of continuous Parts A and B FFS enrollment centering on any one of the months in a given year and was continuously enrolled in the given year. It is important to note that beneficiaries were considered continuously enrolled for 12 months, centered on a given month, if they were alive in that given month and were continuously enrolled up until death. For this purpose, beneficiaries were considered alive up to and including the month of their death. Continuous enrollment in the given year was not required for analyses of quarterly and monthly incidences. Enrollment was determined using the Medicare Enrollment Database (EDB).

ADDITIONAL FINDINGS AVAILABLE ONLINE

The following additional materials are available online at <http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=627>.

Annual Incidence of Foot Ulcer Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

Monthly Incidence of LEA Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

Annual Prevalence of Osteomyelitis Among Diabetic Medicare Parts A and B FFS Beneficiaries With and Without Foot Ulcer, 2006-2008

Annual Incidence of LEA Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

Annual Incidence of LEA Among Diabetic Medicare Parts A and B FFS Beneficiaries With Prevalent Foot Ulcer, 2006-2008

Annual Prevalence of Micro- and Macrovascular Complications Among Diabetic Medicare Parts A and B FFS Beneficiaries With and Without Foot Ulcer, 2006-2008

Quarterly Incidence of Foot Ulcer Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

Mortality Rates in Diabetic Medicare Parts A and B FFS Population, Diabetic Foot Ulcer Prevalent Population, and Diabetic Foot Ulcer Incident Population, 2006-2008

Annual Prevalence of Micro- and Macrovascular Complications Among Diabetic Medicare Parts A and B FFS Beneficiaries With and Without LEA, 2006-2008

Quarterly Incidence of LEA Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

Mortality Rates in Diabetic Medicare Parts A and B FFS Population, LEA Prevalent Population, and LEA Incident Population, 2006-2008

Monthly Incidence of Foot Ulcer Among Diabetic Medicare Parts A and B FFS Beneficiaries, 2006-2008

DEFINITIONS AND METHODOLOGY

Definition and Prevalence of Diabetes

Individuals were determined to have diabetes if they had two or more claims with International Classification of Diseases, 9th Revision (ICD-9) codes consistent with diabetes or at least one inpatient claim with ICD-9 codes consistent with diabetes (250.00-03, 250.10-13, 250.20-23, 250.30-33, 250.40-43, 250.50-53, 250.60-63, 250.70-73, 250.80-83, 250.90-93) in the 12-month period of continuous enrollment. Gender, race/ethnicity, and age were all extracted from the EDB. Geographic distribution of diabetes prevalence varied widely based on Dartmouth Atlas of Health Care HRRs (www.dartmouthatlas.org) but little by year, as presented in Figures 1 and 2.

Definition and Incidence of Foot Ulcer

Beneficiaries with diabetes, as defined above, were considered to have an incident foot ulcer if they had a primary or secondary (i.e., nonprimary) diagnosis of foot ulcer during any given year (based on the following ICD-9 codes: 681.9, 682.7, 707.10, 707.13, 707.14, 707.15, 707.8, 707.9, 730.06-09, 730.16, 730.19, 730.26-29, 891.0, 891.1, 891.2, 892.0, 892.1, 892.2), but had at least a preceding 6-month period of none of these codes. Any beneficiary with diabetes and a venous leg ulcer code (454.0, 454.1, 454.2, 454.9) was not defined as having a foot ulcer and was excluded. Incidence was calculated by dividing the number of beneficiaries identified with diabetes and an incident foot ulcer for the given year by the number of beneficiaries in the Medicare FFS population who were continuously enrolled in Parts A and B throughout the given year and identified with diabetes for that year.

Definition and Incidence of Lower Extremity Amputation

Beneficiaries with diabetes, as defined above, for any given year were defined as having an incident LEA if they had any of a group of specific Current Procedural Terminology (CPT) codes (27590, 27591, 27592, 27594, 27596, 27598, 27880, 27881, 27882, 27884, 27886, 27888, 27889, 28800, 28805, 28810, 28820, 28825), ICD-9 procedure codes (84.10-17, 84.3), or ICD-9 diagnosis codes (895.0, 895.1, 896.0-3, 897.0-7, V497.0-6) and a previous 6-month period without

any of these CPT codes or ICD-9 codes. Incidence was calculated by dividing the number of beneficiaries identified with diabetes and an incident LEA by the number of beneficiaries in the Medicare FFS population who were continuously enrolled in Parts A and B FFS throughout the given year and were identified with diabetes for that year.

Definition of Macro- and Microvascular Disease

Beneficiaries with diabetes and prevalent diabetic foot ulcer or LEA, as defined above, were defined as having macrovascular complications if they had a primary or secondary (i.e., nonprimary) diagnosis based on the following ICD-9 codes: 250.70-73, 410.00-.02, 410.10-12, 410.20-22, 410.30-.32, 410.40-42, 410.50-52, 410.70-72, 410.80-82, 410.90-92, 413.9, 428.0., 428.1, 428.9, 430, 431, 432.1, 432.9, 434.00, 434.01, 434.10, 434.11, 434.90, 434.91, 435.1-435.3, 435.8, 435.9, 436, 437.1-9, 438.10-12, 438.19-22, 438.30-32, 434.40-42, 438.50-53, 438.6, 438.7, 438.81-85, 438.89, 438.9. Beneficiaries were defined as having microvascular complications if they had a primary or secondary diagnosis based on the following ICD-9 codes: 250.40-43, 250.50-53, 250.60-63. The former set of ICD-9 codes represents the following macrovascular diseases: peripheral arterial disease, myocardial infarction, heart failure, angina, and cerebrovascular disease. The latter set of ICD-9 codes represents the following microvascular diseases: diabetic renal disease, diabetic ophthalmic disease, and diabetic neurologic disease.

Mortality

Annual mortality was calculated separately for each relevant population (e.g., the prevalent diabetic foot ulcer subpopulation of Medicare FFS beneficiaries as previously defined). For each population, the numerator was the number of beneficiaries within the particular population who died in the given year, and the denominator was the total number of beneficiaries in the population of analysis. Beneficiary death dates were obtained from the EDB.

REFERENCES

1. Wild S, Roglic G, Green A, *et al.* Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004;27(5):1047-1053.
2. Narayan KM, Boyle JP, Thompson TJ, *et al.* Lifetime risk for diabetes mellitus in the United States. *JAMA* 2003;290(14):1884-1890.
3. Honeycutt AA, Boyle JP, Broglio KR, *et al.* A dynamic Markov model for forecasting diabetes prevalence in the United States through 2050. *Health Care Manage Sci* 2003;6(3):155-164.
4. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995 - 2025: prevalence, numerical estimates, and projections. *Diabetes Care* 1998; 21(9):1414-1431.
5. Imperatore G, Cadwell BL, Geiss L, *et al.* Thirty-year trends in cardiovascular risk factor levels among U.S. adults with diabetes: National Health and Nutrition Examination Surveys, 1971-2000. *Am J Epidemiol* 2004;160(6):531-539.
6. Engelgau MM, Geiss LS, Saaddine JB, *et al.* The evolving diabetes burden in the United States. *Ann Intern Med* 2004;140(11):945-950.
7. Reiber GE, Ledous WE. Epidemiology of diabetic foot ulcers and amputations: evidence for prevention. In: Williams R, Herman W, Kinmonth A-L, *et al.*, eds. The evidence base for diabetes care. London: John Wiley & Sons; 2002. p. 641-665.
8. American Diabetes Association. Peripheral arterial disease in people with diabetes. *Diabetes Care* 2003;26(12):3333-3341.
9. Centers for Disease Control and Prevention. Diabetes-a serious public health problem. 1-5 pages. Atlanta: U.S. Department of Health and Human Services; 1998.
10. Eggers PW, Gohdes D, Pugh J. Nontraumatic lower extremity amputations in the Medicare end-stage renal disease population. *Kidney Internat* 1999; 56(4):1524-1533.
11. Gregg EW, Sorlie P, Paulose-Ram R, *et al.* Prevalence of lower-extremity disease in the U.S. adult population ≥ 40 years of age with and without diabetes: 1999-2000 National Health and Nutrition Examination Survey. *Diabetes Care* 2004;27(7):1591-1597.
12. U.S. Department of Health and Human Services. Healthy People 2010: understanding and improving health. Vol. 2. Washington, D.C.: Government Printing Office; 2000.
13. Unwin N, The Global Lower Extremity Amputation Study Group. Epidemiology of lower extremity amputation in centres in Europe, North America and East Asia. The global LEA study group. *Br J Surg* 2000;87(3):328-337.
14. Wrobel JS, Mayfield JA, Reiber GE. Geographic variation of lower-extremity major amputation in individuals with and without diabetes in the Medicare population. *Diabetes Care* 2001;24(5):860-864.
15. Tentolouris N, Al-Sabbagh S, Walker MG, *et al.* Mortality in diabetic and nondiabetic patients after amputations performed from 1990 to 1995: a 5-year follow-up study. *Diabetes Care* 2004;27(7):1598-1604.
16. Larsson J, Agardh CD, Apelqvist J, *et al.* Long-term prognosis after healed amputation in patients with diabetes. *Clin Orthop Relat Res* 1998;(350):149-158.
17. Reiber GE, LeMaster JW. Epidemiology and economic impact of foot ulcers and amputations in people with diabetes. In: Bowker JH, Pfeifer M, eds. Levin and O'Neal's the diabetic foot. Philadelphia: Mosby-Elsevier, 2008. p. 3-22.

AUTHORS

David J. Margolis, M.D., Ph.D.^{1,2}
 D. Scot Malay, D.P.M., M.S.C.E.^{1,3}
 Ole J. Hoffstad, M.A.¹
 Charles E. Leonard, Pharm.D.¹
 Thomas MaCurdy, Ph.D.⁴
 Karla López de Nava, Ph.D.⁴
 Yang Tan, B.A.⁴
 Teresa Molina, B.A.⁴
 Karen L. Siegel, P.T., M.A.⁵

¹ University of Pennsylvania School of Medicine Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Center, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA

² Department of Dermatology, University of Pennsylvania School of Medicine, Philadelphia, PA

³ Director of Podiatric Research and Staff Surgeon, Ankle and Foot Medical Centers of the Delaware Valley; Department of Surgery, Penn Presbyterian Medical Center; and Post-doctoral Research Fellow, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, Philadelphia, PA

⁴ Acumen LLC DEcIDE Center, Burlingame, CA

⁵ Agency for Healthcare Research and Quality, Rockville, MD

This project was funded under Contract No. HHS-A290200500411 from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services as part of the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) program. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Acknowledgments: The authors wish to thank David Hsia for his critical review of this brief, Mary A. Leonard and Doreen Bonnett for their graphic design expertise, and Edmund Weisberg for his medical editing expertise.

Suggested Citation: Margolis D, Malay DS, Hoffstad OJ, *et al.* Incidence of diabetic foot ulcer and lower extremity amputation among Medicare beneficiaries, 2006 to 2008. *Data Points* #2 (prepared by the University of Pennsylvania DEcIDE Center, under Contract No. HHS-A290200500411). Rockville, MD: Agency for Healthcare Research and Quality. January 2011. AHRQ Publication No. 10(11)-EHC009-1-EF.