

March 27, 2025

Representative Susan R. Donovan
Chair, House Health & Human Services
State of Rhode Island General Assembly
82 Smith Street
Providence, RI 02903

Sent electronically to HouseHealthandHumanServices@rilegislature.gov

Re: Opposition to RI 6088 - Permits a certified foot care nurse or a certified foot care specialist, to provide certain at-home foot care, including routine foot and nail care including nail clipping

Dear Chairwoman Donovan and members of the House Health & Human Services Committee:

On behalf of the American Podiatric Medical Association (APMA), I write in opposition of the introduced legislation H6088, "Permits a certified foot care nurse or a certified foot care specialist, to provide certain at-home foot care, including routine foot and nail care including nail clipping." APMA is the premier professional organization representing a vast majority of the estimated 15,000 licensed podiatrists, also known as Doctors of Podiatric Medicine (DPMs), in the United States. Within APMA's umbrella of organizations, there are 53 component societies in states, including Rhode Island, and other jurisdictions, as well as several affiliated and related organizations. APMA adamantly supports increasing and improving access to care, however, we do not believe RI H6088 is the correct vehicle to accomplish this goal.

Furthermore, we are deeply concerned that codifying nurses' scope of practice to overlap with podiatrists in will lead to worse patient outcomes and create a threat to public safety, as nurses do not have the extensive training to treat at-risk diabetic foot and ankle concerns in the same manner as podiatrists.

Podiatrists are physicians and surgeons qualified by their education and training to diagnose and treat conditions affecting the lower extremity, i.e., the foot, ankle, and where appropriate, muscles, tissues, and bones of the leg. They have an intimate knowledge of the anatomic structures involved with at-risk foot care services and extensive training related to this delicate service, completing four years of undergraduate and four years of podiatric medical education followed by a three-year postgraduate hospital-based residency program. Comparatively, a nurse will only receive two to four years of undergraduate or associate degree training in order to become a registered nurse, with some additional graduate level courses for a nurse practitioner. There is no dedicated focus on foot and ankle care generally in this underlying education, let alone a focus on providing at-risk foot care. When reviewing the eligibility requirements for certification by either the American Foot Care Nurses Association (AFCNA) or the Wound, Ostomy, and Continence Nursing Certification Board (WOCNCB), the level of education required to obtain certification is only 24 continuing medical education credits and 30 to 40 hours of supervised clinical care, depending on the certification. This is equivalent to a weekend conference and one week of supervised care, versus the hundreds of hours of training and years of education a DPM receives. Aside from the quantitative comparison, the AFCNA and WOCNCB certifications are not subject to the same rigor and training a DPM undergoes, and both represent too low of a bar to suffice for providers that are treating these vulnerable populations.

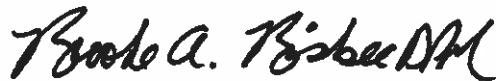
Simply put – registered nurses and nurse practitioners do not receive adequate education and training to universally provide this care to these complex and elderly patients. Patients who qualify for covered at-risk foot care are at extraordinary risk for lower extremity pathology, including non-healing wounds, infection, and amputation. In comparison to podiatrists, registered nurses and nurse practitioners, even those with one of the specified designations, lack sufficient breadth and depth of training and expertise to ensure optimal patient outcomes. When performing at-risk foot care, podiatric physicians often encounter tinea pedis, xerosis, fissures, pre-ulcerative lesions and other pathology that can be managed more efficiently when caught early. Many of the patients who qualify for this service have profound neuropathy which leads to their inability to sense and seek attention for such pathologies. Registered nurses and nurse practitioners do not have sufficient training or licensed to diagnose these pathologies or initiate treatment for these pathologies, nor should they be relied upon to find them and bring them to the attention of the supervising provider. Delaying or missing care for these complications can lead to worse patient outcomes, including amputation and possible loss of life.

Studies such as APMA's Thomson Reuters study (attached) support how care provided by podiatrists to diabetic patients, including at-risk foot care, can have a significant reduction on future amputations and hospitalizations. The study estimated that \$10.5 billion in savings nationally over three years can be realized if every at-risk patient with diabetes sees a podiatrist at least one time in a year preceding the onset of an ulceration. Another independent study conducted by Duke University (attached) and published in Health Services Research found that Medicare-eligible patients with diabetes were less likely to experience a lower extremity amputation if a podiatrist was a member of the patient care team, and patients with severe lower extremity complications who only saw a podiatrist experienced a lower risk of amputation compared with patients who did not see a podiatrist.

APMA strongly supports legislative and regulatory changes that improve and expand access to care. However, we believe that this goal should be balanced with patient safety in mind, and RI H6088 does not sufficiently protect patient safety or improve outcomes. Registered nurses and nurse practitioners play a particularly important role in healthcare delivery, but this responsibility extends beyond their formal training. **RI H6088 should not be moved forward for passage and implementation.**

APMA appreciates your consideration and is pleased to discuss this matter further with you. Please contact APMA Center for Professional Advocacy, Gail M. Reese, JD, at 301-581-9230 or greesee@apma.org with any further questions or concerns.

Sincerely,



Brooke A. Bisbee, DPM
President

Attached:

- *The Economic Value of Specialized Lower-Extremity Medical Care by Podiatric Physicians in the Treatment of Diabetic Foot Ulcers*
- *Receipt of Care and Reduction of Lower Extremity Amputations in a Nationally Representative Sample of U.S. Elderly*

The Economic Value of Specialized Lower-Extremity Medical Care by Podiatric Physicians in the Treatment of Diabetic Foot Ulcers

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Background: We sought to examine the economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers by evaluating cost outcomes for patients with diabetic foot ulcer who did and did not receive care from a podiatric physician in the year before the onset of a foot ulcer.

Methods: We analyzed the economic value among commercially insured patients and Medicare-eligible patients with employer-sponsored supplemental medical benefits using the MarketScan Databases. The analysis consisted of two parts. In part I, we examined cost or savings per patient associated with care by podiatric physicians using propensity score matching and regression techniques; in part II, we extrapolated cost or savings to populations.

Results: Matched and regression-adjusted results indicated that patients who visited a podiatric physician had \$13,474 lower costs in commercial plans and \$3,624 lower costs in Medicare plans during 2-year follow-up ($P < .01$ for both). A positive net present value of increasing the share of patients at risk for diabetic foot ulcer by 1% was found, with a range of \$1.2 to \$17.7 million for employer-sponsored plans and \$1.0 to \$12.7 million for Medicare plans.

Conclusions: These findings suggest that podiatric medical care can reduce the disease and economic burdens of diabetes. (J Am Podiatr Med Assoc 101(2): 93-115, 2011)

Foot ulcers are a serious and common complication in people with diabetes. It has been estimated that 25% of patients with diabetes will develop a foot ulcer during their lifetime.¹ Cases where ulcers fail

to heal and progress to deep infection or gangrene may lead to lower-extremity amputation. Although 6% to 22% of ulcers result in amputation,² 85% of lower-extremity amputations are associated with diabetic complications, and almost all of these are preceded by a foot ulcer.³ In 2004, approximately 71,000 nontraumatic lower-limb amputations in the United States were performed on patients with diabetes.⁴

Diabetic foot ulcers also represent a significant economic burden. In 2007, direct costs of treatment of diabetes and its complications in the United States were approximately \$116 billion; 33% of these costs were associated with the treatment of foot ulcers.⁵ In 2001, the costs of diabetes-related

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amputations were estimated to be \$38,077 per amputation.⁶ The average costs for foot ulcer care in the United States were estimated to be \$13,179 per episode, with costs increasing with severity of ulceration.⁷

Diabetes has been described as an epidemic in the United States. According to the Centers for Disease Control and Prevention, in 2007, 1.6 million new cases of diabetes were diagnosed in adults older than 20 years. If current trends continue, the Centers for Disease Control and Prevention estimates that one in three Americans will develop diabetes sometime in their lifetime,⁸ highlighting the value of foot ulcer prevention programs for patients with diabetes. In addition, Healthy People 2010⁹ national objectives for diabetes are directly related to improving the prevention and treatment of foot ulcers and reducing the risk of unnecessary amputations.

Previous studies have found that specialized foot care by podiatrists (physicians or surgeons of the foot and ankle) improves outcomes for patients with diabetes, and, as part of a multidisciplinary team, podiatric physicians can take a lead role in the management of diabetic foot disorders.¹⁰ However, few studies have examined the cost implications of diabetic foot ulcers, and these studies have not evaluated the relationships among podiatric medical care, foot ulcers, and costs. The objective of this study was to examine the economic value of specialized lower-extremity medical care provided by podiatric physicians in the treatment of diabetic foot ulcers by evaluating cost outcomes for patients with diabetic foot ulcer who did and did not receive care from a podiatric physician.

Methods

Summary of Approach

Analysis of the economic value of the receipt of care from podiatric physicians for patients with diabetic foot ulcer among commercially insured patients and Medicare-eligible patients with employer-sponsored supplemental medical benefits consisted of two parts. In part I, we examined cost or savings per patient associated with care provided by podiatric physicians, and in part II, we extrapolated cost or savings to populations.

Specifically, in part I of this study, we used a large national claims database to examine total health-care costs in the year before the onset of a diabetic foot ulcer (index date) and in the 2 years after the onset of a diabetic foot ulcer. We also measured

amputation rates and costs for patients with a diabetic foot ulcer in the 2 years after the index date. We compared outcomes for patients who received care from a podiatric physician before the onset of a foot ulcer with those for a matched group of patients who did not receive care from a podiatric physician before the onset of a foot ulcer (comparison group). Matching and regression techniques were used to control for potential confounding factors in observable differences in the characteristics of patients who did and did not receive care from a podiatric physician.

In part II, we simulated the net present value of a 1% increase in the share of at-risk patients receiving care from a podiatric physician in employer-sponsored health plans and Medicare. We used the cost results obtained from part I to calculate a comprehensive net present value taking into consideration differences in total (all-cause and all-provider) medical costs for the podiatric medical and comparison groups. We also calculated a more conservative procedure-based net present value by measuring only podiatric medical costs in the year before the index date and measuring savings due to reductions in amputations for the podiatric medical care group in the 2 years after the index date.

Part I: Cost or Savings per Patient with Diabetic Foot Ulcer

The purpose of part I was to measure health-care costs and amputation rates for patients with diabetic foot ulcer. We compared outcomes for patients who received care from a podiatric physician before the onset of a foot ulcer with those for patients who did not receive care from a podiatric physician before the onset of a foot ulcer.

Patient Selection. Adult patients (age ≥ 18 years) with diabetes and a diagnosis of foot ulcer were found in the Thomson Reuters MarketScan Research Databases, 2005–2008. These databases contain fully adjudicated health insurance claims (inpatient and outpatient medical and outpatient pharmacy) linked to enrollment and demographic information. The study included patients in the Commercial Claims and Encounters Database who were enrolled in an employer-sponsored health plan, typically large and medium-sized firms in the United States. The study also included patients from the Medicare Supplemental Coordination of Benefits Database (age ≥ 65 years) who were enrolled in supplemental coverage sponsored by a previous employer. The MarketScan databases conform to the confidentiality requirements of the Health

Insurance Portability and Accountability Act of 1996; thus, the study did not require informed consent or institutional review board approval.

Patients eligible for this study were required to have a diabetes diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* code 250.xx) on at least one inpatient or two outpatient claims at least 30 days apart, excluding claims for diagnostic procedures (eg, laboratory tests). Patients who entered the sample due to an outpatient diabetes diagnosis were required to have a second diagnosis to exclude those who may have been screened for diabetes but not actually diagnosed. All of the patients were also required to have a diagnosis code indicating a foot ulcer (*International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis code 707.00, 707.06, 707.07, 707.09, 707.10, 707.12, 707.13, 707.14, or 707.15).

The date of the first claim with a diagnosis of a foot ulcer was assigned as the index date (Fig. 1). All of the study participants were required to have been enrolled in medical and drug plans offered by one of the employers contributing to the Market-Scan databases during the 12 months before the index date and the 24 months (2 years) after the index date. To find patients at the beginning of an episode of care for diabetic foot ulcer, patients with diagnosis of a foot ulcer, or lower-extremity amputation, during the 12 months before the index date were excluded. This study focused on new episodes of care for foot ulcer, rather than on prevalent episodes, to describe outcomes during the year before and the 2 years after the onset of a foot ulcer and to ensure that each patient was observed for the same amount of time relative to the start of treatment. *International Classification of Diseases, Ninth Revision, Clinical Modification* procedure codes and *Current Procedural Terminology* codes were used to assess the occurrence of amputations (Table 1).

Podiatric Medical Care. Comparisons were made between patients who received specialized lower-extremity care from a podiatric physician (case group) and patients who did not (comparison group). We classified patients as receiving care from a podiatric physician if they had any health-care claims indicating a visit with a podiatric physician during the 12 months before foot ulcer diagnosis (the index date). Thus, this study evaluates the value of earlier (pre-ulcer) specialized foot care by a podiatric physician.

Outcomes. Total health-care costs per patient were measured in two periods: the 2 years after the

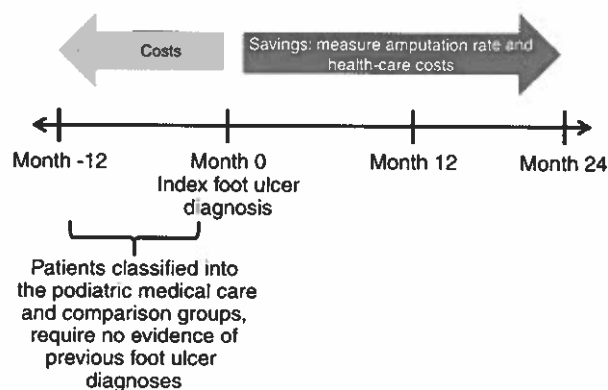


Figure 1. Measurement periods.

date of foot ulcer diagnosis (index date) and the year before the index date. Total health-care costs were measured as total allowed charges from medical (inpatient, outpatient, and emergency department) and outpatient pharmacy claims. Total allowed charges included all payments made for the claim, including those made by the patient (eg, copayments and deductible) and by the employer. For patients enrolled in Medicare, payments by Medicare, by the employer (supplemental benefits), and by the patient were captured in the database. Costs were inflation adjusted to 2008 dollars using the Medical Consumer Price Index.

We measured costs and rates of lower-extremity amputation in the 2 years after the index date because much of the economic effects of foot ulcer care are driven by avoidance of amputation and related costs.

To calculate podiatric medical costs occurring in the year before the onset of foot ulcer, the cost of foot care procedures (Table 1) provided by a podiatric physician were summed. Podiatric medical costs for patients not receiving care from a podiatric physician were assumed to be zero.

Control Variables. Because this was an observational study and randomization of patients was not possible, propensity score matching and regression adjustment were used to control for observable characteristics that may confound results.

Demographic and Insurance Plan Characteristics. Patient demographic and insurance characteristics included patient-level, plan-level, and zip code-level variables. Patient-level characteristics included age at index foot ulcer diagnosis (index date), sex, type of insurance plan, geographic location (urban or rural, US Census region), employee relationship (employee, spouse, or dependent), employee job classification (salary or union with negotiated benefits), and employment

Table 1. Codes

Code	Description
Codes Used to Define Patients with an Amputation During 2-Year Follow-up	
895.0, 895.1, 896.0, 896.1, 896.2, 896.3, 997.61, 997.62, 84.11	ICD-9-CM procedure codes
10180, 12020, 12021, 27880, 27881, 27882, 27884, 27886, 27888, 28116, 28126, 28153, 28160, 28800, 28805, 28810, 28820, 28825	CPT-4 codes
HCPCS Procedure Codes Used to Define Podiatric Medical Costs	
10060	I&D abscess, cutaneous/subcutaneous, simple
10061	I&D abscess, cutaneous/subcutaneous, complicated
11000	Debridement, eczematous/infect skin
11040	Debridement, skin, partial thickness
11041	Debridement, skin, full thickness
11042	Debridement, skin and subcutaneous tissue
11055	Paring/cutting benign hyperkeratotic lesion, 1
11056	Paring/cutting benign hyperkeratotic lesion, 2–4
11057	Paring/cutting benign hyperkeratotic lesion, >4
11305	Shaving skin lesion, foot, ≤0.5cm
11719	Trimming nondystrophic nails, any number
11720	Nail debridement, any method, 1–5
11721	Nail debridement, any method, ≥6
11730	Nail avulsion, partial/total, single
11732	Nail avulsion, partial/total, after second
11750	Permanent removal nail, partial/total
17110	Destruct any method warts up to 15
20550	Injection, tendon sheath, ligament, ganglion cyst
20600	Arthrocentesis, aspiration, injection; sm joint/bursa
20605	Arthrocentesis, aspiration, injection; intermed joint
29540	Strapping, ankle
29580	Unna boot application
64450	Injection, anesthetic, peripheral nerve
64640	Neurolysis, nerve of foot
73610	X-ray, ankle, three views
73620	X-ray, two views foot, AP/lateral
73630	X-ray, minimum three views foot
97032	Appl modality, electrical stimulation, ea 15 min
97035	Appl modality, ultrasound, ea 15 min
99202	Office/outpatient visit, new, level 2
99203	Office/outpatient visit, new, level 3
99211	Office/outpatient visit, established, level 1
99212	Office/outpatient visit, established, level 2
99213	Office/outpatient visit, established, level 3
99214	Office/outpatient visit, established, level 4

Table 1. continued

Code	Description
99232	Subsequent hospital care, per day, level 2
99243	Office consultation, new/established, level 3
99252	Initial inpatient consult, new/established, level 2
99307	Nursing facility, subsequent, per day, level 1
99308	Nursing facility, subsequent, per day, level 2
99309	Nursing facility, subsequent, per day, level 3
99334	Rest home visit, established patient, self-limit, 15 min
99335	Rest home visit, established patient, low complex, 25 min
99347	Home visit, established patient, self-limit, 15 min
99348	Home visit, established patient, low complex, 25 min
G0127	Trim nail(s)
J0702	Inject betamethasone acet or sodium phosp
J3301	Inject triamcinolone acetoneide
J7342	Metabolically active dermal tissue, per cm ²
Codes Used to Define Diabetes-Related Risk Factors	
Cardiovascular	
401.xx	Essential hypertension
402.xx	Hypertensive heart disease
403.xx	Hypertensive renal disease
404.xx	Hypertensive heart and renal d/ease
405.xx	Secondary hypertension
415.0x	Coronary artery disease
414.00	Arteriosclerotic heart disease
428.0	Congestive heart failure
429.2	Arteriosclerotic cardiovascular disease
429.9	Heart disease, unspecified
Nephropathy	
580.xx	Acute glomerulonephritis
581.xx	Nephrotic syndrome
582.xx	Chronic glomerulonephritis
583.xx	Nephritis and nephropathy not specified
584.xx	Acute renal failure
585.xx	Chronic renal failure
586.xx	Renal failure unspecified
587.xx	Renal sclerosis unspecified
588.xx	Disorders resulting from impaired renal functioning
589.xx	Small kidney of unknown cause
Eye related	
362.0x	Retinopathy
Codes Used to Define Foot-Related Risk Factors	
Callus	
700	Corn, clavus, callus
Deformity	
703.0	Nail, ingrown, with infection
703.8	Nail, hypertrophic/deformed/spur

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Table 1. continued

Code	Description
703.9	Nail disorder, unspecified
734	Rigid flatfoot, acquired
735.2	Hallux limitus/rigidus, acquired
735.3	Hallux flexus, acquired
735.4	Hammer toe, acquired
735.5	Claw toe
735.8	Overlapping toe
735.9	Deformity of toe, unspecified
736.7x	Foot deformity
Nail abnormalities	
110.1	Dermatophytosis of nail
681.11	Onychia of toe
681.10	Cellulitis, toe NOS
703.0	Ingrowing nail
703.8	Diseases of nail NEC
703.9	Diseases of nail NOS
Neuropathy	
355.0	Peripheral neuritis/neuralgia, acute, sciatic nerve
355.2	Peripheral neuritis/neuralgia, acute, femoral nerve
355.3	Peripheral neuritis/neuralgia, acute, lateral popliteal nerve
355.4	Peripheral neuritis/neuralgia, acute, medial popliteal nerve
355.5	Peripheral neuritis/neuralgia, acute, posterior tibial nerve
355.6	Peripheral neuritis/neuralgia, acute, plantar nerve
355.7	Peripheral neuritis/neuralgia, acute, due to infection
355.79	Peripheral neuritis/neuralgia, acute, saphenous nerve
355.8	Peripheral neuritis/neuralgia, acute, lower limb, polyneuritis
357.2	Polyneuropathy in diabetes (always code the diabetes first, 250.6X)
357.4	Polyneuropathy in other diseases classified elsewhere (code the underlying disease first)
713.5	Charcot
782.0	Numbness
Other risk factors	
039.4	Madura foot, nonmycotic
117.4	Madura foot
680.6	Furuncle, of ankle/leg
680.7	Boil, of foot
681.10	Cellulitis, toe
681.11	Abscess, onychia/paronychia nail
681.9	Infection, nail, NOS
682.6	Abscess, ankle/leg
682.7	Cellulitis, foot
682.9	Abscess, unspecified site

Table 1. continued

Code	Description
701.1	Hyperkeratosis, keratoderma NOS
705.81	Vesicular eruption, dyshidrosis
706.8	Xerosis
709.3	Necrobiosis lipoidica
781.2	Gait abnormality
916.2	Blister, ankle, without infection
916.3	Blister, ankle, with infection
916.8	Injury, superficial, ankle, without infection
916.9	Injury, superficial, ankle, with infection
917.0	Abrasion, foot or toes, without infection
917.1	Abrasion, foot or toes, with infection
917.2	Blister, foot or toes, without infection
917.3	Blister, foot or toes, with infection
917.8	Injury, superficial, foot or toes, without infection
917.9	Injury, superficial, foot or toes, with infection
924.20	Contusion or bruise, of foot, without fracture or open wound
924.21	Hematoma, ankle
924.3	Contusion or bruise, of toes, without fracture or open wound
956.20	Injury, posterior tibial nerve
956.30	Injury, peroneal nerve
956.40	Injury, cutaneous sensory nerve
956.50	Injury, other specified nerve, lower limb
956.90	Injury, other unspecified nerve, lower limb
958.3	Infection, post-traumatic
958.90	Compartment syndrome, unspecified
959.70	Injury, foot, ankle, or leg, unspecified
Peripheral artery	
440.20	Arteriosclerosis/atherosclerosis, unspecified
440.21	Arteriosclerosis/atherosclerosis with intermittent claudication
440.22	Arteriosclerosis/atherosclerosis, with rest pain
440.23	Arteriosclerosis/atherosclerosis with ulceration (use additional code 707.10–707.9)
440.24	Arteriosclerosis/atherosclerosis, with gangrene
440.4	Artery of the extremities, chronic total occlusion
443.1	Buerger's disease
443.81	Peripheral vascular disease of diabetes (code underlying diabetes first, 250.7X)
443.9	Peripheral vascular disease
451.0	Phlebitis, superficial
451.11	Phlebitis, femoral vein (deep) (superficial)
451.19	Phlebitis, other (femoropopliteal vein, tibial vein, popliteal vein)
451.2	Phlebitis, unspecified
454.0	Varicose vein, with ulceration
454.1	Stasis dermatitis, with inflammation

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Table 1. continued

Code	Description
454.2	Varicose vein, with ulceration and inflammation
454.8	Varicose vein with other complications (edema, pain, swelling)
454.9	Varicose vein, asymptomatic
459.11	Postphlebotic syndrome with ulcer
459.12	Postphlebotic syndrome with inflammation
459.13	Postphlebotic syndrome with ulcer and inflammation
459.81	Venous insufficiency (use an additional code for any associated ulcer 707.10–707.9)

Abbreviations: AP, anteroposterior; CPT-4, Current Procedural Terminology, 4th Edition; HCPCS, Healthcare Common Procedure Coding System; I&D, incision and drainage; ICD-9-CM, *International Classification of Diseases, Ninth Revision, Clinical Modification*; NEC, not elsewhere classified; NOS, not otherwise specified.

status (active or retired, full time or part time, or other classifications). We also created a variable to measure access to foot care from a podiatric physician because health plans are likely to vary in terms of patient access to a podiatric physician. To do so, we estimated the percentage of patients in each plan within each employer who received care from a podiatric physician during the pre-index period. Thus, all patients enrolled in the same plan within the same employer had the same value for the access to a podiatric physician variable. When included in matching and regression adjustment, this variable operated similar to a plan-level fixed effect in that it controlled for differences between health plans. The final set of demographic variables consisted of median household income, measured at the zip code level from the 2000 US Census data, and percentage of college graduates, obtained from the 2008 Area Resource File.¹¹

Health Status. Health status was measured using several variables: two general health indices, flags for the presence of specific foot-related and diabetes-related high-risk factors, and the patient's adherence to or compliance with diabetes-related medications. Variables were measured during the year before the index foot ulcer diagnosis (index date).

The general health status of patients was measured by the Deyo Charlson Comorbidity Index and the number of psychiatric diagnosis groups during the 12 months before the foot ulcer. The Deyo Charlson Comorbidity Index summarized the patient's health risk based on the diagnosis codes for

18 conditions (myocardial infarction, congestive heart failure, peripheral vascular disease, dementia, cerebrovascular disease, chronic pulmonary disease, connective tissue disease, ulcer diagnosis, mild liver disease, diabetes mellitus, hemiplegia, diabetes with end-organ disease, moderate or severe renal disease, leukemia, lymphoma, moderate or severe liver disease, metastatic solid tumor or any tumor, and acquired immunodeficiency syndrome).¹² Deyo Charlson Comorbidity Index values that exceeded 6 indicated a high risk of death or major disability in the coming year, values ranging from 2 to 6 indicated moderate risk, and values less than 2 indicated low risk of death or serious disability. The Deyo Charlson Comorbidity Index does not address psychiatric illnesses, so we also included a count of the number of psychiatric diagnosis groups observed for each patient during the year before the index foot ulcer diagnosis to measure psychiatric illnesses.¹³ There were 11 possible psychiatric diagnosis groups, which were aggregated from *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes for mental health problems. Examples included alcohol use disorders, other substance use disorders, depression, bipolar disorder, post-traumatic stress disorders, and schizophrenia.

Specific measures were also developed to define risk factors related to diabetes and foot health during the year before the foot ulcer diagnosis (index date). Patients were coded as having diabetes-related high-risk factors if they had cardiovascular disease, nephropathy, or diabetes-related eye conditions. Patients were coded as having foot-related risk factors if they had neuropathy, peripheral artery disease, deformity, callus, nail abnormalities, or other foot problems (eg, abrasions, blisters, and boils).¹⁴ Codes for these conditions are shown in Table 1. We also measured the patient's adherence to antidiabetic medications using the percentage of days covered. Patients who are not taking any diabetes medications are at higher risk for major medical problems, including myocardial infarction and amputation, because they may be receiving inadequate drug therapy.¹⁵ Medication adherence may also be related to patient access to care and health-seeking behaviors, which may also be predictive of future costs. The percentage of days covered was measured using the days supply from outpatient drug fills for all diabetes medications during the year before the foot ulcer. Patients were classified as adherent to therapy if they had diabetes medications on hand for 80% of the days in the year before their foot ulcer diagnosis.^{16, 17}

Table 2. Calculation of the Number of Additional Patients Receiving Care from a Podiatric Physician in the Simulation of a 1% Increase in Podiatric Medical Care

Inputs	Data Source	Commercial ^a	Medicare
(1) No. of people in program	Literature/CMS ^b	116 million	46 million
(2) Percentage of people with diabetes	National Diabetes Fact Sheet 2007 ^c	6.3	23.1
(3) Annual incidence of diabetic foot ulcer in diabetic patients (%)	Gibson et al (2010 working paper), Table Y	4.1	7.0
(4) No. of people at risk for diabetic foot ulcer	(1) × (2) × (3)	299,628	743,820
(5) Current use of podiatric medical care (prevalence in at-risk patients)	Part I results	26.9	40.7
(6) No. of at-risk patients visiting a podiatric physician nationwide	(4) × (5)	82,997	312,404
(7) No. of additional people visiting a podiatrist if podiatric medical visits increased by 1%	(6) × 0.01	899	2,975

Abbreviation: CMS, Centers for Medicare and Medicaid Services.

^aEmployer-sponsored insurance for patients aged 18 to 64 years.

^bThe Medicare estimate from was the Henry J. Kaiser Family Foundation²⁰ and the commercial estimate was from Holahan and Cook.²¹

^cFrom the Centers for Disease Control and Prevention.²² Diabetes prevalence in 2007 was 2.6% for individuals aged 20 to 39 years, 10.8% for those aged 40 to 59 years, and 23.1% for those 60 years and older. A weighted average of the two younger groups was used to obtain the diabetes prevalence rate for people aged 18 to 64 years.

Statistical Methods: Propensity Score Matching and Regression Adjustment. To minimize differences between patients receiving care from a podiatric physician (cases) and the comparison group, propensity score matching was performed. To do so, a logistic regression was estimated using the control variables to predict the probability that patients with diabetic foot ulcer received care from a podiatric physician.¹⁸ This probability is the propensity score. Then, each patient (case) was matched to a comparison patient with a similar propensity score (within a small range, called the caliper).¹⁹ Separate matching models were estimated for Medicare patients and patients without Medicare coverage.

Case patients without a corresponding match in the comparison group were dropped from the matched analysis. We present cost results based on the matched samples and provide results from the unmatched sample. Because matching is never perfect, regression techniques were used to estimate differences in amputation rates and health-care costs between cases and comparison patients, holding patient characteristics constant. Differences in amputation rates were estimated using logistic regression with the control variables described previously herein and an indicator for whether the patient was a case or a control.

To estimate costs in the year before the index date, the model included the control variables described previously herein and an indicator vari-

able for whether the patient was a case. To estimate costs in the 2 years after the index date, the model included the control variables described previously herein, an indicator variable for whether the person was a case, an indicator for whether the patient had an amputation, and the interaction between these two (flag for patients who were cases and had an amputation). This specification allowed costs to be predicted separately for patients who did and did not have an amputation. Costs were estimated using a generalized linear model with log link and gamma distribution to account for the skewed nature of health-care costs.

Part II: Net Present Value of a 1% Increase in Receipt of Care from a Podiatric Physician

In part II, we used total health-care costs and amputation rates from part I and additional literature to assess the impact of the cost or savings associated with receipt of care from a podiatric physician by simulating the net present value of a 1% increase in the receipt of care from a podiatric physician.

Net present value is the sum of costs and savings associated with receipt of care from a podiatric physician during the 3-year study. Because the time frame is short (3 years: 1 year before the index date and 2 years after), we omitted the discount factor from the net present value calculation for simplicity; this discount factor is typically required for studies

Table 3. Matching Regressions

Variable	Commercial (Age <65 Years)					
	2-Year Follow-up (n = 8,855)			≥3-Year Follow-up (n = 5,667)		
	Coefficient	P> z	95% CI	Coefficient	P> z	95% CI
Index year = 2005	0.2182	.1259	-0.0612 to 0.4977	0.1935	.1843	-0.0922 to 0.4791
Index year = 2006	0.1610	.2262	-0.0998 to 0.4218			
Months of follow-up	0.0090	.3102	-0.0084 to 0.0264	0.0257	.0205	0.0040 to 0.0475
Age 18–34/ 65–74 years	-0.2800	.1986	-0.7070 to 0.1469	-1.0187	.0051	-1.7317 to -0.3057
Age 35–44/ 75–84 years	0.0203	.8531	-0.1948 to 0.2354	0.0051	.9698	-0.2591 to 0.2693
Age 45–54/ ≥85 years	0.0283	.6480	-0.0931 to 0.1497	0.0127	.8696	-0.1394 to 0.1649
Female sex	0.3815	.0000	0.2689 to 0.4941	0.3270	.0000	0.1813 to 0.4728
Insurance type = HMO	-0.3106	.0068	-0.5356 to -0.0856	-0.3473	.0182	-0.6356 to -0.0590
Insurance type = POS/EPO	0.2865	.0079	0.0752 to 0.4978	0.0784	.5638	-0.1877 to 0.3444
Insurance type = PPO	0.1473	.0802	-0.0177 to 0.3123	0.2124	.0444	0.0053 to 0.4195
Insurance type = other	0.1980	.3011	-0.1773 to 0.5732	0.3347	.2546	-0.2411 to 0.9106
Resided in urban area	0.2974	.0003	0.1376 to 0.4572	0.3917	.0003	0.1806 to 0.6029
Northeast region	0.5614	.0000	0.3768 to 0.7461	0.6050	.0000	0.3351 to 0.8749
North central region	0.0443	.5434	-0.0986 to 0.1873	0.2289	.0162	0.0423 to 0.4156
West region	-0.1208	.1939	-0.3031 to 0.0615	-0.1303	.2971	-0.3753 to 0.1146
Employee	0.1439	.0178	0.0248 to 0.2629	0.0864	.2689	-0.0667 to 0.2394
Median household income in zip code	0.0001	.9767	-0.0052 to 0.0054	-0.0062	.0811	-0.0132 to 0.0008
Percentage of college graduates in zip code	0.1740	.5857	-0.4517 to 0.7997	1.1042	.0080	0.2883 to 1.9200
Salaried employee	-0.2312	.0056	-0.3947 to -0.0676	-0.1607	.1421	-0.3753 to 0.0539
Hourly employee	-0.2944	.0000	-0.4350 to -0.1537	-0.3563	.0004	-0.5524 to -0.1601
Deyo CCI score in the preperiod	0.0724	.0000	0.0407 to 0.1041	0.1250	.0000	0.0804 to 0.1695
No. of PDGs in the preperiod	-0.0332	.5328	-0.1376 to 0.0711	0.0069	.9168	-0.1234 to 0.1373
Adherent to diabetes treatment	0.6585	.0000	0.5473 to 0.7696	1.1004	.0000	0.9550 to 1.2457
Patient-level risk factor	0.2822	.0000	0.1646 to 0.3999	0.3343	.0000	0.1845 to 0.4841
Foot-level risk factor	2.0648	.0000	1.9515 to 2.1782	2.0849	.0000	1.9387 to 2.2312
Percentage of patients seeking podiatric medical care	22.3033	.0000	17.0821 to 27.5245	27.1005	.0000	18.7373 to 35.4638
Constant	-4.4577	.0000	-5.0656 to -3.8498	-5.5755	.0000	-6.5479 to -4.6032

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where costs and benefits accrue over a longer time frame. Two net present value calculations were completed to provide a range of estimates: comprehensive and procedure based.

Comprehensive Net Present Value. The comprehensive net present value incorporates all of the health-care costs or savings for patients receiving care from a podiatric physician during the entire 3-year period. This is based on results from part I comparing total health-care costs for patients who did and did not receive care from a podiatric physician.

Procedure-Based Net Present Value. The cost estimate for the procedure-based net present value is based on the cost of certain procedures rendered by a podiatric physician during the year before the index date (Table 1). The savings estimate is accrued from differences in 2-year amputation rates for patients who did and did not receive care from a podiatrist and the typical cost (over 2 years) associated with an amputation, found in part I of this study.

Extrapolation to National Estimates. Table 2 shows the method used to extrapolate to national estimates. To extrapolate per-patient costs and

Table 3. continued

Medicare					
2-Year Follow-up (n = 9,657)			≥3-Year Follow-up (n = 7,470)		
Coefficient	P> z	95% CI	Coefficient	P> z	95% CI
0.1535	.2139	−0.0886 to 0.3956			
0.1617	.1548	−0.0610 to 0.3844	0.0725	.5398	−0.1593 to 0.3043
0.0129	.1018	−0.0026 to 0.0284	0.0242	.0074	0.0065 to 0.0419
0.1001	.5723	−0.2473 to 0.4475	−0.0062	.9760	−0.4100 to 0.3976
0.2325	.1888	−0.1143 to 0.5794	0.1383	.5032	−0.2666 to 0.5431
0.4040	.0339	0.0308 to 0.7771	0.3943	.0862	−0.0562 to 0.8447
0.2170	.0000	0.1141 to 0.3199	0.3848	.0000	0.2614 to 0.5081
−1.0662	.0000	−1.3255 to −0.8068	−1.3856	.0000	−1.7068 to −1.0644
0.2410	.3446	−0.2588 to 0.7408	0.5540	.0523	−0.0055 to 1.1135
0.0447	.5060	−0.0870 to 0.1764	0.1098	.1830	−0.0519 to 0.2715
−0.0091	.9714	−0.5080 to 0.4897	0.7394	.0181	0.1265 to 1.3523
0.2448	.0009	0.0999 to 0.3896	0.3840	.0000	0.2092 to 0.5587
0.5790	.0000	0.3936 to 0.7643	0.3828	.0009	0.1560 to 0.6096
0.2627	.0000	0.1383 to 0.3871	0.3118	.0001	0.1572 to 0.4663
0.0047	.9577	−0.1682 to 0.1775	0.0123	.9098	−0.1998 to 0.2243
0.0546	.4093	−0.0751 to 0.1842	0.0884	.2567	−0.0643 to 0.2412
−0.0015	.5426	−0.0065 to 0.0034	−0.0031	.3107	−0.0090 to 0.0029
0.1832	.5294	−0.3879 to 0.7543	0.9641	.0053	0.2857 to 1.6425
−0.2177	.0039	−0.3657 to −0.0697	−0.2574	.0072	−0.4453 to −0.0695
−0.5026	.0000	−0.6466 to −0.3586	−0.4515	.0000	−0.6230 to −0.2800
0.0467	.0004	0.0209 to 0.0725	0.0691	.0001	0.0347 to 0.1035
0.0422	.4124	−0.0588 to 0.1433	−0.0107	.8741	−0.1433 to 0.1219
0.6208	.0000	0.5208 to 0.7207	1.0060	.0000	0.8860 to 1.1260
0.1581	.0059	0.0455 to 0.2706	0.2270	.0006	0.0981 to 0.3559
2.3764	.0000	2.2704 to 2.4823	2.5961	.0000	2.4686 to 2.7236
7.7698	.0000	5.4468 to 10.0928	9.4119	.0000	6.5213 to 12.3026
−4.2069	.0000	−4.9103 to −3.5035	−5.4588	.0000	−6.4665 to −4.4510

Abbreviations: CCI, Charlson Comorbidity Index; CI, confidence interval; EPO, exclusive provider organization; HMO, health maintenance organization; PDG, psychiatric diagnosis group; POS, point of service; PPO, preferred provider organization.

savings to the employer-sponsored health insurance market and Medicare, we calculated the number of new patients receiving care from a podiatric physician in a simulation of the effects of a 1% increase in the receipt of care from a podiatric physician. The number of people at risk for a new episode of diabetic foot ulcer care (row 4 in Table 2) for each year was based on the number of enrollees in Medicare and employer-sponsored health insurance plans. This estimate was derived from the prevalence of diabetes in those plans (row 2 in Table 2) and the incidence of

new episodes of care for diabetic foot ulcer (row 3 in Table 2). We also calculated the number of at-risk patients who currently received care from a podiatric physician in the year before the start of a new episode of care for a foot ulcer based on the prevalence of care from a podiatric physician (26.9% in commercial plans and 40.7% in Medicare plans). Finally, we calculated the increase in the number of people receiving care from a podiatrist by multiplying the number of patients currently visiting a podiatric physician (row 6 in Table 2) by 1%. To calculate total costs and savings for the net

Table 4. Patient Characteristics of Commercial and Medicare Enrollees, Matched and Unmatched Samples

Characteristic	Commercial Enrollees (Age <65 Years)					
	Unmatched			Matched		
	Podiatric Medical Care (n = 3,911)	No Podiatric Medical Care (n = 10,611)	P Value	Podiatric Medical Care (n = 3,367)	No Podiatric Medical Care (n = 3,367)	P Value
Index date (foot ulcer event) (%)						
2005	52.2	48.2	<.001	49.1	47.6	.214
2006	44.8	48.1	<.001	47.6	48.7	.367
2007	3.0	3.8	.018	3.3	3.7	.356
Follow-up (mean months)	33.90	33.83	.570	33.51	33.50	.937
Age (mean) (y)	54.32	53.08	<.001	54.16	54.03	.398
Age group (%)						
18–34 years	1.1	2.9	<.001	1.2	1.1	.653
35–44 years	7.0	9.8	<.001	7.4	7.8	.550
45–54 years	33.3	34.3	.282	33.5	34.8	.258
55–64 years	58.6	53.0	<.001	57.8	56.3	.192
65–74 years	NA	NA	NA	NA	NA	NA
75–84 years	NA	NA	NA	NA	NA	NA
≥85 years	NA	NA	NA	NA	NA	NA
Sex (%)						
Male	49.8	58.2	<.001	51.3	52.7	.223
Female	50.2	41.8	<.001	48.7	47.3	.223
Insurance plan type (%)						
Comprehensive	19.3	15.5	<.001	18.5	17.6	.311
HMO	11.0	18.3	<.001	11.9	13.6	.037
POS/EPO	13.6	13.1	.485	13.6	13.7	.859
PPO	53.8	50.9	.002	53.7	52.6	.393
Other (POS with capitation, CDHP, missing)	2.4	2.2	.404	2.3	2.5	.692
Urbanicity (%)						
Urban	86.4	81.8	<.001	85.5	84.5	.233
Rural	13.2	18.0	<.001	14.1	15.4	.149
Missing	0.4	0.2	.152	0.4	0.2	.108
Geographic region (%)						
Northeast	14.3	8.4	<.001	13.1	11.5	.041
North central	35.9	29.9	<.001	34.9	34.1	.489
South	38.0	43.7	<.001	39.3	40.8	.223
West	11.4	17.7	<.001	12.2	13.3	.189
Unknown	0.4	0.4	.954	0.4	0.3	.548
Employee relationship (%)						
Employee	66.0	66.2	.850	65.9	65.5	.778
Spouse	33.4	33.0	.664	33.4	33.9	.643
Dependent	0.6	0.8	.158	0.7	0.5	.273
Employee wage classification (%)						
Salary	17.5	16.9	.374	17.3	17.3	.923
Hourly	32.9	31.1	.040	32.3	33.0	.499
Other	49.6	52.0	.010	50.5	49.6	.480
Employee union classification (%)						
Union	37.6	31.8	<.001	36.6	35.0	.170

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Table 4. continued

Medicare Enrollees					
Unmatched			Matched		
Podiatric Care Medical (n = 6,979)	No Podiatric Medical Care (n = 10,148)	P Value	Podiatric Medical Care (n = 4,161)	No Podiatric Medical Care (n = 4,161)	P Value
51.8	50.4	.073	50.1	48.9	.303
44.8	45.8	.196	46.6	47.1	.660
3.4	3.8	.172	3.4	4.0	.116
34.65	34.63	.856	34.36	34.22	.370
75.86	74.76	<.001	75.71	75.16	<.001
NA	NA	NA	NA	NA	NA
0.0	0.0	.973	0.0	0.0	.564
0.3	0.4	.319	0.3	0.4	.449
1.6	2.0	.104	1.7	2.0	.295
42.0	48.4	<.001	43.1	45.5	.024
46.0	41.6	<.001	44.8	42.9	.085
10.1	7.7	<.001	10.1	9.1	.118
50.9	59.0	<.001	51.9	54.4	.024
49.1	41.0	<.001	48.1	45.6	.024
69.6	66.4	<.001	70.1	68.2	.058
2.9	6.9	<.001	3.7	5.5	<.001
1.3	0.9	.021	1.2	1.0	.343
25.2	24.9	.695	24.0	24.3	.739
1.0	0.9	.509	1.0	1.0	.913
87.1	83.0	<.001	86.6	84.0	.001
12.8	17.0	<.001	13.3	16.0	<.001
0.1	0.1	.467	0.1	0	.014
12.6	8.1	<.001	13.4	10.6	<.001
46.6	42.0	<.001	45.7	45.1	.582
26.5	32.5	<.001	27.3	29.3	.046
14.2	17.3	<.001	13.5	15.0	.048
0.1	0.1	.343	0.1	0	.014
80.7	80.0	.276	80.9	80.4	.579
19.2	19.9	.267	19.1	19.6	.541
0.1	0.1	.755	0.1	0.0	.317
20.2	20.7	.377	20.5	19.5	.285
40.9	46.4	<.001	41.1	46.0	<.001
38.9	32.8	<.001	38.4	34.5	<.001
46.8	49.6	<.001	46.4	50.8	<.001

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Table 4. continued

Characteristic	Commercial Enrollees (Age <65 Years)					
	Unmatched			Matched		
	Podiatric Medical Care (n = 3,911)	No Podiatric Medical Care (n = 10,611)	P Value	Podiatric Medical Care (n = 3,367)	No Podiatric Medical Care (n = 3,367)	P Value
Nonunion	29.3	32.8	<.001	29.7	32.5	.012
Other	33.1	35.3	.012	33.7	32.5	.288
Employment status						
Active, full time or part time/seasonal	47.8	53.9	<.001	48.8	49.7	.465
Early retiree	30.1	26.0	<.001	28.9	30.3	.219
Medicare-eligible retiree	2.8	1.9	.004	2.7	2.3	.274
Retiree, unknown status	3.1	4.6	<.001	3.4	3.2	.587
Surviving spouse/dependent	1.1	0.7	.059	0.9	1.0	.621
Other/unknown/missing, COBRA, long-term disability	15.2	13.0	.001	15.3	13.5	.044
Median household income in zip code (mean) (\$)	46,127	45,365	.008	45,820	46,012	.612
College graduates in zip code (mean) (%)	22.3	21.9	.061	22.1	22.4	.302
Health status (measured during year before index date)						
Charlson Comorbidity Index (mean)	2.36	1.71	<.001	2.31	2.23	.077
Psychiatric diagnosis groups (mean)	0.18	0.16	.022	0.18	0.18	.875
Adherent to diabetes medications (%)	51.6	31.1	<.001	47.3	42.1	<.001
Any diabetes- or foot-related risk factors (%)	90.4	61.6	<.001	88.8	88.2	.401
Diabetes-related risk factors	66.2	51.0	<.001	64.2	62.9	.265
Cardiovascular	59.9	46.0	<.001	58.2	56.5	.175
Nephropathy	8.9	6.2	<.001	8.5	10.2	.017
Eye	14.8	7.9	<.001	14.0	10.6	<.001
Foot-related risk factors	74.3	25.5	<.001	70.2	68.7	.204
Neuropathy	12.4	3.7	<.001	11.6	9.9	.028
PAD	12.3	7.7	<.001	11.4	21.9	<.001
Other	37.1	15.6	<.001	35.5	41.8	<.001
Deformity	28.9	1.8	<.001	27.6	4.6	<.001
Callus	2.1	0.6	<.001	1.8	1.5	.446
Nail abnormalities	47.4	4.0	<.001	44.2	10.8	<.001

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present value calculation, costs and savings were multiplied by the number of patients shown in row 7 of Table 2.

Results

Part I: Cost or Savings per Patient with Diabetic Foot Ulcer

We found 14,522 patients with diabetic foot ulcer enrolled in the commercial plans without Medicare;

3,911 of these patients (26.9%) received care from a podiatric physician during the year before their foot ulcer diagnosis, and 10,611 did not receive care from a podiatric physician. After applying the matching algorithm, some patients in the podiatric medical care group could not be matched with a comparison patient (n = 544), resulting in a final sample of 3,367 patients in each of the podiatric medical care and comparison groups.

Similarly, the Medicare plus supplemental insurance sample started with 17,127 patients with

Table 4. continued

Medicare Enrollees					
Unmatched			Matched		
Podiatric Care Medical (n = 6,979)	No Podiatric Medical Care (n = 10,148)	P Value	Podiatric Medical Care (n = 4,161)	No Podiatric Medical Care (n = 4,161)	P Value
31.1	28.1	<.001	31.6	27.7	<.001
22.1	22.3	.706	22.0	21.5	.5770
0.4	0.8	<.001	0.5	0.6	.654
0.8	0.8	.976	0.9	0.8	.717
72.2	73.3	.096	72.6	72.4	.864
14.0	14.4	.458	13.6	13.7	.873
10.8	9.1	<.001	10.5	11.1	.359
1.8	1.5	0.151	2.0	1.4	.042
46,310	45,167	<.001	46,186	45,448	.029
23.2	22.0	<.001	23.2	22.5	.024
2.90	2.25	<.001	2.89	2.76	.004
0.16	0.12	<.001	0.16	0.15	.287
55.8	37.6	<.001	53.0	46.0	<.001
94.8	69.6	<.001	91.3	90.2	.081
73.7	61.2	<.001	72.9	70.7	.022
68.9	56.6	<.001	68.1	65.4	.009
12.0	9.8	<.001	11.8	14.1	.002
12.1	7.4	<.001	11.9	9.2	<.001
83.4	29.3	<.001	72.3	69.6	.006
8.6	2.9	<.001	6.9	6.8	.795
24.2	13.2	<.001	20.1	31.5	<.001
35.9	14.9	<.001	30.9	35.6	<.001
33.2	2.5	<.001	28.5	5.7	<.001
3.0	0.6	<.001	3.0	1.4	<.001
62.9	5.4	<.001	54.8	12.7	<.001

Abbreviations: CDHP, consumer-driven health plan; COBRA, Consolidated Omnibus Budget Reconciliation Act; EPO, exclusive provider organization; HMO, health maintenance organization; NA, not applicable; PAD, peripheral artery disease; POS, point of service; PPO, preferred provider organization.

diabetic foot ulcer: 6,979 (40.7%) received care from a podiatric physician and 10,148 did not receive care from a podiatric physician in the first year. After matching, there were 4,161 patients in each group. Thus, 2,818 patients in the podiatric medical care group were excluded owing to not finding a suitable comparison. Details on the matching process are shown in Table 3 (coefficients from the matching regression) and Table 4 (characteristics of patients in each group before and after matching). Matching

resulted in samples with similar characteristics, although a few differences remained between the two groups. To control for these remaining differences, costs during the year before foot ulcer and the 2 years after foot ulcer and amputation rates were regression adjusted. Coefficients from these regressions are shown in Table 5. The results presented in this section focus on the estimates based on the matched sample with regression

Table 5. Cost and Amputation Regressions*

Outcome	Commercial				
	(1)	(2)	(3)	(4)	(5)
	Unmatched		Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Matched	
	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years		Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years
Observations (No.)	14,522	14,522	14,522	6,734	6,734
Podiatric medical use and amputations					
Visited a podiatrist during year before foot ulcer diagnosis	-0.356 (0.093) ^b	-0.182 (0.032) ^b	-0.202 (0.038) ^b	-0.418 (0.098) ^b	-0.226 (0.034) ^b
Amputation during 2-year follow-up (yes or no)	NA	0.928 (0.062) ^b	NA	NA	0.750 (0.082) ^b
Interaction between podiatrist visit and amputation	NA	-0.148 (0.116)	NA	NA	0.063 (0.128)
Year of foot ulcer (reference category is 2005)					
2006	-0.441 (0.096) ^b	-0.168 (0.031) ^b	0.072 (0.040) ^c	-0.303 (0.124) ^d	-0.121 (0.041) ^b
2007	-0.675 (0.251) ^b	-0.351 (0.073) ^b	0.043 (0.093)	-0.554 (0.323) ^c	-0.323 (0.099) ^b
Duration of enrollment after foot ulcer diagnosis (months)	-0.014 (0.007) ^d	-0.012 (0.002) ^b	-0.006 (0.003) ^d	-0.008 (0.009)	-0.012 (0.003) ^b
Age at foot ulcer diagnosis (reference category is age ≥55 years for commercial/age <65 years for Medicare)					
Age 18–34/65–74 years	-0.805 (0.365) ^d	-0.434 (0.079) ^b	-0.116 (0.100)	0.044 (0.475)	-0.385 (0.151) ^d
Age 35–44/75–84 years	-0.259 (0.152) ^c	-0.17 (0.044) ^b	0.035 (0.055)	-0.082 (0.205)	-0.048 (0.064)
Age 45–54/≥85 years	-0.016 (0.081)	-0.053 (0.026) ^d	0.012 (0.033)	0.094 (0.105)	-0.006 (0.036)
Female sex	-0.468 (0.080) ^b	0.019 (0.025)	0.122 (0.031) ^b	-0.481 (0.103) ^b	-0.062 (0.033) ^c
Type of health plan					
Indemnity	0.043 (0.119)	0.011 (0.037)	0.102 (0.047) ^d	0.133 (0.150)	0.012 (0.049)
HMO	-0.117 (0.117)	-0.038 (0.036)	-0.091 (0.045) ^d	-0.053 (0.157)	-0.070 (0.052)
EPO or POS	0.211 (0.115) ^c	-0.005 (0.039)	-0.022 (0.048)	0.278 (0.149) ^c	-0.024 (0.052)
Other plan type (capitated POS, CDHP, or unknown type)	-0.047 (0.256)	-0.083 (0.082)	-0.046 (0.103)	-0.076 (0.331)	-0.062 (0.108)
Location of residence					
Urban area	0.031 (0.103)	-0.039 (0.034)	-0.073 (0.043) ^c	0.062 (0.140)	-0.059 (0.048)
Northeast region	0.071 (0.133)	-0.159 (0.044) ^b	-0.101 (0.056) ^c	-0.103 (0.168)	-0.203 (0.056) ^b
North central region	-0.15 (0.101)	-0.081 (0.032) ^d	-0.064 (0.040)	-0.268 (0.131) ^d	-0.100 (0.044) ^d
West region	-0.304 (0.129) ^d	-0.058 (0.040)	-0.081 (0.050)	-0.193 (0.168)	-0.048 (0.057)
Employee characteristics (primary beneficiary)					
Employee (reference category is spouse or dependent)	-0.026 (0.081)	-0.147 (0.026) ^b	-0.082 (0.033) ^d	-0.061 (0.106)	-0.182 (0.035) ^b
Salary (reference category is hourly)	-0.148 (0.134)	0.122 (0.041) ^b	-0.001 (0.051)	-0.150 (0.173)	0.154 (0.056) ^b
Unknown if salary or hourly employee	-0.078 (0.113)	0.046 (0.037)	-0.006 (0.046)	-0.258 (0.150) ^c	0.017 (0.050)

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Table 5. continued

Commercial		Medicare				
(6) Matched	(7)	(8) Unmatched	(9)	(10)	(11) Matched	(12)
Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years	Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years	Health-care Costs in 1 Year Before Foot Ulcer Diagnosis
6,734	17,127	17,127	17,127	8,322	8,322	8,322
-0.254 (0.039) ^b	-0.317 (0.088) ^b	-0.081 (0.021) ^b	-0.038 (0.023) ^c	-0.271 (0.101) ^b	-0.079 (0.024) ^b	-0.033 (0.025)
NA	NA	0.735 (0.053) ^b	NA	NA	0.675 (0.067) ^b	NA
	NA	0.000 (0.081)		NA	0.050 (0.101)	NA
0.045 (0.051)	-0.276 (0.100) ^b	-0.223 (0.022) ^b	0.033 (0.026)	-0.181 (0.132)	-0.180 (0.029) ^b	-0.006 (0.033)
-0.098 (0.120)	-0.351 (0.245)	-0.616 (0.052) ^b	-0.042 (0.059)	-0.215 (0.323)	-0.550 (0.070) ^b	-0.167 (0.076) ^d
-0.004 (0.004)	-0.008 (0.007)	-0.011 (0.002) ^b	-0.005 (0.002) ^d	0.002 (0.010)	-0.011 (0.002) ^b	-0.008 (0.002) ^b
0.076 (0.181)	-0.425 (0.202) ^d	-0.227 (0.058) ^b	-0.184 (0.065) ^b	-0.482 (0.261) ^c	-0.154 (0.078) ^d	-0.094 (0.084)
0.047 (0.077)	-0.595 (0.203) ^b	-0.245 (0.058) ^b	-0.212 (0.066) ^b	-0.605 (0.262) ^d	-0.192 (0.078) ^d	-0.189 (0.084) ^d
-0.016 (0.043)	-1.022 (0.254) ^b	-0.275 (0.063) ^b	-0.311 (0.072) ^b	-0.960 (0.321) ^b	-0.251 (0.085) ^b	-0.200 (0.091) ^d
0.016 (0.040)	-0.430 (0.082) ^b	0.005 (0.017)	0.063 (0.020) ^b	-0.416 (0.107) ^b	0.017 (0.024)	0.043 (0.025) ^c
0.021 (0.059)	0.064 (0.106)	-0.268 (0.023) ^b	-0.277 (0.025) ^b	0.122 (0.143)	-0.203 (0.031) ^b	-0.266 (0.033) ^b
-0.099 (0.063)	0.306 (0.188)	-0.039 (0.042)	-0.122 (0.047) ^b	0.043 (0.273)	-0.075 (0.060)	-0.174 (0.065) ^b
-0.108 (0.062) ^c	0.508 (0.332)	-0.070 (0.086)	-0.095 (0.096)	0.415 (0.463)	-0.161 (0.115)	-0.039 (0.123)
-0.143 (0.129)	0.303 (0.360)	0.348 (0.087) ^b	0.352 (0.098) ^b	0.272 (0.485)	0.451 (0.116) ^b	0.459 (0.124) ^b
-0.052 (0.058)	-0.136 (0.106)	0.020 (0.024)	-0.078 (0.027) ^b	-0.136 (0.142)	0.035 (0.034)	-0.084 (0.036) ^d
-0.103 (0.067)	0.246 (0.135) ^c	-0.060 (0.032) ^c	-0.114 (0.036) ^b	0.203 (0.178)	-0.084 (0.041) ^d	-0.096 (0.045) ^d
-0.049 (0.052)	-0.020 (0.096)	-0.150 (0.021) ^b	-0.190 (0.024) ^b	0.069 (0.128)	-0.180 (0.029) ^b	-0.204 (0.032) ^b
-0.111 (0.068)	-0.219 (0.142)	-0.123 (0.029) ^b	-0.131 (0.033) ^b	-0.036 (0.185)	-0.149 (0.041) ^b	-0.134 (0.044) ^b
-0.081 (0.043) ^c	0.179 (0.107) ^c	-0.025 (0.022)	-0.016 (0.024)	0.103 (0.140)	-0.038 (0.030)	-0.024 (0.032)
0.043 (0.066)	0.016 (0.152)	-0.055 (0.032) ^c	-0.014 (0.036)	-0.015 (0.198)	-0.062 (0.043)	-0.084 (0.047) ^c
-0.057 (0.059)	0.042 (0.138)	-0.099 (0.029) ^b	-0.008 (0.033)	0.121 (0.181)	-0.092 (0.039) ^d	-0.016 (0.042)

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Table 5. continued

Outcome	Commercial				
	(1)	(2)	(3)	(4)	(5)
	Unmatched		Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Matched	
	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years		Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years
Union-negotiated plan	0.054 (0.118)	0.085 (0.038) ^d	-0.058 (0.047)	0.099 (0.156)	0.110 (0.051) ^d
Unknown if union-negotiated plan	0.01 (0.116)	-0.036 (0.037)	-0.005 (0.047)	0.194 (0.154)	-0.002 (0.051)
Health status during year before foot ulcer diagnosis					
Charlson Comorbidity Index	0.154 (0.019) ^b	0.214 (0.008) ^b	0.315 (0.011) ^b	0.166 (0.023) ^b	0.219 (0.010) ^b
No. of PDGs	-0.186 (0.084) ^d	0.14 (0.024) ^b	0.353 (0.031) ^b	-0.176 (0.101) ^c	0.097 (0.030) ^b
Any foot-level risk factors	0.842 (0.083) ^b	0.21 (0.028) ^b	0.406 (0.034) ^b	0.604 (0.124) ^b	0.184 (0.036) ^b
Any patient-level risk factors	0.038 (0.081)	0.16 (0.026) ^b	0.526 (0.032) ^b	0.176 (0.110)	0.146 (0.035) ^b
Adherence to diabetes medications	-0.216 (0.081) ^b	-0.094 (0.026) ^b	0.122 (0.032) ^b	-0.238 (0.101) ^d	-0.097 (0.034) ^b
Availability of podiatrist at the employer					
Percentage of patients at the firms who received care from a podiatrist	-9.833 (3.989) ^d	-5.698 (1.248) ^b	-3.896 (1.632) ^d	-9.482 (5.272) ^c	-5.697 (1.643) ^b
Sociodemographics, measured based on the employee's zip code					
Log of median income	-0.37 (0.165) ^d	0.034 (0.053)	0.089 (0.068)	-0.460 (0.212) ^d	0.094 (0.073)
Percentage college graduates	-0.514 (0.428)	-0.072 (0.131)	-0.059 (0.165)	-0.160 (0.542)	-0.128 (0.181)
Constant	2.008 (1.712)	10.553 (0.551) ^b	7.94 (0.709) ^b	2.739 (2.199)	10.013 (0.763) ^b
Model predictions					
No podiatric medical care	6.1%		\$21,959	8.5%	
Podiatric medical care	4.4%		\$17,942	5.8%	
No amputation					
No podiatric medical care (average cost)		\$46,273			\$56,438
Podiatric care (average cost)		\$38,579			\$45,027
Amputation during 2-year follow-up					
No podiatric medical care (average cost)		\$117,102			\$119,498
Podiatric medical care (average cost)		\$84,195			\$101,562

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adjustment. Regression-adjusted results were similar in the unmatched sample (Table 6).

Total Health-Care Costs. Figure 2 compares average total health-care costs for patients who did and did not receive care from a podiatric physician

before their index foot ulcer. We found that patients who received care from a podiatric physician had significantly lower costs than did patients in the comparison group who did not receive care from a podiatrist during the year before their foot ulcer.

Table 5. continued

Commercial		Medicare				
(6) Matched	(7)	(8) Unmatched	(9)	(10)	(11) Matched	(12)
Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years	Health-care Costs in 1 Year Before Foot Ulcer Diagnosis	Amputation (Yes or No) Within 2 Years	Health-care Costs over 2 Years	Health-care Costs in 1 Year Before Foot Ulcer Diagnosis
-0.090 (0.060)	0.071 (0.136)	0.003 (0.029)	-0.048 (0.032)	0.058 (0.174)	-0.012 (0.038)	-0.088 (0.041) ^d
-0.030 (0.061)	-0.139 (0.142)	0.117 (0.030) ^b	0.012 (0.033)	-0.194 (0.188)	0.145 (0.040) ^b	-0.001 (0.042)
0.274 (0.012) ^b	0.128 (0.018) ^b	0.124 (0.005) ^b	0.219 (0.006) ^b	0.120 (0.022) ^b	0.125 (0.006) ^b	0.198 (0.007) ^b
0.311 (0.038) ^b	-0.263 (0.093) ^b	0.069 (0.019) ^b	0.242 (0.022) ^b	-0.358 (0.128) ^b	0.056 (0.024) ^d	0.219 (0.027) ^b
0.301 (0.043) ^b	0.827 (0.091) ^b	0.108 (0.020) ^b	0.249 (0.022) ^b	0.813 (0.139) ^b	0.131 (0.026) ^b	0.230 (0.027) ^b
0.432 (0.042) ^b	0.084 (0.087)	0.119 (0.018) ^b	0.435 (0.021) ^b	0.178 (0.121)	0.139 (0.026) ^b	0.391 (0.028) ^b
-0.014 (0.040)	-0.209 (0.078) ^b	-0.059 (0.017) ^b	0.085 (0.019) ^b	-0.317 (0.102) ^b	-0.025 (0.023)	0.004 (0.025)
-5.644 (2.033) ^b	-1.715 (1.819)	1.606 (0.382) ^b	0.932 (0.435) ^d	-2.588 (2.412)	1.588 (0.515) ^b	1.113 (0.550) ^d
0.184 (0.087) ^d	-0.447 (0.170) ^b	0.084 (0.039) ^d	0.105 (0.044) ^d	-0.333 (0.225)	0.069 (0.053)	0.124 (0.056) ^d
-0.435 (0.212) ^d	0.635 (0.413)	0.022 (0.091)	0.000 (0.104)	0.855 (0.533)	0.067 (0.122)	-0.098 (0.132)
7.451 (0.916) ^b	2.119 (1.791)	9.997 (0.410) ^b	8.021 (0.464) ^b	0.583 (2.365)	10.000 (0.558) ^b	8.096 (0.592) ^b
\$27,730	0.0513		\$17,584	0.0604		\$19,668
\$21,518	0.0381		\$16,932	0.0469		\$19,021
		\$38,873			\$41,140	
		\$35,860			\$38,015	
		\$81,079			\$80,830	
		\$74,765			\$78,486	

Abbreviations: CDHP, consumer-driven health plan EPO, exclusive provider organization; HMO, health maintenance organization; NA, not applicable; PDG, psychiatric diagnosis group; POS, point of service.

^aValues are given as mean (SE) except where noted otherwise. Amputation models (1, 3, 5, and 7) were estimated using a logit, implemented with the logit command in STATA. Cost models (2, 4, 6, and 8) were estimated using a generalized linear model with log link and gamma distribution, implemented using the glm command in STATA.

^bSignificant at 1%.

^cSignificant at 10%.

^dSignificant at 5%.

Table 6. Regression-Adjusted Amputation Rates and Costs During the Year Before and the 2 Years After the Index Foot Ulcer Diagnosis*

	Unmatched Sample			Matched Sample		
	Podiatric Medical Care (≥ 1 Visits in Pre-index)	Comparison Group	Difference (Podiatric Medical – Comparison)	Podiatric Medical Care (≥ 1 Visits in Pre-index)	Comparison Group	Difference (Podiatric Medical – Comparison)
Commercial enrollees	n = 3,911	n = 10,611	NA	n = 3,367	n = 3,367	NA
Year before foot ulcer diagnosis						
Cost (\$)	17,942	21,959	–4,017 ^b	21,518	27,730	–6,212 ^b
2-year follow-up						
Amputation during 2-year follow-up (%)	4.37	6.06	–1.69 ^b	5.82	8.49	–2.67 ^b
Average cost per patient during follow-up (total over 2 years) (\$)						
Cost if no amputation	38,579	46,273	–7,693 ^b	45,027	56,438	–11,41 ^c
Cost if amputation	84,195	117,102	–32,907 ^b	101,562	119,498	–17,936
Cost of all patients ^d	40,573	50,565	–9,992 ^b	48,318	61,792	–13,474 ^b
Additional cost associated with amputations, by group (difference between patients with and without amputation) (\$)	45,616	70,829	NA	56,535	63,060	NA
Cost if no amputation	44,201		NA	50,733		NA
Cost if amputation	108,240		NA	110,530		NA
Additional cost of an amputation	64,039		NA	59,798		NA
Medicare enrollees with supplemental employer insurance	n = 6,979	n = 10,148	NA	n = 4,161	n = 4,161	NA
Year before foot ulcer diagnosis						
Cost (\$)	16,932	17,584	–652 ^e	19,021	19,668	–647
2-year follow-up						
Amputation during 2-year follow-up (%)	3.81	5.13	–1.32 ^b	4.69	6.04	–1.35 ^b
Cost during follow-up (total over 2 years) (\$)						
Cost if no amputation	35,860	38,873	–3,014	38,015	41,140	–3,125
Cost if amputation	74,765	81,079	–6,314	78,486	80,830	–2,344
Cost of all patients ^a	37,342	41,038	–3,696 ^b	39,913	43,537	–3,624 ^b
Additional cost associated with amputations, by group (difference between patients with and without an amputation) (\$)	38,905	42,206	NA	40,471	39,690	NA
Cost if no amputation	37,645		NA	39,578		NA
Cost if amputation	78,506		NA	79,658		NA
Additional cost of an amputation	40,861		NA	40,081		NA

Abbreviation: NA, not applicable.

*Amputation models were estimated using a logit, implemented with the logit command in STATA. Cost models were estimated using a generalized linear model with log link and gamma distribution, implemented using the glm command in STATA. For the

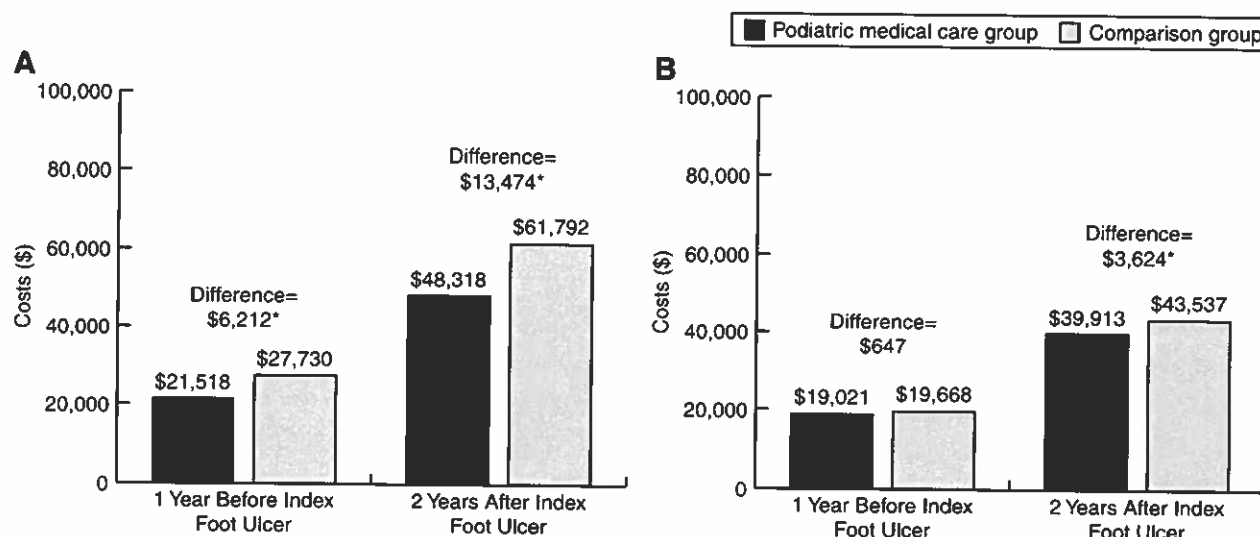


Figure 2. Comparison of health-care cost during the year before and the 2 years after the index foot ulcer diagnosis in the podiatric medical care and comparison groups. A, The matched commercial sample had 3,367 patients in each group (podiatric medical care and comparison). B, The matched Medicare sample had 4,161 patients in each group (podiatric medical care and comparison). Differences were calculated as comparison group minus podiatric medical care group; thus, positive values imply savings associated with the podiatric medical care group. Estimates were regression adjusted using the models shown in Table 5. *Statistically significant difference at 99% confidence levels.

Costs for patients in the Medicare sample who received care from a podiatric physician were \$647 lower than those for the comparison group ($P = .17$), and costs for patients in the commercial sample were \$6,212 lower than those for the comparison group ($P < .01$).

During the 2 years after the index foot ulcer diagnosis, patients who received care from a podiatric physician continued to have significantly lower costs than the comparison group. Costs were \$3,624 (Medicare, $P < .01$) to \$13,474 (commercial, $P < .01$) lower for patients who received care from a podiatric physician than for the comparison group. These results were used to calculate the comprehensive net present value in the simulation.

Amputation Rates. Figure 3 shows regression-adjusted amputation rates from the matched samples. We found that patients under the care of a podiatric physician had significantly lower rates of amputation than did those in the comparison group

who did not receive care from a podiatric physician during the year before their foot ulcer. The amputation rate for patients in the commercial sample was 5.82% for patients under the care of a podiatric physician compared with 8.49% for the comparison group, a difference of 2.67 percentage points ($P < .01$). The amputation rate for patients in the Medicare sample was 1.35 percentage points lower for patients under the care of a podiatric physician than for the comparison group ($P < .01$).

Figure 4 shows that patients with an amputation had significantly higher costs during the 2 years after the index foot ulcer diagnosis than patients without an amputation. Patients with an amputation had \$40,081 (Medicare, $P < .01$) to \$59,798 (commercial, $P < .01$) higher costs than patients without an amputation during the 2 years after the index foot ulcer diagnosis. These results were used as part of the procedure-based net present value calculation.

(Table 6, continued) amputation models, significance was based on the significance of the coefficient on having a podiatric medical care visit. For the cost models, the delta method was used to estimate the standard error (implemented in STATA using predictnl), and a t test was used to test for statistical significance.

^bSignificant at 1% confidence levels.

^cSignificant at 5% confidence levels.

^dCost of all patients is the weighted average based on the share of patients receiving amputations in each group.

^eSignificant at 10% confidence levels.

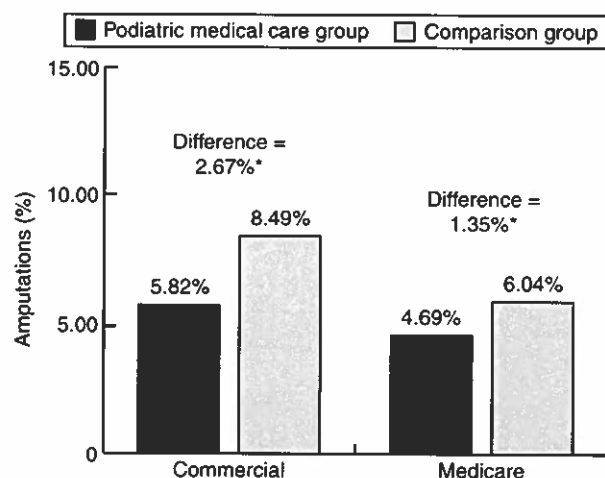


Figure 3. Comparison of amputation rates during the year after the index foot ulcer diagnosis in the podiatric medical care and comparison groups. The matched commercial sample had 3,367 patients in each group (podiatric medical care and comparison). The matched Medicare sample had 4,161 patients in each group (podiatric medical care and comparison). Differences were calculated as comparison group minus podiatric medical care group; thus, positive values imply savings associated with the podiatric medical care group. Estimates were regression adjusted using the models shown in Table 5. *Statistically significant difference at 99% confidence levels.

Part II: Simulation of Net Present Value of a 1% Increase in Receipt of Care from a Podiatric Physician

Commercial Population. Figure 5 shows the estimated net present value. This analysis revealed significant savings associated with receipt of care

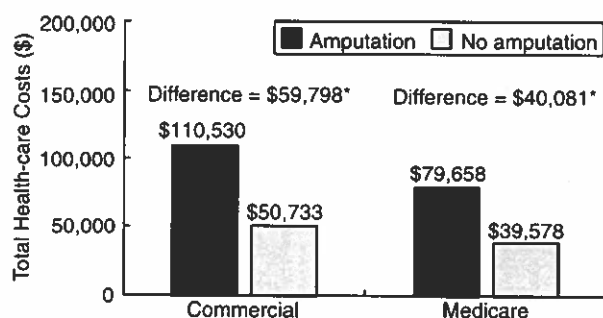


Figure 4. Total health-care costs during 2-year follow-up for patients with and without amputation during follow-up. Differences were calculated as amputation group minus no amputation group; thus, positive values imply that patients with an amputation cost more. Estimates were regression adjusted using the models shown in Table 5. *Statistically significant difference at 99% confidence levels.

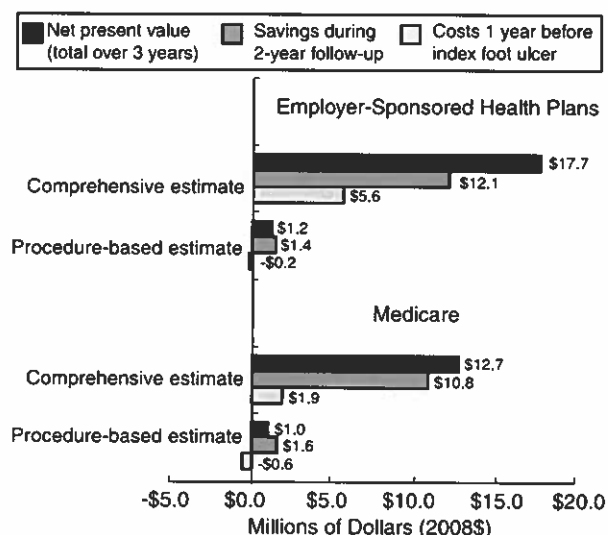


Figure 5. Health-care savings in the year before foot ulcer and 2-year follow-up and net present value during 3 years associated with a 1% increase in the percentage of at-risk patients who visit a podiatric physician before foot ulcer. Positive values imply savings associated with receipt of care by a podiatric physician. The comprehensive estimate is based on differences between the podiatric medical care group and the comparison group in total health-care expenditures during the study, shown in Figure 2 (before and after the index foot ulcer), multiplied by the number of people affected by the program (Table 2). During the pre-index period, the procedures-only estimate is based on differences in costs between the podiatric medical care group and the comparison group associated with certain procedure codes commonly used by podiatric physicians (\$248 per patient in commercial plans and \$214 per patient in Medicare plans) multiplied by the number of people affected by the program (Table 2). During follow-up, the procedures-only estimate is based on differences in amputation rates in the podiatric medical care and comparison groups (Fig. 3) and the cost of an amputation (Fig. 4), multiplied by the number of people affected by the program (Table 2).

from a podiatric physician during the 3-year study. In the commercial population, the comprehensive net present value of a 1% increase in receipt of care from a podiatric physician before foot ulcer was \$17.7 million, and the procedure-based net present value was \$1.2 million.

Comprehensive Net Present Value. During the year before the index foot ulcer, the savings was approximately \$5.6 million, estimated by multiplying the per-patient savings (\$6,212 from Fig. 2) by the number of patients ($n = 899$ from Table 2). During the 2 years after the foot ulcer diagnosis, the podiatric medical care program would be expected to save \$12.1 million, calculated by multiplying per-

patient savings (\$13,474 from Fig. 2) by the number of patients ($n = 899$). This resulted in a 3-year cumulative net present value of \$17.7 million (\$5.6 million + \$12.1 million).

Procedure-Based Net Present Value. The calculation for the procedure-based net present value was slightly different: podiatric medical costs during the 1 year before the index foot ulcer were \$248 in the commercial population. These costs were multiplied by the number of patients ($n = 899$), resulting in approximately -\$0.2 million during the year before the index foot ulcer, and are negative because they represent costs (negative savings). For the procedure-based estimate of savings, the number of saved amputations was calculated using the difference in amputation rates (Figure 3) multiplied by the additional cost of an amputation and the number of patients ($0.0267 \times \$59,798 \times 899$ patients = \$1.4 million).

Medicare Population. We used similar calculations for the Medicare population for the 3-year net present value of a 1% increase in receipt of care from a podiatric physician in the Medicare population. Costs during the year before the index foot ulcer were \$214, which resulted in a comprehensive net present value of \$12.7 million and a procedure-based net present value of \$1.0 million.

Discussion

There is ample evidence to support the effectiveness of prevention and treatment of diabetic foot ulcers. The present analysis allows decision makers to consider the costs and clinical evidence and quantifies the value of foot care by a podiatric physician for patients with diabetes and foot ulcers.

This study compared costs and amputation rates for patients who did and did not visit a podiatric physician before the foot ulcer diagnosis and found evidence that patients under the care of a podiatric physician have lower costs and fewer amputations after controlling for confounding patient characteristics. Potential confounding was controlled in two ways: regression and propensity score matching. The matched and regression-adjusted results indicated that patients who visited a podiatric physician had \$13,474 lower costs in commercial plans and \$3,624 lower costs in Medicare plans during 2-year follow-up; both differences were statistically significant at 95% confidence levels.

A positive net present value of increasing the share of patients at risk for diabetic foot ulcer by 1% was found with a range of \$1.2 million to \$17.7 million for employer-sponsored plans and \$1.0

million to \$12.7 million for Medicare plans. The estimate at the upper end of the range is most comprehensive because it is based on actual observed differences in costs and amputation rates during the year before the index foot ulcer diagnosis and the 2 years after the foot ulcer diagnosis. The lower bound is a conservative estimate in that the savings are based on differences in amputation rates (assumes that costs are otherwise the same). This estimate makes the strong assumption that the procedures listed in Table 1 are not provided by other providers and are an additional cost.

Previous evidence^{23, 24} indicates that approximately 4% of patients with diabetes experience an incident foot ulcer each year. The present data reveal that 4.1% of patients with diabetes in the commercial population and 7.0% of patients with diabetes in the Medicare population experience a new (incident) diabetic foot ulcer each year. The population-weighted average suggests that the incidence of diabetic foot ulcer is 4.9% in patients with diabetes, slightly higher than in previous studies. One reason we may find a higher estimate for the incidence of new cases is that previous studies have measured the incidence as first foot ulcers whereas we measure it as a new episode of care for a foot ulcer. This is an important distinction because it is more likely that a subsequent foot ulcer will occur in someone who has had a previous foot ulcer.

A previous comparable study²⁵ of patients in the United States found that patients with diabetic foot ulcer had costs of \$43,263 during the 2 years after the initial diagnosis of foot ulcer (inflated to 2008 US\$ to be comparable with this study), which is similar to the average health-care costs found in this study. Other studies of the cost of treating diabetic foot ulcer are difficult to compare with this study because they examined a variable-length episode of treatment (several weeks to months)^{26, 27} or were conducted outside the United States, where reimbursement patterns and costs are not comparable.²⁸⁻³¹

This study is subject to some limitations. Common to all studies based on administrative medical claims data, this study depends on accurate and consistent coding of diagnoses, treatments, comorbidities, and conditions. This is particularly a problem for some types of providers who are more likely to use certain codes (foot ulcer, comorbidities, diabetes, and foot-related risk factors) than others. Systematic coding differences between podiatrists and other providers could occur due to differences in training and practice (some providers

may be more likely to look for certain things³²) and could also be driven by incentives created by reimbursement schedules. This may explain the increased incidence of foot ulcerations in those receiving care from a podiatric physician because there is a greater likelihood that podiatric physicians would detect, appropriately evaluate, and properly code treatment of foot ulcerations. However, it is not anticipated that these types of coding differences would affect the incidence of hospitalizations or amputations.

The comparison between patients who received early specialized foot care from a podiatric physician and those who did not may be confounded by differences in each group of patients. We attempted to control for observed differences between each group using matching and regression adjustment. This study, and previous studies,¹⁰ found that patients with more severe diabetes and diabetic foot complications tend to visit a podiatric physician. Even if the regression adjustment and matching did not completely control for differences between the groups, it is likely that the savings estimates presented herein would be biased downward.

Podiatric physicians, because of their education, training, and specialty, are in the unique position to cost-effectively manage high-risk foot care treatment programs and can reduce the incidence and complications of foot ulceration through early intervention and the formulation of treatment protocols. As already cited, the multidisciplinary team approach to diabetic foot disorders has been demonstrated to be a successful method of care for the high-risk diabetic patient. The present findings suggest that podiatric medical care can reduce the disease and economic burdens of diabetes.

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Conflict of Interest: Drs. Carls, Gibson, and Wang and Ms. Bagalman were salaried employees of Thomson Reuters (Healthcare) at the time the study was performed. Thomson Reuters is under contract with the American Podiatric Medical Association to perform this study. Drs. Driver, Wrobel, and DeFrancis served as unpaid consultants to the project. Dr. Garoufalis is Treasurer of the Board of Trustees for the American Podiatric Medical Association, and Dr. Christina is Director of Scientific Affairs at the American Podiatric Medical Association.

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Receipt of Care and Reduction of Lower Extremity Amputations in a Nationally Representative Sample of U.S. Elderly

Frank A. Sloan, Mark N. Feinglos, and Daniel S. Grossman

Objective. To determine effectiveness of receipt of care from podiatrist and lower extremity clinician specialists (LEC specialists) on diabetes mellitus (DM)-related lower extremity amputation.

Data Sources. Medicare 5 percent sample claims, 1991–2007.

Study Design. Individuals with DM-related lower extremity complications (LECs) were followed 6 years. Visits with podiatrists, LEC specialists, and other health professionals were tracked to ascertain whether receipt of such care reduced the hazards of an LEC amputation.

Data Collection. Individuals were stratified based on disease severity, Stage 1—neuropathy, paresthesia, pain in feet, diabetic amyotrophy; Stage 2—cellulitis, charcot foot; Stage 3—ulcer; Stage 4—osteomyelitis, gangrene.

Principal Findings. Half the LEC sample died within 6 years. More severe lower extremity disease increased risk of death and amputation. Persons visiting a podiatrist and an LEC specialist within a year before developing all stage complications were between 31 percent (ulceration) and 77 percent (cellulitis and charcot foot) as likely to undergo amputation compared with individuals visiting other health professionals.

Conclusions. Individuals with an LEC had high mortality. Visiting both a podiatrist and an LEC specialist in the year before LEC diagnosis was protective of undergoing lower extremity amputation, suggesting a benefit from multidisciplinary care.

Key Words. Diabetes mellitus, amputation, podiatrist, mortality

Diabetes mellitus (DM) is a major cause of morbidity and mortality, accounting for nearly 7 percent of excess mortality in the U.S. elderly, and prevalence continues to increase (Mokdad et al. 2004; Roglic et al. 2005; Cowie et al. 2006). Lower extremity complications (LECs) are common among persons with DM (Caputo et al. 1994; Williams, Van Gaal, and Lucioni 2002; Jeffcoate and Harding 2003; Bethel et al. 2007); half of all amputations occur among such persons (Zoorob and Hagen 1997). Nearly 85 percent of amputations are precipitated by foot ulcers among persons with a DM diagnosis (Apelqvist and Larsson 2000).

Recommended care guidelines for DM care include foot examinations at each diabetes visit with a comprehensive foot examination performed annually and tight glycemic control (Zoorob and Hagen 1997; American Diabetes Association 2002, 2005, 2006, 2008b, 2009). Annual foot examination and glycemic control adherence rates have improved (Saaddine et al. 2002; Eliasson et al. 2005), but many persons still do not receive adequate foot care (Apelqvist and Larsson 2000). Nonadherence is generally high and not limited to persons with LECs (Lee et al. 2003; McClellan et al. 2003; McGlynn et al. 2003; Koro et al. 2004; Sloan et al. 2004). Diabetes education interventions have been associated with decreased risk of lesions on the feet, better self foot care, and reduced risk of ulceration and amputation by up to 50 percent (Litzelman et al. 1993; Mayfield et al. 1998; Rith-Najarian et al. 1998; Reiber and Ledoux 2002; Plank et al. 2003; Lavery, Wunderlich, and Tredwell 2005). These interventions are more effective when performed by a specialist with lower extremity care expertise (Singh, Armstrong, and Lipsky 2005).

These interventions may also decrease cost: individuals with a DM diagnosis and foot ulcers tend to incur substantially higher expenditures on personal health care services than do persons with DM without foot ulcers (Ramsey et al. 1999; O'Brien, Patrick, and Caro 2003). Incremental expenditures of up to U.S.\$46,000 per year have been attributed to foot ulcers in persons with osteomyelitis; the cost of a first lower extremity amputation is U.S.\$30,000–U.S.\$50,000 (Ramsey et al. 1999; Gordoys et al. 2003; O'Brien, Patrick, and Caro 2003; Shearer et al. 2003). Substantial long-term care expenditures are also incurred by individuals with DM and LECs in particular (Ramsey et al. 1999; Gordoys et al. 2003; O'Brien, Patrick, and Caro 2003). There is also a cost in terms of lost productivity (American Diabetes Association 2008a).

Persons diagnosed with neuropathy have a low life expectancy (Ramsey et al. 1999; Chaturvedi et al. 2001; Faglia, Favales, and Morabito 2001; Jeffcoate and Harding 2003; Cusick et al. 2005). Ulceration increases risk of death by 85+ percent, while amputation more than doubles mortality risk in persons with DM (Chaturvedi et al. 2001; Cusick et al. 2005). Given pressures on

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public budgets, particularly for Medicare, gauging the productivity of health interventions is a high priority.

In this study, we used national longitudinal Medicare claims data to examine whether care provided by clinicians specializing in treating DM and DM-related LECs was associated with better health outcomes, measured by the probability of an amputation of part or all of a leg or foot. We studied care received from podiatrists, clinician specialists in diagnosing and treating LECs (“LEC clinician specialists”), podiatrists in combination with LEC specialists, and other clinicians who care for persons with a DM diagnosis but who are not specialized in lower extremity DM complications. We assessed productivity of receipt of services from these health provider types taken individually and in combination.

METHODS

Data

Medicare 5 percent inpatient, outpatient, Part B, and durable medical equipment claims files were used to identify a nationally representative sample of Medicare beneficiaries aged 65+ diagnosed with DM, DM-related LECs, and other related adverse outcomes (described below under “Other explanatory variables”) during 1991–2007. The data contained information on demographic characteristics and zip code of residence of beneficiaries and diagnosis (International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM]), procedure (Current Procedural Terminology [CPT-4]; Healthcare Common Procedure Coding System [HCPCS]), U.S. Centers for Medicare and Medicaid Services (CMS) provider specialty, and provider zip codes submitted with each claim. Data on dates of death and enrollment in Medicare fee-for-services came from Medicare 5 percent annual denominator files.

Sample Selection

Individuals entered into our analysis sample after receiving a DM-related, LEC diagnosis between 1994 and 2001. We classified sample persons into five mutually exclusive stages of increasing severity based on ICD-9-CM and CPT-4 codes. We developed this severity scale based on the expert opinion of the endocrinologist on our team. This scale is based on implications for treatment at each stage (see Table 1). The incremental LEC stages, denoting increasing invasiveness of therapy and complication severity, were Stage 1 (neuropathy: 250.6, 357.2, 355.xx; paresthesia: 782.xx; pain in feet: 729.5;

Table 1: Clinical Implications and Rationale for Lower Extremity Severity Stage Hierarchy and Clinician Specialists in Diagnosing and Treating Lower Extremity Complications

<i>Stage Diseases</i>	<i>Clinical Implications/Rationale</i>
<i>Panel A: Clinical implications and rationale for lower extremity severity stage hierarchy</i>	
<i>Stage 1: Neuropathy, paresthesia, pain in feet, diabetic amyotrophy</i>	Stage 1 diagnoses are based on electrical data and lower extremity examinations. Neurological dysfunction but no significant physical alteration
<i>Stage 2: Cellulitis, charcot foot</i>	Now need antibiotics, or cast. Not usually a surgical problem, but need to use other therapeutic maneuvers
<i>Stage 3: Ulceration</i>	Extensive dermatology, infectious disease, and/or podiatrist input; debridement often needed
<i>Stage 4: Osteomyelitis, gangrene</i>	Extremity in danger, with extensive antibiotic therapy and likely surgical procedure
<i>Panel B: Lower extremity clinician (LEC) specialists to prevent progression to a specific stage</i>	
<i>Stage 1: Neuropathy, paresthesia, pain in feet, diabetic amyotrophy</i>	General surgeon (code 02), dermatologist (07), neurologist (13), orthopedic surgeon (20), physical medicine and rehabilitation (25), diagnostic radiology (30), physical therapist (65)
<i>Stage 2: Cellulitis, charcot foot</i>	Same as Stage 1
<i>Stage 3: Ulceration</i>	General surgeon, orthopedic surgeon, diagnostic radiology, infectious disease (44)*
<i>Stage 4: Osteomyelitis, gangrene</i>	General surgeon, dermatologist, orthopedic surgeon, plastic and reconstructive surgeon (24), diagnostic radiology, infectious disease

*We did not include dermatologists as LEC specialists for Stage 3 individuals. While we recognize that dermatologists may be beneficial to individuals previously diagnosed with cellulitis, they would likely not be seen by individuals diagnosed with charcot foot. We therefore excluded them from this stage analysis.

diabetic amyotrophy: 358.1) in which diagnoses were based largely on electrical data and individuals had neurological dysfunction but otherwise no significant physical alteration; Stage 2 (cellulitis: 681.1, 682.6, 682.7; charcot foot: 094.0) in which individuals experienced major physical changes and for whom use of nonsurgical therapies is appropriate, for example, antibiotics or casting, but more invasive therapy is unlikely to be used; Stage 3 (ulcer: 707.10, 707.12-9) in which individuals would likely benefit from more extensive dermatological treatment and possibly invasive therapy, for example, debridement; Stage 4 (osteomyelitis: 730.06-7, 730.16-7, 730.26-7; gangrene:

250.7, 785.4) in which individuals would benefit from intensive intravenous antibiotic treatment and likely major surgical procedures; and Stage 5 (amputation: 84.1x; CPT-4: 27290, 27295, 27590-2, 27594-6, 27598, 27880-2, 27884, 27886, 27888, 28800, 28805, 28810, 28820, 28825) in which part of the lower extremity is removed. Being in Stage 5 was the main study outcome. We created subsamples for each of the four other stages and a combined sample including all individuals from the four subsamples. Individuals could appear in more than one stage sample if they were classified in more than one stage during 1994–2001. However, individual sample persons appeared only once in the combined sample, classified by their first diagnosed LEC stage and the associated date. The combined sample was only used for descriptive purposes.

For each subsample, we used a 3-year look-back period using the stage complication diagnosis date as baseline. To ensure a full 3-year look-back period, which we used to define comorbidities present at baseline, we excluded all persons initially diagnosed with the stage complication before 1994; diagnosed with the stage complication before age 68; and participating in a Medicare risk plan (HMO) or living outside of the United States for over 12 months during the look-back period. There are no data for beneficiaries in risk plans (Figure 1). We also excluded individuals lacking valid zip code data, which we needed to calculate distance to the nearest provider.

Individuals diagnosed with a higher LEC stage before entry in a particular stage were also excluded from that sample to ensure that individuals in that analysis were at a similar level of severity in the LEC disease progression at analysis baseline. For example, the Stage 1 group consisted of all Medicare beneficiaries receiving a first diagnosis of a Stage 1 complication during the study period but who had not experienced a more severe stage complication before the Stage 1 diagnosis date. Finally, we excluded persons diagnosed with DM < 1 year before the stage diagnosis date to allow a full year in which to track individuals' health care utilization, our main explanatory variables. After exclusions, there were 117,879 individuals in Stage 1, 31,582 in Stage 2, 31,199 in Stage 3, 55,068 in Stage 4 subsamples, and 189,598 in the combined analysis sample.

Sample individuals were followed for 2,190 days (6 years) after entry into the sample. Individuals were censored if, after entering the sample, they joined an HMO, moved outside the United States for more than a year, or died. Data on whether an individual resided in the United States were collected annually; thus, if a person was coded as not living in the United States during a given year, we considered the observation to be censored as of January 1 of that calendar year.

Figure 1: Attrition by Study Exclusion Criteria

Attrition by stage				
Had diagnosis of Stage	Stage 1: 656,590	Stage 2: 145,932	Stage 3: 118,923	Stage 4: 132,838
First diagnosis prior to 1994	197,721	37,010	25,561	34,027
Under age 68 or over age 95	146,860	28,418	21,844	24,882
Lived out of U.S. during look-back	5,398	2,227	1,194	1,470
Joined HMO during Look-back	10,088	1,796	2,016	2,203
Had higher stage prior	42,680	20,230	16,096	548
Invalid zip code	3,958	637	549	920
Developed initial Stage diagnosis within 1 year DM diagnosis	132,006	24,032	20,464	13,720
Final sample	117,879	31,582	31,199	55,068

Dependent Variables

Dependent variables were hazards of a first amputation of the lower extremity within 6 years following baseline.

Types of Health Services

Key explanatory variables related to receipt of health services during the *year before being diagnosed* with a study stage diagnosis. We classified care received from health professionals into five mutually exclusive categories, defining binary variables for each (Table 1, panel B): (1) podiatrist (CMS provider specialty code 48) with or without care from other health professionals; (2) lower extremity clinician specialist (LEC specialist) with or without care from other health professionals; (3) podiatrist and LEC specialist with or without care from other health professionals; (4) other health professional (no care

from podiatrists or LEC specialists)—general/family practitioner (01, 08), internist (11), endocrinologist (46),¹ nurse practitioner (50), and physician assistant (97); and (5) no care from any of the study health professionals (but receipt of care from nonstudy health professionals, e.g., pathologists, psychiatrists).² The omitted reference group was “other health professional.” LEC specialists were identified by using Medicare 5 percent claims data to determine which specialists were most likely to see individuals with a primary diagnosis of Stages 1–4 LECs. We classified specialists appropriate for each LEC stage according to which type of health professional would be most likely to treat individuals and prevent them from progressing to a higher stage LEC (see Table 1, panel B).

Although by definition individuals in the fifth group did not see a study health provider, most persons classified in this group had in fact received some form of care from a health professional during this time period, measured by a Medicare Part B claim. Percentages not having a Part B claim were 11.6 percent Stage 1, 14.4 percent Stage 2, 8.8 percent Stage 3, and 11.4 percent Stage 4.

Other Explanatory Variables

We included covariates for DM severity, which is likely to increase with disease duration; for DM duration, we created a binary variable using the look-back period, with 1 designating individuals diagnosed with DM 3+ years before entry in the sample and 0 for other sample persons. Persons with insulin-dependent DM were identified using the five-digit ICD-9-CM DM diagnoses “250.01” and “250.03.” Individuals with 2+ claims with such diagnoses were considered to be insulin dependent.

We accounted for renal, ocular, cardiovascular, and cerebrovascular system function, and other body systems frequently affected by DM. Covariates for each system were (1) renal—DM with renal manifestations (ICD-9-CM code: 250.4), proteinuria/nephrotic syndrome (791.0, 581.8), chronic renal failure,³ and end-stage renal disease⁴; (2) ocular—background diabetic retinopathy (362.01), proliferative diabetic retinopathy (362.02), and diabetic macular edema (362.07, 362.53, 362.83); (3) cardiovascular—coronary artery disease (410, 411, 413, 414), with separate variables for diagnosis in an outpatient or inpatient setting, and congestive heart failure⁵; (4) cerebrovascular—carotid bruit (785.9; CPT-4: 76536), occlusion or stenosis of cerebral artery (433–434), transient ischemic attack (435), and stroke (430–432, 436).

Other DM-associated conditions were hypertension (401), lipidemia (272.0–272.4), and obesity (278.0). Strict adherence to American Diabetes Association guidelines for all three of these conditions is part of optimal DM control (American Diabetes Association 2002, 2005, 2006, 2008b, 2009). Persons diagnosed with hypertension or lipidemia are more likely to have been receiving medications for these diagnoses. We included a binary variable for arthritis because it may affect use of the lower extremities. We also included a binary variable for Alzheimer's disease or other dementia (ADOD: 331.0, 290.x, 310.1, 331.2, 438.0) because ADOD may affect an individual's ability to control his/her DM and investments in care (Sloan et al. 2003).

The Charlson index (Charlson et al. 1987), a widely used comorbidity measure, was constructed from data from the calendar year before diagnosis of the sample complication being studied. We excluded diagnoses of DM and DM complications from the Charlson index because we included separate covariates for these.

We included binary variables representing the quartile ranking of Medicare payments in the previous year, measured by services performed by nonstudy health professionals (those not included in the podiatrist, LEC specialist, or other health professional groups). The omitted reference group was the lowest payment quartile.

Accounting for Endogeneity of Receipt of Podiatric and Medical Care

Rationale. A problem with observational data is that the intervention of interest, here receipt of particular types of personal health care services, is plausibly endogenous to outcomes. Endogeneity may occur when procedures are performed in response to clinical problems that are not recorded in the claims data. Although we included various covariates for health, some dimensions of health affecting receipt of services were plausibly observable to providers and patients but were not captured by our data.

Approach. To deal with endogeneity, we included variables to account for omitted heterogeneity. These variables were sets of residuals from a multinomial logit analysis of choice among the five mutually exclusive provider-type categories (Shea et al. 2007; Terza, Basu, and Rathouz 2008). Main covariates in the multinomial logit regression were measures of minimum distance to other health professionals, and relative minimum distances to podiatrists and LEC specialists (distance to the nearest podiatrist or LEC specialist minus distance to nearest other health professional). Other

explanatory variables were listed above under “Other explanatory variables.”

Next, we used the residuals from the multinomial logit analysis to construct four explanatory variables, one for each of the residuals for four visit-type categories, other health professional being the omitted reference group.

Data on distances to the nearest health professional came from Medicare 5 percent claims. The database contained information on the beneficiary’s and the provider’s zip code. Because we lacked more precise location information, we measured distance in miles (air distance) between the center of the beneficiary’s zip code of residence and the zip code in which the provider’s office was located. Each DM care provider in the claims data was considered to be an alternative for each beneficiary. Thus, even if a particular beneficiary obtained care from a provider who was not the nearest from his or her place of residence, we only considered the nearest provider in the calculations of minimum distance. Individuals living in a zip code with an other health professional were considered to have 0 miles to the nearest other health professional. For all others, we used *SAS* 9.2 software (SAS; Cary, NC, USA) to calculate the distance to the nearest other health professional. *SAS* 9.2 evaluated the distance between the centroids of two zip codes. Our program then saved this distance and calculated distance between the individual and another zip code with a study health professional. With each iteration, *SAS* kept the shorter of the distances. We expected minimum distances to be negatively related to visits, but not to affect disease progression. We found minimum distances to be highly correlated with receipt of visits of various types (not shown).

Statistical Analysis

A Cox proportional hazards model was used to analyze time to amputation. The analysis was performed both with and without the variables for the residuals as covariates. A log likelihood test revealed whether the covariates for the residuals were statistically significant when considered as a group.

RESULTS

There were 189,598 individuals in the combined sample, 84.2 percent of whom were white, 11.3 percent black, and 4.5 percent other race (Table 1).

Nearly two fifths of individuals were male; mean age was 77.7 years. Compared with the DM with no reported LEC, our sample was older, more female, much more likely to have seen “other health professionals,” and had higher rates of comorbidities. Mean distances to the nearest health professional, podiatrist, and LEC specialist did not differ by stage by more than 0.3 miles. A higher proportion of individuals never diagnosed with DM were white compared with our sample.

Adjusting for censoring, 6 percent of the combined sample underwent an amputation of the lower extremity during the study period (Figure S1). Individuals classified in the other health professional group were slightly more likely to receive an LEC amputation. Individuals diagnosed with diabetes LEC experienced high rates of mortality. Approximately half of sample individuals died during the 6-year follow-up.

Considering amputation rates at any time before death, persons entering the analysis at Stage 1 were least likely (2.3 percent, Table 2) and at Stage 4 were most likely (14.4 percent) to have an amputation. As with amputations, death within the 6-year follow-up period increased monotonically by stage—from 44.4 percent for Stage 1 to 64.2 percent for Stage 4.

There were also systematic differences by group in the mix of health professionals seen. Stage 1 persons were most likely to have only seen an other health professional and an LEC specialist only, and least likely to have seen a combination of a podiatrist and LEC specialist. By contrast, Stage 3 and Stage 4 persons were more likely to have seen a podiatrist and an LEC specialist and least likely to have not seen a study health care provider.

Persons in Stage 4 had more severe diabetes, measured by duration of diabetes, insulin dependence, and DM complications. Over four fifths of Stage 4 individuals had been diagnosed with DM 3 years prior, while nearly half of them had insulin-dependent diabetes. Corresponding rates for those in Stage 1 were 68 percent and 22 percent. Patterns by stage for other comorbidities are mixed. A higher percentage of persons at Stage 4 were black than for the other stages.

Sample persons lived less than a mile from the nearest other (study) health professional. Persons at Stages 1 and 2 had higher relative distance to the nearest podiatrist than did those at Stages 3 and 4, the mean differences ranging from slightly under 1 mile to about 1.5 miles. Relative distance to the nearest LEC specialist did not differ by more than 0.2 miles for all four stages.

Based on the results of log likelihood ratio tests, the null hypothesis of exogeneity of receipt of care was accepted for Stage 2, and hence covariates for the residuals were excluded in the results shown in Table 2. By contrast, for

Table 2: Descriptive Statistic Means

	Combined Sample	DM No LEC [†]	Non DM [†]	Stage 1 [‡]	Stage 2 [‡]	Stage 3 [‡]	Stage 4 [‡]
Outcome variables							
Underwent lower extremity amputation	0.059	0.001***	0.004***	0.023***	0.080***	0.085***	0.144
Total died (regardless of amputation)	0.499	0.379***	0.337***	0.444***	0.571***	0.614***	0.642
Explanatory variables							
Receipt of care in the year before stage diagnosis							
Saw an other health professional (HP) only	0.151	0.293***	0.181***	0.180***	0.127***	0.080***	0.080
Saw a podiatrist	0.221	0.062***	0.089***	0.041***	0.059***	0.130***	0.088
Saw a podiatrist and other HP	0.909	0.889***	0.863***	0.901	0.915	0.914	0.919
Saw a lower extremity clinician (LEC) specialist	0.061	0.026***	0.031***	0.592***	0.514***	0.334***	0.400
Saw an LEC specialist and other HP	0.822	0.805*	0.740***	0.827***	0.822*	0.812	0.822
Saw a podiatrist and LEC specialist	0.525	0.527***	0.444***	0.138***	0.264***	0.436***	0.411
Saw a podiatrist and LEC specialist and other HP	0.898	0.869***	0.826***	0.893***	0.906	0.916	0.912
Did not see any study HP	0.042	0.092***	0.254***	0.050***	0.030***	0.020	0.021
Severity of diabetes mellitus (DM)							
Diagnosed with DM 3 year prior	0.687	0.005***	NA	0.675***	0.729***	0.753***	0.811
Insulin dependent	0.259	0.075***	NA	0.215***	0.288***	0.299***	0.452
Renal comorbidities							
DM with renal manifestations	0.007	0.002***	NA	0.005***	0.008***	0.008***	0.015
Proteinuria/nephrotic syndrome	0.024	0.009***	0.004***	0.022***	0.027***	0.028***	0.033
Chronic renal failure	0.083	0.037***	0.017***	0.063***	0.109***	0.127***	0.142
End-stage renal disease	0.017	0.005***	0.002***	0.011***	0.019***	0.030***	0.041
Ocular comorbidities							
Background diabetic retinopathy	0.119	0.033***	NA	0.098***	0.127***	0.141***	0.214
Proliferative diabetic retinopathy	0.031	0.008***	NA	0.022***	0.034***	0.039***	0.063
Diabetic macular edema	0.040	0.017***	NA	0.034***	0.043***	0.047***	0.062

continued

Table 2. Continued

	Combined Sample	DM No LEC [†]	Non DM [†]	Stage 1 [†]	Stage 2 [†]	Stage 3 [†]	Stage 4 [†]
Cardiovascular comorbidities							
Coronary artery disease—inpatient	0.252	0.136***	0.090***	0.215***	0.318***	0.297***	0.351
Coronary artery disease—outpatient	0.511	0.381***	0.251***	0.474***	0.565***	0.577***	0.594
Congestive heart failure	0.353	0.195***	0.128***	0.298***	0.458***	0.449***	0.475
Cerebrovascular comorbidities							
Carotid bruit	0.064	0.033***	0.031***	0.059***	0.070***	0.075***	0.083
Occlusion/stenosis of cerebral artery	0.190	0.102***	0.079***	0.169***	0.205***	0.232***	0.262
Transient ischemic attack	0.127	0.067***	0.061***	0.112***	0.141***	0.156**	0.165
Stroke	0.165	0.088***	0.066***	0.137***	0.181***	0.223***	0.241
Other comorbidities							
Hypertension	0.813	0.704***	0.485***	0.803***	0.832***	0.841**	0.849
Lipidemia	0.495	0.453***	0.276***	0.511***	0.481***	0.494***	0.469
Obesity	0.046	0.017***	0.006***	0.041***	0.066***	0.060	0.060
Arthritis	0.320	0.179***	0.202***	0.296***	0.372***	0.396***	0.344
Charlson index	1.581	1.196***	0.904***	1.358***	1.833***	2.060	2.069
Alzheimer's and other dementia	0.080	0.053***	0.055***	0.080***	0.114***	0.169***	0.155***
Demographic characteristics							
Black	0.113	0.108***	0.061***	0.109***	0.087***	0.122***	0.141
Other race	0.045	0.062***	0.036***	0.046	0.043*	0.043*	0.046
Male	0.396	0.476***	0.402***	0.406	0.389***	0.365***	0.408
Baseline age	77.662	75.718***	77.068***	76.86***	78.13	79.10***	78.05
Distance to HPs							
Distance to nearest other HP (miles)	0.854	0.880*	0.967***	0.913	0.927	0.682	0.723
Relative distance to nearest podiatrist (miles)	-4.202	-4.358***	-4.477***	-4.490	-4.556	-3.220	-3.598
Relative distance to nearest LEC specialist (miles)	-1.638	-1.617	-1.615	-1.673	-1.706	-1.619	-1.590
Observations	189,598	110,330	698,909	117,879	31,582	31,199	55,068

[†] *T*-tests compared with combined sample.

[‡] *T*-tests compared with Stage 4 sample.

****p* < 0.001;

***p* < 0.01;

**p* < 0.05.

Stages 1, 3, and 4, the null hypothesis of exogeneity of care was rejected, and therefore results with the covariates for the residuals in the results are presented.

Adjusting for Medicare expenditures from care received from nonstudy health professionals, overall care, measured by the hazard of the first LEC amputation during the 6-year follow-up period, was productive for persons at all stages. For Stage 1, the hazard ratio for “saw a podiatrist” implies that persons diagnosed with DM were more than twice as likely to have an LEC amputation during follow-up (hazard ratio [HR] = 2.20; 95 percent confidence interval [CI]: 1.15, 4.22), while individuals who “saw a podiatrist and LEC specialist” were 47 percent as likely to have an LEC amputation (HR: 0.47; 95 percent CI: 0.27, 0.81) (Table 3).

For Stage 2, persons receiving care from an LEC specialist only were 16 percent less likely than those receiving care from an other health professional to have had an LEC amputation during follow-up (HR = 0.84; 95 percent CI: 0.74, 0.95); those seeing a podiatrist and an LEC specialist experienced about the same risk of having an amputation (HR = 0.81; 95 percent CI: 0.70, 0.93). Persons not seeing any of the study health professionals had a higher risk of an amputation than those who saw an other health professional (HR = 1.29; 95 percent CI: 1.07, 1.57). To put these results in perspective, the annual hazard of an amputation during follow-up was 1.3 percent annually.

For Stage 3, hazard ratios tended to be appreciably lower than for Stage 2. In particular, persons receiving care from both a podiatrist and an LEC specialist were 36 percent as likely to have received an amputation during follow-up than were those who only saw an other health professional (HR = 0.36; 95 percent CI 0.14, 0.94). The annual hazard of having been amputated for Stage 3 was 1.4 percent. Seeing a podiatrist only was productive for persons at Stage 3 (HR = 0.44; 95 percent CI: 0.14, 1.42), although this result was not statistically significant.

Stage 4 results were similar to Stage 3's. Both seeing a podiatrist only (HR = 0.36; 95 percent CI: 0.17, 0.78) and seeing a combination of a podiatrist and an LEC specialist (HR = 0.42; 95 percent CI: 0.24, 0.74) reduced the hazard of an LEC amputation. Individuals seeing an LEC specialist only were 85 percent more likely to undergo amputation (HR = 1.85; 95 percent CI: 1.03, 3.33). The annual hazard of an amputation for Stage 4 individuals was nearly double that of Stage 3. The hazard ratio for “residual—saw a podiatrist” and “residual—saw a podiatrist and LEC specialist” was slightly higher for Stage 4 than for Stage 3.

Diabetes diagnosis duration, being insulin dependent, having chronic renal failure, end-stage renal disease, diabetic retinopathy, coronary artery

Table 3: Hazard Ratios of Undergoing Amputation from Cox Proportional Hazards Models (with 95% Confidence Intervals in Parentheses)

	Stage 1*	Stage 2	Stage 3*	Stage 4*
Receipt of care in the year before stage diagnosis				
Saw a podiatrist	2.20 (1.15, 4.22)	0.85 (0.70, 1.03)	0.44 (0.14, 1.42)	0.36 (0.17, 0.78)
Saw a lower extremity clinician (LEC) specialist	0.80 (0.54, 1.18)	0.84 (0.74, 0.95)	2.23 (0.82, 6.09)	1.85 (1.03, 3.33)
Saw a podiatrist and LEC specialist	0.47 (0.27, 0.81)	0.81 (0.70, 0.93)	0.36 (0.14, 0.94)	0.42 (0.24, 0.74)
Did not see any study health professional (HP)	0.93 (0.49, 1.76)	1.29 (1.07, 1.57)	0.87 (0.11, 6.91)	1.40 (0.46, 4.22)
Severity of diabetes mellitus (DM)				
Diagnosed with DM 3 year prior	1.23 (1.13, 1.35)	1.26 (1.14, 1.39)	1.35 (1.22, 1.50)	1.01 (0.95, 1.07)
Insulin dependent	1.56 (1.43, 1.69)	1.53 (1.40, 1.67)	1.57 (1.44, 1.71)	1.11 (1.06, 1.17)
Renal DM comorbidities				
DM with renal manifestations	1.66 (1.25, 2.20)	1.36 (1.04, 1.78)	0.87 (0.63, 1.21)	1.05 (0.91, 1.22)
Proteinuria/nephrotic syndrome	1.19 (0.97, 1.47)	1.17 (0.96, 1.43)	1.01 (0.83, 1.23)	1.02 (0.91, 1.15)
Chronic renal failure	1.70 (1.48, 1.96)	1.16 (1.01, 1.33)	1.12 (0.98, 1.28)	1.19 (1.10, 1.28)
End-stage renal disease	3.40 (2.76, 4.18)	2.87 (2.33, 3.52)	2.39 (1.99, 2.87)	2.10 (1.90, 2.33)
Ocular DM comorbidities				
Background diabetic retinopathy	1.84 (1.66, 2.05)	1.65 (1.48, 1.84)	1.65 (1.48, 1.83)	1.25 (1.18, 1.33)

continued

Table 3. *Continued*

	Stage 1*	Stage 2	Stage 3*	Stage 4*
Proliferative diabetic retinopathy	1.50 (1.27, 1.78)	1.49 (1.28, 1.75)	1.44 (1.24, 1.67)	1.46 (1.35, 1.59)
Diabetic macular edema	1.14 (0.97, 1.35)	1.03 (0.87, 1.22)	1.07 (0.91, 1.25)	1.05 (0.96, 1.15)
Cardiovascular DM comorbidities	1.25 (1.12, 1.39)	1.23 (1.11, 1.37)	1.19 (1.06, 1.34)	1.19 (1.11, 1.26)
Coronary artery disease—inpatient	0.93 (0.85, 1.03)	0.83 (0.76, 0.92)	0.94 (0.85, 1.04)	0.91 (0.86, 0.97)
Coronary artery disease—outpatient	1.48 (1.36, 1.62)	1.26 (1.15, 1.38)	1.19 (1.08, 1.31)	1.28 (1.21, 1.35)
Congestive heart failure				
Cerebrovascular DM comorbidities	1.09 (0.93, 1.27)	1.05 (0.90, 1.22)	0.94 (0.81, 1.10)	0.94 (0.86, 1.02)
Carotid bruit	1.23 (1.10, 1.37)	1.30 (1.17, 1.45)	1.12 (1.01, 1.24)	1.09 (1.03, 1.16)
Occlusion/stenosis of cerebral artery	0.90 (0.79, 1.02)	0.92 (0.81, 1.04)	0.93 (0.83, 1.05)	0.91 (0.85, 0.97)
Transient ischemic attack	1.59 (1.43, 1.78)	1.30 (1.16, 1.45)	1.22 (1.10, 1.36)	1.21 (1.14, 1.28)
Stroke				
Other comorbidities	0.98 (0.88, 1.08)	1.06 (0.95, 1.18)	1.09 (0.96, 1.22)	0.93 (0.87, 1.00)
Hypertension	0.64 (0.59, 0.70)	0.73 (0.67, 0.79)	0.83 (0.76, 0.90)	0.75 (0.71, 0.79)
Lipidemia	1.03 (0.84, 1.26)	0.73 (0.60, 0.88)	0.77 (0.65, 0.92)	0.84 (0.75, 0.94)
Obesity	0.92 (0.84, 1.01)	0.88 (0.80, 0.96)	0.96 (0.87, 1.06)	0.98 (0.93, 1.04)
Arthritis				

continued

Table 3. *Continued*

	Stage 1*	Stage 2	Stage 3*	Stage 4*
Charlson index	1.01 (0.98, 1.04)	1.00 (0.97, 1.02)	1.05 (1.02, 1.08)	1.03 (1.01, 1.04)
Alzheimer's and other dementia	1.45 (1.25, 1.69)	1.27 (1.11, 1.44)	1.26 (1.12, 1.42)	1.33 (1.25, 1.43)
Demographic characteristics				
Black	2.03 (1.84, 2.23)	1.89 (1.69, 2.10)	1.64 (1.48, 1.81)	1.63 (1.54, 1.73)
Other race	1.12 (0.94, 1.34)	1.09 (0.91, 1.32)	0.79 (0.64, 0.97)	1.05 (0.95, 1.17)
Male	1.79 (1.65, 1.95)	1.75 (1.61, 1.89)	1.67 (1.52, 1.83)	1.49 (1.42, 1.56)
Baseline age	1.01 (1.00, 1.02)	1.00 (1.00, 1.01)	1.01 (1.00, 1.01)	1.02 (1.01, 1.02)
Residuals				
Residual—saw a podiatrist	0.51 (0.26, 1.01)		1.41 (0.44, 4.58)	2.03 (0.94, 4.39)
Residual—saw an LEC specialist	1.13 (0.76, 1.70)		0.46 (0.17, 1.26)	0.54 (0.30, 0.97)
Residual—saw a podiatrist and an LEC specialist	2.33 (1.33, 4.09)		2.27 (0.87, 5.95)	2.39 (1.35, 4.22)
Residual—did not see a study HP	1.33 (0.68, 2.59)		1.54 (0.19, 12.49)	0.86 (0.28, 2.63)
Quartile of spending on non study health professionals				
Second	0.88 (0.79, 0.97)	0.83 (0.74, 0.94)	0.99 (0.87, 1.13)	0.80 (0.74, 0.86)
Third	0.90 (0.80, 1.01)	0.86 (0.76, 0.97)	0.85 (0.74, 0.96)	0.82 (0.76, 0.88)
Fourth	0.95 (0.84, 1.08)	0.88 (0.78, 1.01)	0.88 (0.77, 1.00)	0.87 (0.80, 0.94)

Note. Bold type denotes p value < 0.05.

*Specification included residuals.

disease diagnosed from an inpatient claim, chronic heart failure, occlusion/stenosis of a cerebral artery, stroke, and Alzheimer's or other dementia tended to increase the hazard of an LEC amputation. Blacks, males, and older individuals were more likely to have an LEC amputation. Some of the other diagnoses were associated with a lower hazard of amputation. But for these diagnoses, especially lipidemia, the favorable results may reflect the treatment for the diagnoses, for example, use of statins, rather than the diagnosis itself. Individuals incurring higher Medicare expenditures from health professionals besides podiatrists, LEC specialists, and "other health professionals" were generally less likely to have an amputation.

DISCUSSION

About half of Medicare beneficiaries diagnosed with a LEC of diabetes died during the 6-year follow-up. The hazard of a first amputation of part or all of a foot or leg was far lower than for mortality, but it was appreciably higher for persons who entered the analysis with a Stage 4 diagnosis—osteomyelitis or gangrene—than for persons at less advanced stages.

The main study question was whether care oriented to treatment of lower extremity complications is productive as measured by reduced rates of first lower extremity amputations. The results were most favorable to a pattern of care involving a combination of podiatrists and lower extremity specialists; the latter group included general surgeons, orthopedic surgeons, diagnostic radiologists, and depending on the stage, dermatologists, neurologists, physical medicine, and rehabilitation specialists, physical therapists, infectious disease specialists, and plastic and reconstructive surgeons. That this combination was especially productive in terms of preventing or forestalling LEC amputations was particularly evident after we accounted for endogeneity of LEC care receipt.

Survival should primarily reflect success in patient diabetes control rather than control of LEC in particular. Yet each patient encounter with a health professional *potentially* contributes to improved general diabetes control. Mortality rates increased with increasing severity of the LEC, with over 64 percent of those with a Stage 4 LEC dying within 6 years of diagnosis.

Previous literature has suggested podiatric care, foot education programs, and multidisciplinary care for individuals with DM-related LECs lead to better LEC outcomes. One study, examining the effect of podiatrist care on callosities, found that the podiatrist group had a lower prevalence and reduced

size of calluses compared with individuals only receiving written instructions for foot care (Ronnemaa et al. 1997). Persons under 50 experienced a greater reduction in callosities. Our study expands on these results, demonstrating that podiatric intervention is effective in an elderly cohort.

We found an even stronger association between visits to a podiatrist and an LEC specialist and lower amputation rates. Previous studies examining multidisciplinary disease management programs were limited to single community settings or randomized, controlled trials with shorter follow-up periods than ours (Litzelman et al. 1993; Patout et al. 2000; Lavery, Wunderlich, and Tredwell 2005; Trautner et al. 2007; Canavan et al. 2008; Hedetoft et al. 2009). These studies documented falling rates of diabetes-related lower extremity amputations after entering community-based podiatric services. Other services provided in these community-based clinics included educational programs (Litzelman et al. 1993; Patout et al. 2000), access to podorthotists (Patout et al. 2000; Lavery, Wunderlich, and Tredwell 2005), DM specialists, orthopedic surgeons (Trautner et al. 2007; Hedetoft et al. 2009), and vascular surgeons (Trautner et al. 2007).

Individuals receiving care from both podiatrists and LEC specialists in the year before all stage diagnoses were much less likely to undergo a lower extremity amputation. Receiving care from multiple specialists may have allowed for a more coordinated care.

Our study has several strengths. The sample is representative of the U.S. elderly population with a DM diagnosis. The follow-up period extended for 6 years. We used a technique to account for the potential endogeneity of receipt of care. We studied the most severe LEC complication, amputation, and accounted for other DM complications in our analysis of the hazard of amputation.

We acknowledge the following limitations. First, we used observational data from Medicare records. Medicare claims data are designed for administrative purposes, not for comparative effectiveness analysis.

Second, many studies have used patient and provider education programs as an intervention measure. Our analysis did not permit this type of comparison. Third, health care provider variables were defined for care received during the year before the diagnosis of an LEC stage. Care patterns may have changed subsequently in ways that our analysis did not capture. Fourth, although we included many covariates and adjusted for endogeneity, we could not completely account for patients' differences in case mix, differences that could have been apparent to both patients and providers but are not observable to researchers.

While randomized controlled trials and other studies have demonstrated the positive impact of educational programs and other interventions on amputation rates in more limited settings, we found that, in a large Medicare sample, coordinated care between podiatrists and LEC specialists substantially reduced amputation rates compared with care only provided by other health professionals, while care provided by podiatrists alone was also highly protective of undergoing amputation in those with severe LECs.

Additional research should be conducted on care coordination and LEC outcomes, in particular whether actual coordinated care improves LEC outcomes. Our analysis just accounted for the presence of Medicare claims from particular types of providers during a year. Specific practice arrangements and financial incentives may improve care coordination and thus health outcomes. More should also be learned about the patient's role in a diabetes diagnosis and his/her role—both positive and normative—in coordinating care for this complex and highly prevalent disease.

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Disclaimers: None.

NOTES

1. Because endocrinologists are more involved in DM control than in treating LEC complications, we included them in the “other health professional” category rather than the LEC category.
2. Cardiologists were not study physician specialists if they were not listed as internists; however, we included measures of heart disease as covariates. We did not include cardiologists because they would most likely not have treated lower extremity complications.
3. 404.12, 404.13, 404.92, 404.93, 403.01, 403.11, 585.xx, 586.xx.
4. 50340, 50360, 50365, V42.0, V56.0, V45.1, V56.8, 39.27, 39.42, 39.43, 39.49, 39.50, 39.53, 39.93, 39.94, 90921, 90935, 90937, 90940, 90989, 90993, 90997, 90999, 93990.
5. 428.0, 428.1, 428.9, 428.2x, 428.3x, 428.4x, 398.91, 402.01, 402.11, 402.91, 404.01, 404.11, 404.91.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Figure S1. Kaplan–Meier Survival Curve—Time to Amputation.

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