Potential Economic Benefits of Lower-Extremity Amputation Prevention Strategies in Diabetes

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OBJECTIVE — To estimate the potential economic benefits of selected strategies from published literature—educational interventions, multidisciplinary clinics, and insurance coverage for therapeutic shoes—to reduce the incidence of lower-extremity amputation among individuals with diabetes.

RESEARCH DESIGN AND METHODS — We developed a model to estimate the expected incidence and associated costs of lower-extremity amputation in a hypothetical cohort of 10,000 people with diabetes. Prevention strategies were assumed to be targeted at individuals with a history of foot ulcer, and benefits were estimated over a period of 3 years.

RESULTS — The total potential economic benefits (discounted at 5%) of strategies to reduce amputation risk ranged from $2.0 to $3.0 million ($2,900 to $4,442 per person with a history of foot ulcer) over 3 years. Benefits were highest for educational interventions. Most benefits were found to accrue among individuals aged ≥70 years.

CONCLUSIONS — Strategies to reduce the risk of lower-extremity amputation may generate substantial economic benefits and should be a standard component of routine diabetes care. Benefits may best be achieved through a partnership of government, private payers, health care service providers and producers, and individuals with diabetes.

An estimated 16 million Americans suffer from diabetes; a total of 798,000 new cases were recorded in 1996 alone (1). It has been estimated that 5–15% of individuals with diabetes will undergo lower-extremity amputation during their lifetime (2). Approximately half of the 110,000 lower-extremity amputations performed in the U.S. each year are on individuals with diabetes (3,4). U.S.-based population studies report annual incidence rates of lower-extremity amputation ranging from 5.3 to 8.1 per 1,000 individuals with diabetes (2,5–7). In addition, 30–50% of first-time amputees will require additional amputations within 1–3 years (8), and 50% will die within 5 years of an initial major amputation (9–11).

One of the major risk factors for lower-extremity amputation is an antecedent foot ulcer. An estimated 15% of individuals with diabetes will develop foot ulcers, of which 15–20% are expected to require lower-extremity amputation (4). Of all diabetes-related amputations, 70–80% are preceded by chronic foot ulcers (5,12,13).

Estimates of the direct costs of lower-extremity amputation have been reported to range from $20,000 to $60,000 (14–18). It has been estimated that up to 50% of lower-extremity amputations could be prevented by modifying risk factors (e.g., neuropathy, smoking, glycemic control) and improving foot care among individuals with diabetes (11,19). Because of the high cost of amputations and their adverse effect on patients, it is not surprising that several attempts have been made to develop strategies to prevent amputation among individuals with diabetes. Literature-based effectiveness data are available for three such strategies: educational interventions for patients and providers, multidisciplinary clinics, and insurance coverage for therapeutic shoes.

Studies of educational interventions have reported reductions in the risk of lower-extremity amputation of between 50 and 85% (3,20–24). Additionally, multidisciplinary care has been shown to be effective in reducing the number of lower-extremity amputations among individuals with diabetes (25,26). Lastly, improperly fitting shoes may increase the risk of infection and foot ulcer among individuals with diabetes (27). Therapeutic shoes aid in preventing these conditions, by protecting feet with previous deformities or ulcers and preventing new trauma. Insurance coverage for therapeutic shoes has been associated with reductions in the rate of lower-extremity amputation among individuals with diabetes (28,29).

Given the significant economic and physical burden of lower-extremity amputation, the importance of a cost-effective and comprehensive diabetes disease management program targeted at reducing the incidence and cost of amputation cannot be underestimated. Accordingly, a series of analyses were undertaken to estimate the potential economic impact of the above-mentioned strategies targeted at the prevention of lower-extremity amputation. The perspective of a managed care organization was used, since the multidisciplinary practice settings and preventive focus typical of managed care providers are well suited to strategies of this nature.

RESEARCH DESIGN AND METHODS

Population

The population for this study was a hypothetical cohort of 10,000 individuals with

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diabetes. Assuming a prevalence rate of diabetes in the general U.S. population of 4%, this is approximately the number of individuals with diabetes that would be expected in a managed care plan with a total membership of 250,000. Because foot ulcers are a major precursor of lower-extremity amputation, it was assumed that all interventions to reduce amputation risk would be targeted at individuals with diabetes and a history of foot ulcer. A schematic of the model used to follow the cohort is presented in Fig. 1.

Estimation of economic benefits

Table 1 provides information on key parameters used in model estimation. Economic benefits were calculated as follows: assuming the hypothetical cohort would match the age distribution of individuals with diabetes in the U.S. general population, data from the 1991–1993 National Health Interview Survey (NHIS) were used to distribute the 10,000 individuals across several age-groups (i.e., 0–29, 30–39, 40–49, 50–59, 60–69, and ≥70 years) (30–32).

Next, assuming that interventions to prevent lower-extremity amputations would be aimed at individuals with diabetes and a history of foot ulcer, the number of such individuals over 3 years was estimated using population-based data on the percentage of individuals with a history of diabetic ulcer in each age-group of interest (33) along with age-specific mortality rates for individuals with diabetes (34). Individuals aged <40 years were excluded from the analysis because a history of foot ulcer is rare in this population (33).

The number of individuals with a history of foot ulcer who would be expected to undergo a first lower-extremity amputation each year was estimated assuming an annual incidence rate of 4.8%. This estimate was obtained using the midpoint of the reported range of the incidence of first lower-extremity amputation among individuals with diabetes (2,6,7), which was in turn multiplied by the relative risk (6.6) of first lower-extremity amputation among individuals with diabetes and a history of foot ulcer versus those without such a history (5). All levels of lower-extremity amputation (i.e., above-knee, below-knee, ankle, foot, and toe) were included in the calculation of risk of first amputation. Patients undergoing a first amputation in a given year were excluded from the at-risk population in subsequent years, since each of the preventive strategies of interest was

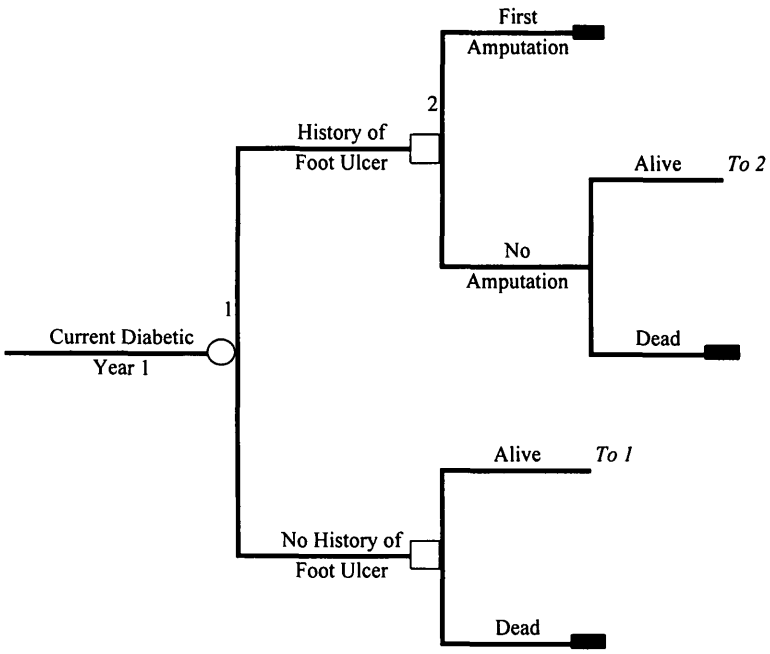

Figure 1—*Schematic diagram of first lower-extremity amputation prevention model.*

Table 1—***Model parameters used to estimate potential economic benefits of prevention of first lower-extremity amputation***

Parameter	Estimate	References
Age distribution (years)		30–32
0–39	10.0	
40–49	9.2	
50–59	18.9	
60–69	18.9	
70–79	26.3	
80+	16.7	
Mortality (years)		34
0–39	1.0	
40–49	1.0	
50–59	2.8	
60–69	2.8	
70–79	5.8	
80+	13.6	
History of foot ulcer (years)		33
0–39	0.0	
40–49	4.0	
50–59	2.9	
60–69	6.0	
70–79	8.8	
80+	14.0	
Annual incidence of first lower-extremity amputation	4.8	2,5–7
Cost of lower-extremity amputation ($)	48,152	14
Discount rate	5	
Percent of amputations averted by prevention		
Patient/provider education	72.0	24,25
Multidisciplinary clinic	47.0	3,20,31
Therapeutic shoe coverage	53.5	24,27,29

Data are %, unless otherwise indicated.

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Table 2—*Potential economic benefits of strategies to prevent lower-extremity amputation over a 3-year period in a hypothetical cohort of 10,000 individuals with diabetes*

	Individuals with diabetes	Individuals with history of foot ulcer	Cases of lower-extremity amputation	Expected cost per case ($)	Projected number of cases averted	Potential economic benefits (not discounted) ($)	Potential economic benefits (discounted at 5%) ($)
Education programs							
Year 1	10,000	679	32.7	48,152	23.6	1,134,654	1,134,654
Year 2	9,493	628	30.3	48,152	21.8	1,049,283	999,317
Year 3	9,018	582	28.1	48,152	20.2	972,813	882,370
Multidisciplinary clinics							
Year 1	10,000	679	32.7	48,152	15.4	740,677	740,677
Year 2	9,493	628	30.3	48,152	14.2	684,949	652,332
Year 3	9,018	582	28.1	48,152	13.2	635,031	575,992
Therapeutic shoe coverage							
Year 1	10,000	679	32.7	48,152	17.5	843,111	843,111
Year 2	9,493	628	30.3	48,152	16.2	779,676	742,548
Year 3	9,018	582	28.1	48,152	15.0	722,854	655,650

assumed to be targeted at individuals who had not yet undergone any amputation related to diabetes.

An average lifetime cost of all lower-extremity amputations of $48,152 (14) was used to estimate the cost per case of lower-extremity amputation. This estimate was inflated to 1996 dollars using the medical care services component of the Consumer Price Index.

Next, the estimated annual number of cases of first lower-extremity amputation averted with each prevention strategy was calculated using the midpoint of the range of risk reduction reported in the published literature, as follows: patient and provider education, 72% (24,25); multidisciplinary clinic care, 47% (3,20,35); and insurance coverage for therapeutic shoes, 53.5% (24,27,29). We assumed that all targeted individuals would participate in each prevention strategy. No synergy related to overlapping implementation of the three types of strategies was assumed, since the model was designed to measure the independent effects of each strategy.

Finally, the expected number of cases of first lower-extremity amputation averted was multiplied by the estimated average cost per case to calculate the expected potential economic benefits for each prevention strategy of interest. Potential benefits were estimated over a 3-year time frame; those benefits accruing in the 2nd and 3rd years were discounted by 5%. The costs of the interventions were not included in our estimates of economic benefit because of a paucity of available data.

Sensitivity analyses

Sensitivity analyses were undertaken to examine the robustness of estimates of economic benefits in relation to assumed changes in selected parameter estimates, including the risk of lower-extremity amputation among individuals with a history of foot ulcer, the cost of lower-extremity amputation, and the effectiveness of each strategy in reducing risk. The risk of lower-extremity amputation was between 4.0 and 5.4%, consistent with the range of risk reported in the literature. Cost per case was between 50 and 150% of the base-case estimate. Finally, the effectiveness of each strategy in reducing the risk of lower-extremity amputation was reduced by half.

RESULTS

Number of lower-extremity amputations

An estimated 679 individuals in the hypothetical cohort would be expected to have a history of foot ulcer during the 1st year (Table 2). This number would decline over years 2 and 3 because of mortality in the cohort. More than two-thirds of the individuals were aged >70 years (not shown).

The number of cases of lower-extremity amputation that would be expected to occur in the absence of intervention are 32.7, 30.3, and 28.1 for years 1, 2, and 3 respectively, or a total of 91 cases. Numbers of cases averted through educational interventions, multidisciplinary clinics, and insurance coverage for therapeutic shoes over the 3-year period are estimated to be 66, 43, and 49, respectively.

Potential economic benefits

Potential economic benefits for the 1st year are estimated to be ~$1.1 million for educational interventions, $750,000 for multidisciplinary clinics, and $850,000 for therapeutic shoe coverage (Table 2). Over 3 years, corresponding (discounted) potential economic benefits would total $3.0, $2.0, and $2.2 million. For each prevention strategy of interest, nearly 70% of total economic benefits would accrue among individuals ≥70 years of age (not shown).

Sensitivity analyses

Our results are fairly sensitive to assumed changes in the risk of lower-extremity amputation among individuals with a history of diabetic ulcer, the cost of lower-extremity amputation, and reductions in the risk of lower-extremity amputation. Table 3 displays the results of variation in the level of risk reduction for each intervention. Even when the rate of risk reduc-

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Table 3—*Sensitivity analysis of potential economic benefits over 3 years with respect to reduction in the risk of lower-extremity amputation*

Reduction in risk of lower-extremity amputation	Total cases of lower-extremity amputation	Cost per case ($)	Total number of cases averted	Total potential economic benefits (discounted at 5%) ($)
Education programs				
Base-case estimate (72%)	91.1	48,152	65.6	3,016,342
Low estimate (36%)	91.1	48,152	32.8	1,508,171
Multidisciplinary clinics				
Base-case estimate (47%)	91.1	48,152	42.8	1,969,001
Low estimate (23.5%)	91.1	48,152	21.4	984,500
Therapeutic shoe coverage				
Base-case estimate (53.5%)	91.1	48,152	48.7	2,241,310
Low estimate (26.8%)	91.1	48,152	24.4	1,122,749

tion is reduced by half, potential economic benefits still ranged from approximately $1.0 to $1.5 million over a 3-year period.

CONCLUSIONS — Our results suggest that, among individuals with diabetes at high risk for lower-extremity amputation, selected strategies to reduce the risk of amputation may result in improved quality of diabetes care, reduced risk of amputation, and substantial economic benefits for managed care organizations. In a population of 10,000 individuals with diabetes, 3-year potential savings are estimated to range from $2,900 to $4,442 per person with a history of foot ulcer. Corresponding total potential benefits would range from $2.0 to $3.0 million over 3 years. Approximately 70% of the benefits would accrue in individuals ≥70 years of age; therefore, managed care providers with significant Medicare enrollment may be best served by these strategies.

Our findings suggest that the highest economic benefit may be realized through the use of educational interventions. Educational interventions, which are often inexpensive to implement, may be effective in reducing the risk of lower-extremity amputation. Even when the rate of risk reduction for these interventions was reduced by half, estimated cost savings still totaled ~$1.5 million over 3 years. Litzelman et al. (3) identified several low-cost examples of educational interventions, including instructions to patients to remove their shoes and socks during routine physician visits to increase the rate of foot examination by providers, and instruction on daily foot care and self-examination via brochures or handouts.

Several limitations of this analysis should be noted. First, our estimates of economic benefit do not include the costs of intervention because of a paucity of available data. Even if such data were available, however, cost estimation would be complicated by variation in provider types and practice settings. Nevertheless, the costs of these strategies must be considered in any formal evaluation of their economic feasibility. At a minimum, the estimates of potential benefits per high-risk patient may serve as a guide to calculating a reasonable cost threshold for prevention strategies in a managed care setting.

We note, too, that published evidence of the effectiveness of strategies to prevent lower-extremity amputation, on which the calculations of economic benefits were based, is severely limited. Most of the studies cited were uncontrolled, nonrandomized, and/or retrospective; in addition, these studies reported benefits over multiple time frames. We also assumed that all individuals targeted by these interventions would be served by each strategy. In reality, participation rates for some interventions, particularly voluntary strategies, may be minimal; this in turn may diminish the effectiveness of each strategy substantially. For these reasons, our estimates of economic benefits and reductions in the risk of lower-extremity amputation should be interpreted with caution.

We also used estimates of the risk of first lower-extremity amputation from large surveillance studies (2,6,7), which may underestimate such a risk in certain ethnic groups known to be susceptible to amputation (e.g., Native Americans). In addition, our model focused solely on the risk of first amputation, despite the increased risk of multiple amputations among individuals with an initial amputation (14). Our interest, however, was in creating a simple straightforward model designed to provide generic estimates of the benefits of primary prevention (i.e., for nonamputees). Because we used population-wide risk estimates and focused on primary prevention only, we feel that our estimates of the risk of (and associated benefits of preventing) lower-extremity amputation are conservative.

There is also some uncertainty as to the generalizability of findings regarding the effectiveness of interventions among different populations and practice settings. It is unknown, for example, whether an educational program that is effective in an inner-city population would achieve similar results in a managed care setting. The generalizability of our results to other diabetic populations at high risk for foot ulcer and/or amputation (e.g., those with peripheral vascular disease and/or neuropathy) is also unclear.

Our analysis also did not incorporate estimates of turnover in managed care enrollment, which may be a significant issue for realization of economic benefits. In addition, while recent studies indicate that diabetic complications (including amputation) result in significant lifetime costs to the patient (36), we only consider costs accrued over 3 years. However, the 3-year time horizon used in these analyses matches the time frames used by many managed care organizations for program planning. From a managed care perspective, an amputation performed after the patient disenrolls is not a cost to the organization providing the intervention. There also is evidence that high turnover rates are less likely to be observed in elderly diabetic populations because of the need among individuals with diabetes for comprehensive benefits and long-standing provider relationships (American College of Physicians, unpublished observations). In addition, employment-related turnover would not be expected to be an issue among individuals aged ≥70 years. For these reasons, we consider our estimates to reflect the conservative planning process used by many managed care organizations.

Even if minimal effectiveness of these strategies is assumed upon implementation in a managed care setting, however, economic benefits may still be substantial; a strategy that prevents only 10% of first

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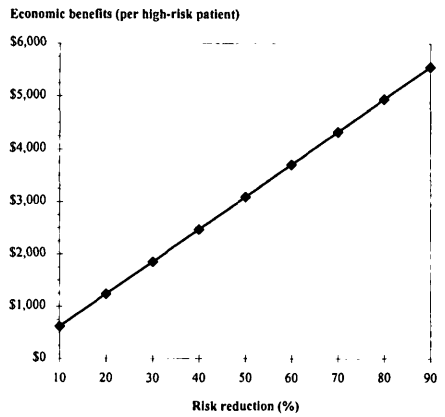

Figure 2—*Potential economic benefits per high-risk patient (discounted) over 3 years at defined levels of reduction in the risk of first lower-extremity amputation.*

lower-extremity amputations, for example, may still provide over $600 in savings per high-risk patient over 3 years (Fig. 2). Low-cost voluntary strategies such as educational handouts or brochures may, in fact, be the managed care organization's initial effort of choice; other, more comprehensive strategies may then be used after the benefits of the initial program are measured.

Our findings provide additional support for the benefits of preventive strategies targeted at reducing the rate of lower-extremity amputation among individuals with diabetes, although further study is necessary to evaluate these strategies across multiple populations and practice settings. Given the significant cost, morbidity, and mortality associated with lower-extremity amputation, we advocate the formation of a partnership between government, private payers, health care service providers and producers, and individuals with diabetes to establish amputation prevention strategies as standard components of routine diabetes care.

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