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An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds

Samuel R. Nussbaum, MD¹, Marissa J. Carter, PhD, MA², Caroline E. Fife, MD^{3,4,5},
Joan DaVanzo, PhD, MSW⁶, Randall Haught⁶, Marcia Nusgart, RPh^{7,*}, Donna Cartwright, MPA⁸

¹Schaeffer Center for Health Policy and Economics, University of Southern California, Los Angeles, CA, USA; ²Strategic Solutions, Inc., Cody, WY, USA; ³Baylor College of Medicine, Houston, TX, USA; ⁴CHI St. Lukes Hospital, The Woodlands, TX, USA; ⁵The US Wound Registry, The Woodlands, TX, USA; ⁶Dobson/DaVanzo & Associates LLC, Vienna, VA, USA; ⁷Alliance of Wound Care Stakeholders, Bethesda, MD, USA; ⁸Integra Lifesciences, Plainsboro, NJ, USA

ABSTRACT

Objective: The aim of this study was to determine the cost of chronic wound care for Medicare beneficiaries in aggregate, by wound type and by setting. **Methods:** This retrospective analysis of the Medicare 5% Limited Data Set for calendar year 2014 included beneficiaries who experienced episodes of care for one or more of the following: arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections. The main outcomes were the prevalence of each wound type, Medicare expenditure for each wound type and aggregate, and expenditure by type of service. **Results:** Nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound or infection (not pneumonia). Surgical infections were the largest prevalence category (4.0%), followed by diabetic infections (3.4%). Total Medicare spending estimates for all wound types ranged from \$28.1 to \$96.8 billion. Including infection costs, the most expensive estimates were for surgical wounds (\$11.7, \$13.1, and \$38.3 billion), followed by

diabetic foot ulcers (\$6.2, \$6.9, and \$18.7 billion). The highest cost estimates in regard to site of service were for hospital outpatients (\$9.9–\$35.8 billion), followed by hospital inpatients (\$5.0–\$24.3 billion). **Conclusions:** Medicare expenditures related to wound care are far greater than previously recognized, with care occurring largely in outpatient settings. The data could be used to develop more appropriate quality measures and reimbursement models, which are needed for better health outcomes and smarter spending for this growing population.

Keywords: Medicare 5% Limited Data Set, Medicare spending, prevalence of wounds, wound care.

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The true cost of wound care, including chronic wounds, such as venous leg ulcers, diabetic foot ulcers, and pressure ulcers, remains unknown for the national population of the United States [1]. This is also true for subgroups, such as Medicare beneficiaries.

A rough prevalence rate for chronic nonhealing wounds in developed countries is 1% to 2% of the general population [2,3], similar to the prevalence rate for heart failure [4]. Unlike heart failure, the morbidity and associated costs of chronic wounds, including amputation and death, have been largely ignored from a public policy standpoint in the United States, perhaps because no specific medical specialty is clearly responsible. Nonhealing wounds are likely to be older adults, nonambulatory or paralyzed, unable to provide self-care, and/or suffering from dementia. Their ulcers may occur as a result of unique medical conditions (e.g., sickle cell anemia, vasculitis) [5,6]; in association with immunosuppression (e.g., steroid use) [7,8], renal impairment (e.g., calciphylaxis) [9],

autoimmune diseases (e.g., systemic lupus erythematosus), dermatologic diseases (e.g., epidermolysis bullosa), and age-related debility or paralysis (which can lead to pressure ulcers) [10,11]; result from peripheral neuropathy (e.g., diabetes); and occur in patients with peripheral arterial and venous disease (e.g., arterial and venous ulcers). From an International Classification of Diseases 9 (ICD-9) coding perspective, these cutaneous lesions are divided into “ulcers”—related to an underlying chronic disease—and “wounds” resulting from physical trauma or surgical intervention. We use the term “wound” to encompass both meanings.

Traditionally, wound care procedures were done in the hospital setting, but like many chronic, complex conditions, nonhealing wounds have been usually treated in the outpatient setting since 2000, when the Centers for Medicare and Medicaid Services (CMS) created the hospital-based outpatient payment system with the goal of providing care in complex cases where patients did not require hospitalization. Approximately 1500

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* Address correspondence to: Marcia Nusgart, 5225 Pooks Hill Road, Suite 627 south, Bethesda, MD 20814, USA.

E-mail: marcia@woundcarestakeholders.org.

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specialized hospital-based outpatient “wound centers” across the United States provide standard wound care treatment, as well as numerous therapeutic treatments. Additionally, wound care is provided in patients’ homes by home health services and in skilled nursing facilities (SNFs). We postulated that CMS’s current methods for allocating resource use fails to identify the financial burden of chronic wounds because the majority of their costs accrue from outpatient services rather than sentinel inpatient events. As a result, the prevalence and the financial burden of chronic nonhealing wounds are not fully appreciated by Medicare policy leaders. Therefore, the goal of this study was to determine the cost of chronic wound care for Medicare beneficiaries in aggregate, by wound type and by setting.

Materials and Methods

Database

The database used for this analysis was the Medicare 5% Limited Data Set for calendar year 2014, and all costs were evaluated for that 1-year timeframe and calculated in 2014 US dollars. Medicare beneficiaries included in the analysis were those enrolled in Medicare Part A or B any time during the year and not enrolled in a managed care plan.

To ensure that we captured the entirety of diagnostic, procedural, and evaluation and management (E/M) codes used in outpatient wound care services, we harnessed the US Wound Registry (USWR). The USWR is a Qualified Clinical Data Registry that collects clinical data from approximately 2,000 wound care clinicians to satisfy the requirements of programs such as the Physician Quality Reporting System, Meaningful Use, and now the Merit Based Incentive Payment System. Participating in the USWR are 129 hospital-based outpatient wound centers in 32 states using an EHR specifically designed for wound care. This EHR internally audits the structured language within the chart to ensure accurate billing of both physician and hospital outpatient charges and transmits data to the USWR for benchmarking. Using this repository, a detailed list of all ICD-9 Clinical Modification (CM) codes with their long descriptors was created, as well as all Common Procedural

Terminology codes, and all E/M codes used in the delivery of outpatient wound care. The master list was reviewed by two authors (Author 3, Author 7) to remove any nonvalid codes, leaving a total of 1814 ICD-9-CM codes and 196 Common Procedural Terminology codes. The diagnosis codes were organized into 12 broad wound categories ([Supplemental Table 1](#)): arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, and venous infections. This list of codes was then applied to the Medicare Limited Data Set.

Determining the Prevalence of Wounds in the Medicare Population

To determine the number of beneficiaries with each type of wound, we searched the primary and up to 24 secondary diagnosis codes (ICD-9) on all Medicare claims data for inpatient and outpatient hospital, SNF, home health agency (HHA), and hospice services. For Medicare Part B Carrier and durable medical equipment claims, we used the specific line level diagnosis codes to identify specific services for wound care.

For each beneficiary, we compiled claims across all the types of services to determine the presence of each wound type. Because beneficiaries could have multiple wounds during the year, we created an overall category that counts the number of beneficiaries with any wound type, and we did not double count beneficiaries with multiple wound types. Prevalence rates were computed as the number of beneficiaries receiving wound care during the year divided by the total number of beneficiaries in the sample. Prevalence rates were calculated by age group (< 65, 65–74, and ≥ 75 years), gender, and type of wound.

Determining Medicare Spending Associated with Wound Care

In most sites of care, Medicare reimburses providers for an episode of care (e.g., an entire hospital stay) during which time multiple diagnoses are identified for a beneficiary. However, it is difficult to determine what portion of the payment is attributable to each of the patient’s conditions. Therefore, a methodology must be developed which allows payment to be apportioned among the diagnoses. Previous cost-of-illness studies attribute the total cost of a

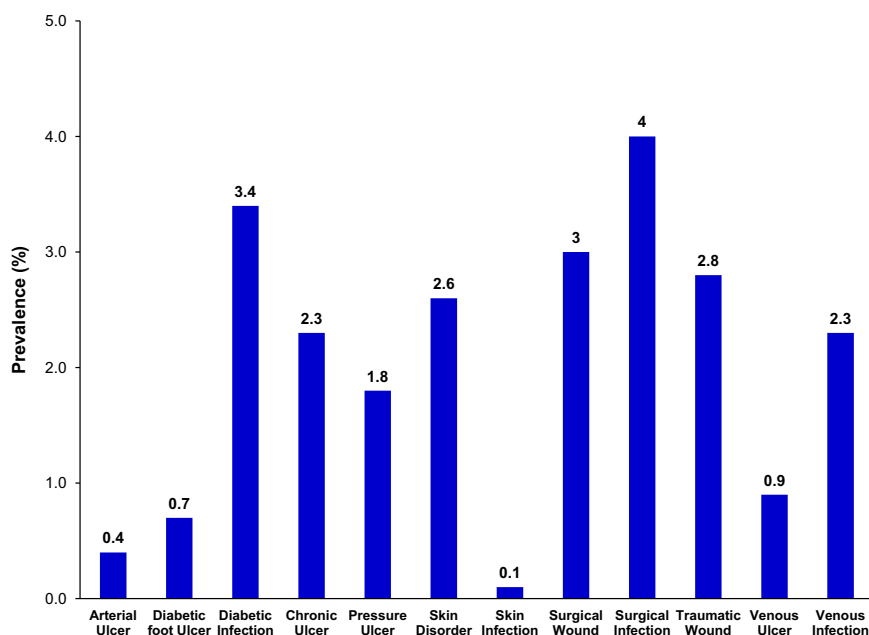


Fig. 1 – Prevalence of wound types in the Medicare population based on 2014 claims data.

service to the principal diagnosis only [12], or a portion of the cost or payment to secondary diagnoses that were the underlying cause of the primary diagnosis or were complicating factors to the primary diagnosis [13]. For this analysis, we employed three different estimates for the cost of wound care. The first method (low-range estimate) counted only Medicare provider payments when a wound was the primary diagnosis on the claim, excluding beneficiary deductible and co-insurance. The second method (midrange estimate) attributed the entire payment of a claim to wound care if a wound diagnosis was the primary diagnosis. However, the following methodology for attribution was incorporated when a wound was a secondary diagnosis:

(a) Hospital inpatient, SNF, HHA, and hospice: Each secondary diagnosis had equal weight and was attributed half of the total cost of the stay. For example, if there were 10 secondary diagnoses and one was a wound, then the wound was attributed $1/10 \times 50\%$ of the total claim payment.

(b) Hospital outpatient: All revenue center-specific wound care service payments were 100% attributed to wound care. The remaining amount (total payment – direct wound care payments) were attributed assuming each secondary diagnosis had equal weight and were attributed half of the remaining amount. These were based on specific Healthcare Common Procedure Coding System codes associated with wound care. We assumed the cost of these services were 100% related to the cost of a wound only if a wound diagnosis was also found on the claim.

(c) Part B carrier and DME (durable medical equipment): At the procedure line level, Medicare provider payments were counted if the Healthcare Common Procedure Coding System code or the line level diagnosis code was associated with wound care.

The third method counted Medicare provider payments when a wound was either the primary or secondary diagnosis and provided an upper bound estimate to total spending associated with wound care assuming the wound was always the underlying cause of the service.

Total Medicare spending estimates were extrapolated from the 5% sample to the entire Medicare fee-for-service (FFS) population by multiplying each cost by 20. To estimate the spending attributable to wound care in the Medicare Advantage (MA) population, it was assumed that wound care spending in MA plans was proportional to FFS and that total Medicare payments to MA plans was equal to 28% of Medicare FFS spending based on Congressional Budget Office March 2016 Medicare baseline estimates [14].

Results

About 14.5% of Medicare beneficiaries (8.2 million patients) were diagnosed in 2014 with at least one type of wound or wound-related infection. In this overall “snapshot” of prevalence, surgical wound infections were the largest category (4.0%), followed by diabetic wound infections (3.4%) (e.g., abscesses, cellulitis), and nonhealing surgical wounds (3.0%); the prevalence of other wound types was 0.1% to 2.7% (Fig. 1). When prevalence of wound types was categorized by gender and age group, there was no particular pattern by sex, but beneficiaries 75 years or older nearly always had the highest prevalence (Table 1).

Total Medicare spending estimates for all wound types were \$28.1 billion under the low-range estimate, \$31.7 billion under the midrange estimate, and \$96.8 billion under the upper-bound estimate. When spending was combined for each wound type (i.e., wound type + infection), the most expensive estimates were for surgical wounds (\$11.7, \$13.1, and \$38.3 billion, for the same estimates) followed by diabetic foot ulcers (\$6.2, \$6.9, and \$18.7 billion); the least wound costs were incurred for venous wounds (\$0.72, \$0.78, and \$1.5 billion) (Table 2). On an individual basis,

Table 1 – Prevalence of wounds (%) in the Medicare population in 2014 by type of wound and beneficiary demographics*.

Beneficiary demographics	Venous (Infections)	Pressure ulcer	Chronic ulcer	Surgical wounds (Infections)	Skin disorders (Infections)	Traumatic wounds	Arterial ulcer	Diabetic foot ulcer (Infections)	All wounds
Male									
< 65 years	0.6 (2.3)	1.4	2.2	3.5 (4.4)	1.7 (0.03)	2.6	0.4	1.1 (3.2)	12.5
65–74 years	0.6 (1.6)	0.9	1.5	2.6 (3.1)	2.1 (0.05)	2.0	0.3	0.7 (2.4)	11.0
≥ 75 years	1.3 (3.0)	3.3	3.5	3.8 (4.8)	3.5 (0.13)	4.1	0.7	1.0 (4.6)	19.6
Female									
< 65 years	0.6 (2.3)	1.1	1.6	3.4 (5.0)	2.4 (0.04)	2.4	0.3	0.7 (3.1)	13.4
65–74 years	0.8 (1.7)	0.9	1.4	2.5 (3.3)	2.5 (0.05)	1.8	0.2	0.4 (2.5)	11.7
≥ 75 years	1.4 (3.2)	3.6	3.7	3.1 (4.6)	3.4 (0.08)	3.9	0.6	0.7 (5.1)	19.7
All Medicare beneficiaries	0.9 (2.3)	1.8	2.3	3.0 (4.0)	2.6 (0.07)	2.7	0.4	0.7 (3.4)	14.5

* Figures in parentheses represent prevalence of infections for types of wounds. Beneficiaries with multiple types of wounds are counted in each group.

Table 2 – Medicare spending for wound care in 2014 by wound type, in millions of U.S. dollars^a.

Wound type	Principal diagnosis	Principal diagnosis and attributed portion as secondary	Principal diagnosis or any secondary
Arterial ulcers	2085.0	2156.7	3107.7
Chronic ulcers	1420.7	1,772.2	6438.5
Diabetic foot ulcers	631.4 (6,178.0)	880.7 (6,933.6)	4499.9 (18,743.6)
Pressure ulcer	3870.2	4,644.5	22,050.1
Skin disorders	773.3 (786.1)	922.9 (936.2)	3225.6 (3,243.0)
Surgical wounds	5775.6 (11,714.4)	6699.0 (13,063.7)	24,300.1 (38,319.4)
Traumatic wounds	1292.3	1430.6	3411.4
Venous	569.0 (715.7)	605.6 (778.7)	1,027.1 (1,500.0)
Diabetes infections	5546.6	6052.9	14,243.7
Skin infections	12.8	13.3	17.4
Surgical infections	5938.8	6364.7	14,019.3
Venous infections	146.7	173.1	472.9
Total all wounds	28,062.1	31,716.1	96,813.8

^a Figures in parentheses represent total costs for types of wounds when cost of infections is included.

mean Medicare spending per wound was \$3415, \$3859, and \$11,781 for the same estimates (Table 3). The most expensive wounds were arterial ulcers (\$9105, \$9418, and \$13,571) followed by pressure ulcers (\$3696, \$4436, and \$21,060). The least expensive wounds were skin infections (\$346, \$359, and \$470, respectively).

Medicare spending for wound care by type of service was highest for hospital outpatients with \$9.9, \$11.3, and \$35.8 billion for the three estimates, respectively (Table 4). Hospital inpatient expenditures were about half the hospital outpatient costs. Although hospice care was the smallest for the low estimate, this category showed the highest ratio of any service type between low and upper bound estimates (\$4.3 million vs \$207.5 million, respectively). HHA low estimates were more than twice as high as that of SNF (\$1.5 billion vs \$700 million), but upper-bound estimates were similar at approximately \$3.3 billion.

Discussion

This is the first comprehensive study of Medicare spending on wound care. The bottom line is compelling: Wounds impact nearly 15% of Medicare beneficiaries (8.2 million patients), and a conservative estimate of their annual cost is \$28 billion. If we

include wounds as a secondary diagnosis, the cost for wounds may range from \$31.7 billion to \$96.8 billion. Consequently, any national estimate of wound care, which would include individuals not in the Medicare programs, would significantly exceed these Medicare expenditures.

Estimates of chronic wound prevalence in the United States are subject to considerable uncertainty. For example, the often-quoted figure of 6.5 million individuals having chronic wounds actually originates from a marketing report produced by Medical Data International in August 1997 [15–17]. Margolis et al. estimated that the prevalence of diabetic foot ulcers among Medicare beneficiaries with diabetes is about 8% [18]. Assuming a prevalence of diabetes in this population of 28% [19], this would equate to 2.2% for the entire Medicare population. This is similar to our reported prevalence of 0.7% for diabetic foot ulcer and 3.4% for diabetic infections, given the overlapping population in our study between these two categories. Comparisons with previous Medicare studies of the cost of diabetic foot ulcers are difficult. In their 1995 Medicare study, Harrington et al. reported that cost of treating beneficiaries with lower extremity diabetic ulcers was \$1.5 billion [20]. Inflating this cost to 2014 US dollars using the Consumer Price Index results in \$2.2 billion [21]. Given that the Medicare population has grown by 43.6% [22], this would indicate expenditures of \$3.2 billion, if the Harrington study had been

Table 3 – Medicare spending for wound care per beneficiary (mean values) in 2014 by wound type, in U.S. dollars.

Wound type	Principal diagnosis	Principal diagnosis and attributed portion as secondary	Principal diagnosis or any secondary
Arterial ulcer	9105	9418	13,571
Chronic ulcer	1104	1377	5003
Diabetic foot ulcer	1555	2169	11,083
Diabetic infections	2846	3106	7308
Pressure ulcer	3696	4436	21,060
Skin disorders	514	614	2145
Skin infections	346	359	470
Surgical wounds	3364	3902	14,153
Surgical infections	2604	2790	6585
Traumatic wounds	830	919	2191
Venous	1138	1211	2054
Venous infections	114	134	366
Total all wounds	3415	3859	11,781

Table 4 – Medicare spending for wound care by type of service in 2014 by wound type, in U.S. millions of dollars.

Type of service	Principal diagnosis	Principal diagnosis and attributed portion as secondary	Principal diagnosis or any secondary
Hospital inpatient	4990.8	5798.4	24,308.5
SNF	700.7	895.3	3371.5
HHA	1527.7	1703.0	3298.3
Hospice	4.3	28.1	207.5
Hospital outpatient	9927.8	11,374.4	35,785.6
Part B carrier	2867.5	2867.5	2867.5
DME	316.1	316.1	316.1
Total Medicare FFS	20,334.9	22,982.7	70,154.9
Estimated MA spending	7727.2	8733.4	26,658.9
Total FFS and MA	28,062.1	31,716.1	96,813.8

DME, durable medical equipment; FFS, fee for service; HHA, home health agency; MA, Medicare Advantage; SNF, skilled nursing facility.

carried out in 2014. Even accepting the methodologic differences between the Harrington study and ours, we estimate the cost of diabetic foot ulcers at twice their figure and possibly three times greater, suggesting that the cost of treating diabetic foot ulcers has vastly increased in the last 20 years, as has the prevalence of diabetes.

Rice et al. determined that the mean annual incidence rate of venous leg ulcers in the Medicare population was 2.2% [23]. Although differences in methodologies exist between the studies, our snapshot prevalence of venous ulcers and infections (0.9% and 2.3%, respectively) suggests a comparable incidence. The calculated cost of care on an individual basis for the Rice study of \$6391 is quite different from our estimates (\$1252–2420) because we did not estimate costs of all care. However, the comparison does suggest that in the Rice study, cost of care attributable to venous ulcers is at least a fifth of total care.

Neither the overall prevalence of pressure ulcers nor their cost of care in the Medicare population is known, largely because research has focused on hospital and long-term care settings. In 2011, the Agency for Healthcare Research and Quality reported that 2.5 million patients had pressure ulcers, which equates roughly to a prevalence of 0.8% in the general population, with attendant costs of \$9.1 billion to \$11.6 billion [24]. This is slightly less than half the prevalence we found in the Medicare population. Based on the cost of care reported by the Agency for Healthcare Research and Quality, the true costs for pressure ulcers in the Medicare population may lie between the midrange and upper-bound estimates. Previous efforts to understand wound care costs have assumed the primary cost drivers to be pressure ulcers, diabetic foot ulcers, and vascular-related leg ulcers. Surprisingly, our data suggest that the most costly category of nonhealing wounds is that related to surgical complications, including infection. This has important implications for the nation's clinical research priorities.

Currently, the CMS is proposing 41 episode-based measures within Medicare Access and CHIP Reauthorization Act of 2015 for care areas including cardiovascular system, gastrointestinal system, and neurology. None of them encompasses wound care, and all are predicated on an inpatient hospital event. The construction of these episode groups reveals two important misconceptions. The first is that chronic nonhealing wounds represent a less significant burden to the Medicare trust fund compared with other conditions, and the second is that the primary driver of cost is the hospital inpatient stay. Our data dispute both assertions. Not only does chronic wound care represent a large portion of the Medicare budget, but our data suggest there has been a major shift of costs from hospital inpatient to outpatient settings. For example, Harrington et al. [20] reported that 73.7% of

expenditures were related to inpatient service for diabetic ulcers. For the same kind of wound, we estimate that hospital outpatient expenditures are the biggest driver at about 47% to 58%, with hospital inpatient expenditures of around 5% to 31% for diabetic foot ulcers and diabetic infections, respectively. The reason for this is understandable because inpatient costs are controlled by the hospital prospective payment system designed around diagnosis-related groups, and outpatient charges are determined by the Ambulatory Payment Classification system with no cap on spending over an episode of care.

A major strength of this study is the comprehensive inclusion of ICD-9 codes with regard to wound-related diagnoses. A major limitation is the challenge of relating charges specifically to the presence of a wound among patients with many comorbid diseases. This problem is magnified because there is no ICD-9 diagnosis code specific for a diabetic foot ulcer—we assumed that a patient with both a chronic ulcer and diabetes has a chronic ulcer *related to diabetes*. Furthermore, patients with a chronic ulcer, diabetes, and infection might not have an infection related to the chronic ulcer, hence our reason for using the methodology of upper-, mid-, and lower-bound estimates. Although our general approach to estimating costs is a strength, it also reflects the challenge to assigning percentages of bundled services to a particular wound problem. Although the second method of estimating costs provides a more inclusive estimate of total spending for wound care compared with the first method, we did not have information available to create a direct link between the wound as a secondary diagnosis and its relationship to the primary diagnosis. For a patient admitted to the hospital for acute ischemia (who also had at least one leg ulcer) and who underwent revascularization, the ulcer may be the underlying cause for the admission and should be attributed a larger portion of the cost of the hospital stay. Such direct relationships would attribute more of the cost of the service to the wound. In addition, more resources may be required by providers to treat wounds than the resources required for treating other secondary conditions. In general, estimating costs of wounds or chronic ulcers when they are a secondary diagnosis is always problematic and one not easily addressed without conducting much more analysis, and to that extent, this is a limitation of the study. Because of these issues, conservative spending estimates are more likely to be approximated using this second approach, particularly for inpatients. The different mechanics of diagnosis coding in the inpatient versus outpatient settings could provide support for the upper-bound estimate being accurate for outpatient costs. In the inpatient setting, hospital coders strive to maximize reimbursement for that episode of care by capturing all possible diagnoses and conditions, a practice that weakens the correlation

between cost and diagnoses. In contrast, in the outpatient setting, only primary and secondary diagnoses are typically captured, which are the specific reasons for outpatient treatment; consequently, the relationship between spending and specific diagnosis is closely correlated. Finally, there is no easy way to conduct any kind of sensitivity analysis with regard to the three methods employed, and this inability should be regarded as a study limitation.

Conclusions

The cost of wound care for Medicare beneficiaries is conservatively estimated at nearly \$32 billion, with the majority of costs accruing in various outpatient settings. The results of this study have important implications for CMS payment policies, such as the Medicare Access and CHIP Reauthorization Act. The data could also be used to develop more appropriate quality measures and reimbursement models, which are needed for better health outcomes and smarter spending for this growing population.

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Supplemental Materials

Supplemental material accompanying this article can be found in the online version at <http://dx.doi.org/10.1016/j.jval.2017.07.007> or, if a hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

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