Burden of Diabetic Foot Ulcers for Medicare and Private Insurers

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CLIN CARE/EDUCATION/NUTRITION/PSYCHOSOCIAL

OBJECTIVE

To estimate the annual, per-patient incremental burden of diabetic foot ulcers (DFUs).

RESEARCH DESIGN AND METHODS

DFU patients and non-DFU patients with diabetes (controls) were selected using two deidentified databases: ages 65+ years from a 5% random sample of Medicare beneficiaries (Standard Analytical Files, January 2007–December 2010) and ages 18–64 years from a privately insured population (OptumInsight, January 2007–September 2011). Demographics, comorbidities, resource use, and costs from the payer perspective incurred during the 12 months prior to a DFU episode were identified. DFU patients were matched to controls with similar pre-DFU characteristics using a propensity score methodology. Per-patient incremental clinical outcomes (e.g., amputation and medical resource utilization) and health care costs (2012 U.S. dollars) during the 12-month follow-up period were measured among the matched cohorts.

RESULTS

Data for 27,878 matched pairs of Medicare and 4,536 matched pairs of privately insured patients were analyzed. During the 12-month follow-up period, DFU patients had more days hospitalized (+138.2% Medicare, +173.5% private), days requiring home health care (+85.4% Medicare, +230.0% private), emergency department visits (+40.6% Medicare, +109.0% private), and outpatient/physician office visits (+35.1% Medicare, +42.5% private) than matched controls. Among matched patients, 3.8% of Medicare and 5.0% of privately insured DFU patients received lower limb amputations. Increased utilization resulted in DFU patients having $11,710 in incremental annual health care costs for Medicare, and $16,883 for private insurance, compared with matched controls. Privately insured matched DFU patients incurred excess work-loss costs of $3,259.

CONCLUSIONS

These findings document that DFU imposes substantial burden on public and private payers, ranging from $9–13 billion in addition to the costs associated with diabetes itself.

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According to the American Diabetes Association, the annual cost of diabetes, which affects 22.3 million people in the U.S., was $245 billion in 2012: $176 billion in excess health care expenditures and $69 billion in reduced workforce productivity (1). While much of the excess health care cost is attributable to treatment of diabetes itself, a substantial amount of the cost differential arises via treatment of chronic complications such as those related to the heart, kidneys, and nervous system (1).

One common complication of diabetes is the development of foot ulcers. Historically, foot ulcers have been estimated to affect 1–4% of patients with diabetes annually (2,3) and as many as 25% of the patients with diabetes over their lifetimes (2). More recently, Margolis et al. (3) have estimated that the annual incidence of foot ulcers among patients with diabetes may be as high as 6%. Treatment of diabetic foot ulcers (DFUs) includes conventional wound management (e.g., debridement, moist dressings, and offloading areas of high pressure or friction) as well as more sophisticated treatments such as bioengineered cellular technologies and hyperbaric oxygen therapy (HBO) (4).

DFUs often require extensive healing time and are associated with increased risk for infections and other sequelae that can result in severe and costly outcomes (4). For example, studies have estimated that foot ulceration is one of the major sources of hospitalizations among patients with diabetes and precedes 84% of amputations of lower limbs in these patients (5). In addition, DFU patients have a low survival prognosis, with a 3-year cumulative mortality rate of 28% (6) and rates among amputated patients approaching 50% (7).

While DFU patients can require substantial amounts of resource use, little is known about the burden of DFUs imposed on the U.S. health care system and payers. In fact, we are aware of only two studies to date that have estimated the incremental medical resource use and costs of DFU beyond that of diabetes alone (6,8). Neither of these analyses, however, accounted for the many underlying differences between DFU and non-DFU patient populations, such as disproportionate presence of costly underlying comorbid conditions among DFU patients (e.g., congestive heart failure [CHF] and renal disease). In addition, the study by Ramsey et al. (8) used older data (1993–1995) that are not reflective of current treatment options or costs and focused on a specific patient population (i.e., HMO enrollees). Moreover, neither study assessed cost allocation by place of care or costs associated with workplace productivity declines. Other existing literature on the burden of DFUs in the U.S. calculated the overall health care costs (as opposed to incremental) without reference to a non-DFU control population (9–11). As a result of the variety of data and methodologies used, it is not surprising that the burden of DFUs reported in the literature is wide-ranging, with the average per-patient costs, for example, ranging from $4,595 per episode (9) to over $35,000 annually for all services (6).

The objective of this study was to expand and improve on previous research to provide a more robust, current estimate of incremental clinical and economic burden of DFUs. To do so, this analysis examined the differences in medical resource use and costs between patients with DFUs during a recent time period (January 2007–September 2011) and a matched control population with diabetes but without DFUs, using administrative claims records from nationally representative databases for Medicare and privately insured populations. Incremental medical resource use and resulting cost of DFUs (including work-loss costs) were assessed using a matched case-control study design that accounted for potential differences in age, gender, rates of comorbidities, and prior health care resource use.

RESEARCH DESIGN AND METHODS

Data Sources

This study used administrative claims data from two deidentified databases: Standard Analytical Files for a 5% random sample of 3.6 million Medicare beneficiaries, and OptumHealth Reporting and Insights, a database containing approximately 16 million privately insured beneficiaries (employees, spouses, children, and retirees) of 60 large self-insured companies with locations across the U.S. Both databases include information on patient demographics (age and gender), enrollment history, wage information, medical diagnoses received, procedures performed, dates of service, place of service, and payment amounts. Additionally, the private insurance claims include information regarding prescription drug use (e.g., fill dates, National Drug Codes, and payment amounts) for all beneficiaries, and work-loss due to disability for a subset of employees.

Sample Selection

Patients with diabetes were selected from Medicare (January 1999–December 2010) and privately insured (January 1999–September 2011) databases based on presence of at least two medical claims containing ICD-9-CM codes 249.xx or 250.xx. Patients were then divided into two mutually exclusive cohorts based on the presence of at least one foot ulcer diagnosis occurring after a diabetes diagnosis during a recent time period (i.e., January 2007–December 2010 for Medicare and January 2007–September 2011 for private insurance) identified using ICD-9-CM codes 707.1x, 707.8x, and 707.9x, consistent with prior claims-based analyses of DFU (9,10,12).

The index date for the DFU cohort was selected as the start of the most recent foot ulcer episode, identified as the date of a foot ulcer claim with no other foot ulcer diagnoses in the preceding 12 months. For the non-DFU population (controls), a random medical claim during the study period was selected as the index date. Finally, further restrictions were imposed requiring patients to meet age criteria (ages 65+ years for Medicare, ages 18–64 years for private insurance) and to have continuous (non-HMO) coverage throughout the 12 months prior to (preindex period) and 12 months following (follow-up period) the index date in order to ensure that the data for the analytic sample contain all relevant diagnosis and cost information.

These criteria resulted in a final analytic sample of 231,438 Medicare patients, with 29,681 (12.8%) identified as DFU patients and the remaining 201,757 comprising the potential control population of non-DFU diabetic patients. For private insurance, 119,018 patients met the sample selection criteria, with 5,681 (4.8%) DFU patients and 113,337 potential controls (Fig. 1).

Propensity Score Matching

For each database, DFU patients were matched one-to-one [using a "greedy" matching method (13)] to controls based on gender, year of index date, preindex health care costs (±10%), and likelihood of developing a foot ulcer (±1/4 SD) as determined by propensity scores. Propensity scores were calculated using a logistic regression model to account for a variety of potential preindex differences between the DFU and control cohorts. Preindex measures included in the propensity score were age, comorbidities that can affect foot ulcer healing rates (e.g., infections and peripheral vascular disease [PVD]), other conditions that affect health care costs (e.g., cancer, CHF, and renal disease), select medical resource use (e.g., inpatient days and emergency department [ED] visits), and prescription drug use (private insurance only, as Medicare prescription drug data were not available).

Outcomes of Interest

Total and incremental all-cause health care resource utilization and costs (as measured by payments made by third-party payers) in the 12-month follow-up period were compared for DFU patients and non-DFU controls. Resource

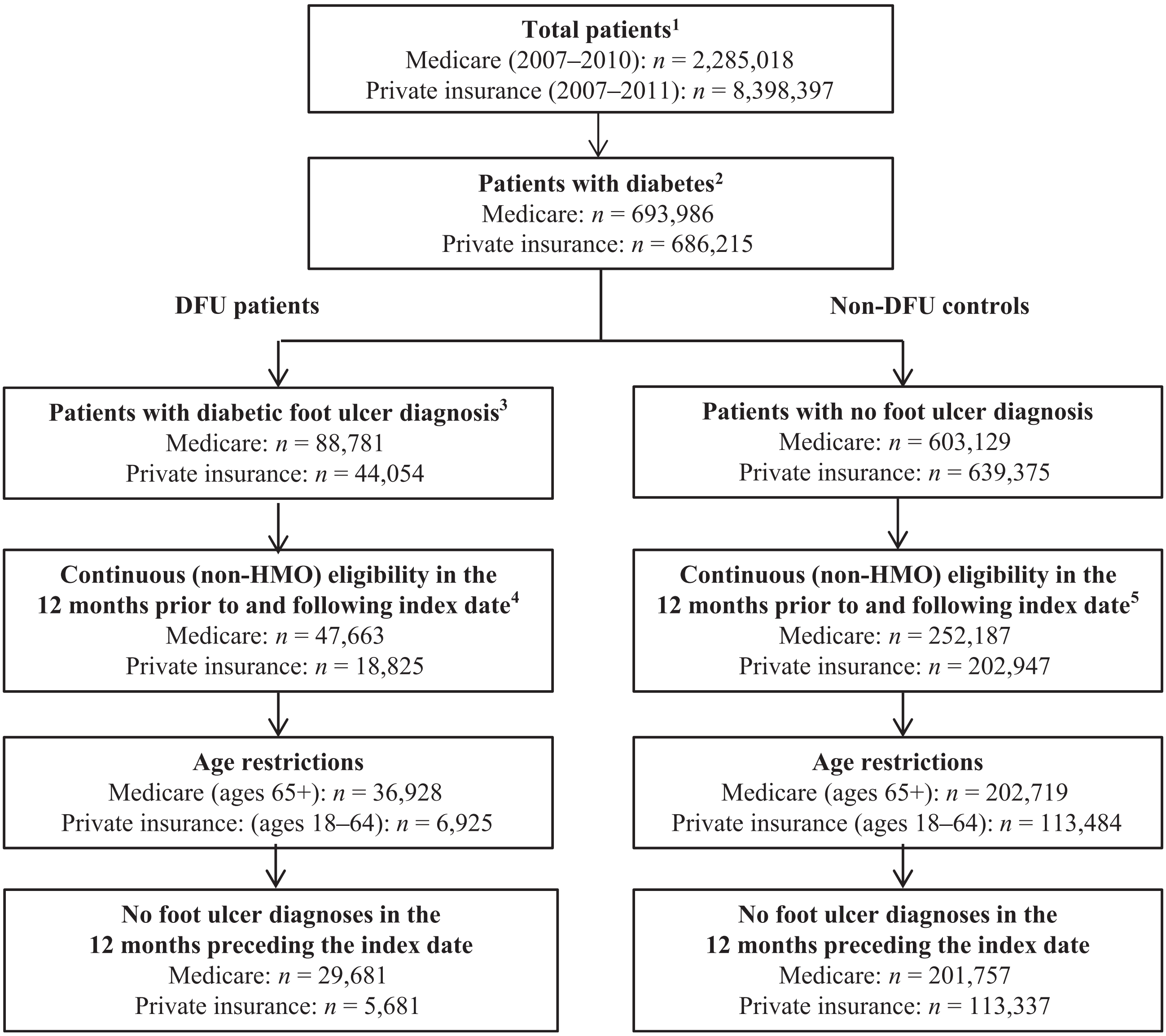

Figure 1—Selection of DFU patients and non-DFU controls. [1]Total patient population includes all beneficiaries with at least one medical claim in years evaluated. [2]Patients defined as those having at least two claims with diabetes diagnosis (ICD-9-CM 249.x, 250.x) at any time in their claims history. [3]Foot ulcer patients defined as those with at least one claim with foot ulcer diagnosis (ICD-9-CM 707.1x, 707.8x, 707.9x) following a diabetes diagnosis in years evaluated (2007–2010 for Medicare; 2007–2011 for private insurance). [4]Index date defined as the most recent DFU diagnosis date meeting all sample selection criteria. [5]Index date defined as the date of a random medical claim in years evaluated.

utilization and costs were categorized by place of service (i.e., inpatient, outpatient/physician office, home health, ED, other [e.g., durable medical equipment, skilled nursing facility, or daycare]) in order to identify sources of utilization that comprise the cost differential. Medical costs were further segmented as "DFU related" if a diagnosis for an ulcer or ulcer-related infection (i.e., cellulitis, osteomyelitis, periostitis, other infections of the bone, and gangrene) or if a procedure code related to ulcer treatment (i.e., debridement, drainage, HBO, skin substitutes, or lower limb amputation) was recorded on the claim. Finally, DFU patients receiving lower-limb amputations, HBO, or skin substitute products were identified. Specific diagnosis codes and procedure code classifications are available upon request.

In addition, incremental indirect work-loss costs due to disability and medical-related absenteeism were estimated for the subset of privately insured patients with disability and wage information available. Information regarding days and cost of missed work due to disability were obtained directly from the database. Following Birnbaum et al. (14), medical-related absenteeism was estimated by multiplying the number of days with medical resource use by the employee's wage: each hospitalization day accounted for a full day of missed work, and outpatient visits accounted for half a day of missed work.

All costs were inflated to 2012 U.S. dollars using the medical care component of the Consumer Price Index (15).

Statistical Analyses

For categorical variables, statistical significance was assessed using χ^2 tests for comparisons between prematch DFU patients and controls, and McNemar tests for the matched cohort. For continuous variables, statistical significance was assessed using Wilcoxon rank sum tests (prematch) and Wilcoxon signed rank tests (postmatch). All analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

Preindex Characteristics

Prior to matching, DFU patients were statistically different from the non-DFU control population on nearly every dimension examined during the 12-month preindex period. For the Medicare sample (Table 1), DFU patients were older (77.7 vs. 75.7 years) and had approximately twice the rates of PVD, infections, renal disease, and CHF in the 12 months prior to the index date. Similarly, for the privately insured sample (Table 2), prior to matching, DFU patients were older (55.3 vs. 52.8 years) and had at least twice the baseline rates of CHF, cerebrovascular disease, chronic obstructive pulmonary disease (COPD), renal disease, and myocardial infarction in addition to the comorbid conditions identified in the Medicare sample.

Compared with the potential controls, both Medicare and privately insured DFU patients had more days hospitalized (+115.7% Medicare, +167.6% private), ED visits (+76.9% Medicare, +139.2% private), and days with an outpatient/physician office visit (+48.7% Medicare, +50.9% private) in the preindex period. These differences resulted in preindex health care costs among DFU patients to be approximately twice those of the potential control population (Tables 1 and 2). (All comparisons above were significant at $P < 0.0001$.)

The matching process resulted in the identification of 27,878 pairs of DFU and control patients for Medicare and 4,536 pairs for private insurance that were very similar with regards to preindex patient characteristics (Tables 1 and 2). In addition, importantly, the matched DFU and control groups had comparable health care costs during the 12 months prior to the index date (Medicare, $17,744 DFU and controls; private insurance, $14,761 DFU vs. $14,766 controls).

Resource Use and Outcomes During the 12-Month Follow-up Period

Despite having matched the groups to ensure similar patient characteristics, DFU patients used significantly ($P < 0.0001$) more medical resources during the 12-month follow-up period than did the matched controls (Table 3). Among matched Medicare patients, DFU patients had 138.2% more days hospitalized, 85.4% more days of home health care, 40.6% more ED visits, and 35.1% more outpatient/physician office visits. The results were similar for the privately insured DFU patients, who had 173.5% more days hospitalized, 230.0% more days of home health care, 109.0% more ED visits, and 42.5% more outpatient/physician office visits than matched controls.

The rate of lower limb amputations was 3.8% among matched Medicare DFU patients and 5.0% among matched privately insured DFU patients. In contrast, observed lower limb amputation rates among diabetic patients without foot ulcer were only 0.04% in Medicare and 0.02% in private insurance. Relatively few DFU patients received more advanced treatments, with 1.2% of matched Medicare and 2.3% of matched privately insured DFU patients receiving HBO and 1.8% of matched Medicare and 1.3% of matched privately insured DFU patients receiving skin substitutes during the follow-up period.

Costs During the Follow-up Period

Increased medical resource utilization resulted in DFU patients having approximately twice the costs as the matched non-DFU controls (Table 3), with annual incremental per-patient medical costs ranging from $11,710 for Medicare ($28,031 vs. $16,320; $P < 0.0001$) to $15,890 for private insurance ($26,881 vs. $10,991; $P < 0.0001$). All places of service (i.e., inpatient, ED, outpatient/physician office, home health care, and other) contributed approximately equally to the cost differential among Medicare patients. For the privately insured, however, increased inpatient costs ($17,061 vs. $6,501; $P < 0.0001$) were responsible for nearly two-thirds of the overall cost differential, where other key contributors were outpatient/physician office visits ($4,888 vs. $2,806; $P < 0.0001$) and home health care ($1,639 vs. $371; $P < 0.0001$). In addition, the privately insured DFU patients had excess prescription drug costs of $993 ($4,538 vs. $3,545; $P < 0.0001$), resulting in total incremental direct health care (i.e., medical + prescription drug) costs of $16,883 ($31,419 vs. $14,536; $P < 0.0001$). Substantial proportions of the incremental medical costs were attributable to claims with DFU-related diagnoses or procedures

Table 1—Patient characteristics, resource utilization, and health care costs during the 12 months prior to the index date for Medicare

	Prematch characteristics			Postmatch characteristics		
	DFU *n* = 29,681	Controls *n* = 201,757	*P**	DFU *n* = 27,878	Controls *n* = 27,878	*P*†
Demographic characteristics						
Age, years, mean (SD)‡	77.7 (7.3)	75.7 (6.8)	<0.0001	77.6 (7.3)	77.7 (7.1)	0.5568
Male, %	43.3	44.2	0.0042	43.0	43.0	1.0000
Year of index date, %						
2007	30.7	31.2	0.0732	30.9	30.9	1.0000
2008	33.8	32.4	<0.0001	33.8	33.8	1.0000
2009	35.5	36.4	0.0031	35.3	35.3	1.0000
Select comorbid conditions, %						
Hypertension	86.4	82.4	<0.0001	85.7	86.4	0.0334
Hyperlipidemia	62.1	66.4	<0.0001	62.2	63.0	0.0533
Diabetes with complications	45.0	24.0	<0.0001	43.1	43.8	0.1225
PVD	34.7	16.3	<0.0001	32.5	32.5	0.9207
CHF	33.3	17.9	<0.0001	31.0	31.5	0.1600
Cerebrovascular disease	22.8	14.5	<0.0001	21.5	22.2	0.0463
COPD	22.5	15.5	<0.0001	21.2	21.7	0.1268
Renal disease	20.9	10.8	<0.0001	18.9	19.3	0.2475
End-stage renal disease	4.2	1.3	<0.0001	3.4	2.8	<0.0001
Infections	19.5	5.0	<0.0001	16.9	15.1	<0.0001
Depression	15.8	10.2	<0.0001	14.7	14.9	0.4747
Any malignancy	12.9	12.3	0.0024	12.7	13.5	0.0047
Obesity	11.0	7.0	<0.0001	10.2	10.3	0.4844
Myocardial infarction	9.9	6.2	<0.0001	9.0	9.3	0.3462
Smoking	6.8	5.9	<0.0001	6.5	7.0	0.0118
Metastatic solid tumor	1.4	1.1	0.0002	1.3	1.4	0.4019
Medical resource use, mean (SD)						
Inpatient days	2.0 (7.1)	0.9 (4.4)	<0.0001	3.5 (8.1)	3.5 (8.0)	0.1907
ED visits	1.0 (1.7)	0.6 (1.3)	<0.0001	0.9 (1.5)	0.9 (1.9)	0.6453
Outpatient days	49.6 (39.6)	33.4 (29.0)	<0.0001	46.1 (33.4)	46.7 (35.2)	0.0696
Total health care costs, mean (SD)§	$22,147 ($33,704)	$11,022 ($21,274)	<0.0001	$17,744 ($24,242)	$17,744 ($24,242)	0.0490

*Calculated using Wilcoxon rank sum tests for continuous variables and χ^2 tests for categorical variables. †Calculated using Wilcoxon signed rank tests for continuous variables and McNemar tests for categorical variables. ‡Estimated in quarter 4 of the year preceding index quarter. §Only medical costs were used, as Medicare data do not contain prescription drug information. Dollar values were inflated to the 2012 U.S. dollar using the medical care component of the Consumer Price Index.

for both Medicare (45.1%) and privately insured samples (60.3%).

Of the 4,536 matched pairs of privately insured patients, work-loss information was available for 575 DFU patients and 857 controls. DFU patients had $3,259 in excess work-loss costs ($6,311 vs. $3,052; $P < 0.0001$) compared with matched controls, with disability and absenteeism comprising $1,670 and $1,589 of the overall differential, respectively (Table 3).

CONCLUSIONS

Of the diabetic patients included in the analysis, approximately 12.8% ages 65+ years and 4.8% ages 18–64 years had recent episodes of foot ulcers during the study period. Prior to their recent DFU episodes, these patients were significantly older, had higher rates of comorbidities, and had significantly more medical resource use and costs than the control population prior to the index foot ulcer episode. However, these differences were largely eliminated after matching, with matched pairs having similar patient characteristics, allowing for more precise estimation of incremental costs following DFU diagnosis.

During the 12-month follow-up period, 3.8% of the matched Medicare DFU patients and 5.0% of matched privately insured DFU patients received lower-limb amputations, compared with almost no amputations among the matched control patients. In addition, both Medicare and privately insured DFU patients had significantly higher medical resource use than did matched controls, which led DFU patients to be approximately twice as costly as non-DFU matched controls (Medicare, $28,031 vs. $16,320; private, $31,419 vs. $14,536). The study also estimated the indirect costs attributable to DFU by calculating costs of missed work due to absenteeism or disability among the subset of patients for whom data on work loss were available. The results indicate that compared with diabetic patients without foot ulcers, DFU patients miss more days of work due to medical-related absenteeism and to disability, imposing additional burden on employers.

While there is little literature on the incremental burden of DFU in the U.S., aspects of our findings are consistent with prior research. For instance, despite differences in study populations and methodology, our finding that 4.8%

Table 2—Patient characteristics, resource utilization, and health care costs during the 12 months prior to the index date for private insurance

	Prematch characteristics			Postmatch characteristics		
	DFU *n* = 5,681	Controls *n* = 113,337	*P**	DFU *n* = 4,536	Controls *n* = 4,536	*P*†
Demographic characteristics						
Age, years, mean (SD)‡	55.3 (7.1)	52.8 (8.7)	<0.0001	55.0 (7.3)	54.5 (7.7)	0.0026
Male, %	59.7	55.0	<0.0001	59.0	59.0	1.0000
Year of index date, %						
2007	24.0	25.6	0.0093	24.1	24.1	1.0000
2008	25.5	23.6	0.0010	26.1	26.1	1.0000
2009	27.4	27.9	0.4106	27.4	27.4	1.0000
2010	23.0	22.9	0.8003	22.5	22.5	1.0000
Select comorbid conditions, %						
Hypertension	65.4	56.0	<0.0001	62.4	61.5	0.3779
Hyperlipidemia	52.1	56.5	<0.0001	53.2	55.0	0.0757
Diabetes with complications	43.8	14.2	<0.0001	36.3	36.5	0.8201
PVD	15.2	3.5	<0.0001	9.6	9.3	0.5988
CHF	15.9	5.1	<0.0001	10.9	9.6	0.0380
Cerebrovascular disease	10.5	4.4	<0.0001	7.6	6.9	0.1976
COPD	7.9	3.4	<0.0001	5.9	5.5	0.3853
Renal disease	14.1	3.1	<0.0001	8.6	8.2	0.4930
End-stage renal disease	6.0	0.9	<0.0001	2.9	1.9	0.0010
Infections	27.3	2.7	<0.0001	16.7	15.4	0.0078
Depression	10.7	7.7	<0.0001	9.6	10.0	0.5144
Any malignancy	6.6	4.9	<0.0001	6.1	6.0	0.8927
Obesity	9.5	6.2	<0.0001	8.4	8.3	0.8485
Myocardial infarction	3.5	1.7	<0.0001	2.1	2.1	0.9397
Smoking	1.7	1.6	0.6880	1.6	1.5	0.7335
Metastatic solid tumor	0.8	0.7	0.0899	0.7	0.9	0.4126
Medical resource use, mean (SD)						
Inpatient days	13.8 (31.5)	5.2 (15.1)	<0.0001	8.4 (20.2)	7.7 (19.6)	0.0002
ED visits	1.3 (3.9)	0.5 (1.4)	<0.0001	0.8 (1.7)	0.8 (1.8)	0.0223
Outpatient days	16.7 (17.3)	11.1 (11.4)	<0.0001	14.2 (12.9)	14.2 (12.5)	0.9112
Prescription drug use						
Unique medications, mean (SD)§	13.2 (11.5)	9.5 (8.5)	<0.0001	12.3 (10.5)	11.7 (10.0)	0.0026
Immunosuppressants, %‖	2.4	0.8	<0.0001	1.9	1.5	0.2160
Total health care costs, mean (SD)¶	$31,844 ($84,565)	$12,790 ($36,898)	<0.0001	$14,761 ($22,149)	$14,766 ($22,153)	0.2328

*Calculated using Wilcoxon rank sum tests for continuous variables and χ^2 tests for categorical variables. †Calculated using Wilcoxon signed rank tests for continuous variables and McNemar tests for categorical variables. ‡Estimated at index date. §Calculated as the number of prescriptions with unique National Drug Code codes according to the first nine digits filled. ‖Includes prescriptions with supply in the 12 months prior to the index date, whether or not the prescription itself was filled in these 12 months. ¶Calculated as the sum of medical and prescription drug costs. Dollar values were inflated to the 2012 U.S. dollar using the medical care component of the Consumer Price Index.

of privately insured patients with diabetes developed new foot ulcers during the study period is consistent with the 5.8% reported by Ramsey et al. (8), which was estimated using a privately insured patient population. Similarly, the study results indicating that DFU patients incur substantial additional costs relative to those without DFU are consistent with conclusions drawn from the analysis of Medicare data by Margolis et al. (6). In addition, the annual total per-patient health care costs estimates for the matched control population with diabetes ($16,320 Medicare, $10,991 private insurance) are consistent with the $13,700 average across all age groups reported by the American Diabetes Association (1).

These estimates indicate that DFU imposes substantial burden on payers beyond that required to treat diabetes itself. For example, prior research has estimated annual per-patient incremental health care expenditures for patients with diabetes (versus those without diabetes) of approximately $7,900 (1). The estimates of this analysis suggest that the presence of DFU further compounds these incremental treatment costs by adding $11,710 to $16,883 per patient. Stated differently, the results indicate that the excess health care costs of DFU are approximately twice that attributable to treatment of diabetes itself, and that the presence of DFU approximately triples the excess cost differential versus a population of patients without diabetes.

Using estimates of the total U.S. diabetes population (22.3 million) (1) and the midpoint (3.5%) of annual DFU incidence estimates (1–6%) (2,3), the results of this analysis suggest an annual incremental payer burden of DFU ranging from $9.1 billion (22.3 million patients with diabetes × 3.5% DFU incidence × $11,710 Medicare cost differential) to $13.2 billion (22.3 million

Table 3—Health care resource utilization and costs during the 12 months following the index date among matched DFU patients and controls

	Medicare			Privately insured		
	DFU *n* = 27,878	Controls *n* = 27,878	*P**	DFU *n* = 4,536	Controls *n* = 4,536	*P**
Medical resource use, mean (SD)						
Inpatient days	2.5 (8.3)	1.1 (4.6)	<0.0001	19.5 (36.3)	7.1 (18.5)	<0.0001
ED visits	1.2 (2.0)	0.8 (1.9)	<0.0001	1.3 (2.8)	0.6 (1.7)	<0.0001
Outpatient/physician days	59.6 (48.3)	44.1 (36.7)	<0.0001	20.2 (17.5)	14.2 (12.9)	<0.0001
Home health care days	1.2 (2.4)	0.7 (1.9)	<0.0001	4.5 (12.3)	1.4 (4.7)	<0.0001
Other	7.5 (9.7)	5.7 (8.6)	<0.0001	9.0 (12.3)	5.1 (9.2)	<0.0001
Patients with select DFU-related procedures, %						
Lower-limb amputation	3.8	—	N/A	5.0	—	N/A
HBO	1.2	—	N/A	2.3	—	N/A
Skin substitute use	1.8	—	N/A	1.3	—	N/A
Direct health care costs, mean (SD)						
Total all-cause medical	$28,031 ($39,502)	$16,320 ($26,223)	<0.0001	$26,881 ($58,856)	$10,991 ($30,461)	<0.0001
Total all-cause medical and prescription drug†	—	—	—	$31,419 ($59,633)	$14,536 ($31,359)	<0.0001
Inpatient	$4,719 ($14,881)	$2,294 ($9,140)	<0.0001	$17,061 ($43,721)	$6,501 ($25,287)	<0.0001
ED	$5,346 ($13,557)	$2,924 ($8,942)	<0.0001	$1,020 ($3,483)	$484 ($1,779)	<0.0001
Outpatient/physician	$8,418 ($11,801)	$6,040 ($9,430)	<0.0001	$4,888 ($19,840)	$2,806 ($9,658)	<0.0001
Home health care	$4,390 ($10,071)	$2,283 ($7,611)	<0.0001	$1,639 ($8,307)	$371 ($2,110)	<0.0001
Other	$5,159 ($11,583)	$2,779 ($8,277)	<0.0001	$2,274 ($10,210)	$829 ($3,857)	<0.0001
Prescription drug	—	—	—	$4,538 ($6,833)	$3,545 ($4,983)	<0.0001
Total DFU-related medical costs, mean (SD)‡	$5,285 ($16,534)	—	N/A	$9,590 ($34,059)	—	N/A
Indirect costs, mean (SD)§						
Total	—	—	—	$6,311 ($9,288)	$3,052 ($5,772)	<0.0001
Absenteeism	—	—	—	$3,599 ($5,897)	$2,010 ($2,982)	<0.0001
Disability	—	—	—	$2,713 ($8,034)	$1,042 ($5,238)	<0.0001

*Calculated using Wilcoxon signed rank tests for continuous variables and McNemar tests for categorical variables. †Prescription drug data were not available for Medicare patients. ‡DFU-related costs include costs for claims with an ulcer or infection diagnosis or amputation or other related procedure codes. §Estimated for subsets of matched privately insured DFU (*n* = 575) and control (*n* = 857) patients for whom work-loss data were available. N/A, not applicable.

patients with diabetes × 3.5% DFU incidence × $16,883 private insurance cost differential). These estimates, moreover, likely understate the actual burden of DFU because the incremental costs referenced in this calculation do not include excess work-loss costs described above, prescription drug costs for Medicare patients, out-of-pocket costs paid by the patient, costs borne by supplemental insurers, and other (non-work loss) indirect costs such as those associated with premature mortality, reduced quality of life, and informal caregiving. Some of the costs not included in this payer-perspective analysis are substantial, such as the 20% of medical costs not covered by Medicare.

This study had certain additional limitations, primarily inherent to claims-based analysis. First, while the propensity score matching led to matched cohorts with similar baseline characteristics in terms of magnitude, there were a few measures for which statistically significant differences remained, and it is possible that an exact match on all dimensions would lead to different results with unknown directional impact. Relatedly, the effects of not matching patients for other risk factors for developing foot ulcers (e.g., prior amputations and foot deformities) are not known. Second, the results of this analysis potentially understate the incremental burden of DFU, because the matching process removed relatively high-cost DFU patients with higher rates of comorbidities and medical resource use and relatively low-cost control patients with lower rates of comorbid conditions and medical resource use from the analysis (Tables 1 and 2), because these outliers could not be matched. Total incremental costs in the year postindex date increase from $11,710 to $18,756 for Medicare and from $16,883 to $31,851 for private insurance when these severely sick or costly patients are retained (data not shown). Third, the objective of this analysis was to estimate the annual burden associated with DFU; however, it should be noted that prior research has found that many patients remain unhealed after 12 months (16) and/or experience reulceration (17). As a result, the estimates of this study understate the true incremental costs associated with a DFU episode, and further research is warranted to examine the potentially large costs of DFU beyond the first year. Fourth, as with any claims data analysis, this analysis relied on the accuracy of diagnosis codes to identify patients with or without DFU and to evaluate their comorbidity profiles at baseline and resource use and cost information in the follow-up period. Any miscoding along these lines would affect our results, although we have no reason to believe that any inaccuracies in the data may have affected the DFU and non-DFU groups differently. Fifth, it is not known how the study results may be extrapolated to patient populations other than Medicare and private insurance. Sixth, claims data have limited clinical detail regarding wound-specific information (e.g., healing time and presence of a single versus multiple DFUs), and further research is warranted to examine the correlation between costs of DFUs and time to healing/wound closure as well as to the presence of concomitant ulcers. Finally, as noted earlier, the Medicare database used here does not contain pharmacy claims. Although the privately insured analysis suggests an annual per-patient cost burden of approximately $1,000, future research is warranted to assess the analogous figure for Medicare.

Despite these limitations, this study is the first to use rigorous methodologies to estimate incremental burden of DFU using recent, nationally representative administrative claims data, controlling for a broad set of underlying differences between DFU and diabetes control populations. As a result, the findings of this study may help health plans and providers quantify the substantial incremental costs associated with DFUs. Such knowledge may optimize wound management, including potential implementation of better monitoring and identification of risk factors, education for patients and clinicians, and targeted early intervention with advanced therapies that could help accelerate healing and avoid some severe and costly outcomes such as amputation.

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Author Contributions. J.B.R. contributed to the conceptual design, reviewed and discussed the study results, and wrote the manuscript. U.D. contributed to the conceptual design, performed data analysis, and wrote the manuscript. A.K.G.C. contributed to the conceptual design, performed data analysis, and reviewed and edited the manuscript. H.G.B. contributed to the conceptual design, reviewed and discussed the study results, and reviewed and edited the manuscript. M.S. reviewed and discussed the study results and reviewed and edited the manuscript. N.B.P. contributed to the study design, reviewed and discussed the study results, and reviewed and edited the manuscript. J.B.R. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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