

Economic Value of the Prevention and Treatment of Diabetic Ulcers

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Summary

Foot ulcers are a significant problem in patients with diabetes. Prevention programs should be targeted to those patients identified in a managed care population with major risk factors for ulceration. To minimize overall costs, the treatment of ulcers should include advanced therapies in those patients likely to have a difficult healing process.

Key Points

- Diabetic ulcers are common, costly, easy to identify, and frequently recurrent but are preventable and treatable.
- Neuropathy, previous history of ulcer or amputation, and peripheral vascular disease are the most important risk factors for ulcer development in a patient with diabetes.
- Prevention programs should target patients with the major risk factors.
- An organized evidence based approach to prevention and treatment should be used.
- Patients with a history of poor healing, exposed tendon or bone, or large tissue defects should receive treatment with advanced products as a first line of therapy.

THE INCIDENCE OF FOOT WOUNDS IN patients with diabetes is 2 to 7 percent. Nine to 20 percent of these ulcers end in amputation. Twenty eight to 83 percent of patients will re-ulcerate within 12 months.^{1,2,3} Amputation rates are significantly higher in Mexican and African Americans compared with Caucasians (Exhibit 1).^{4,5} Men have twice the rate of amputations compared to women. Approximately half of all ulcers will become infected and about 20 percent will infect the bone adjacent to the ulcer.⁶⁻⁸ Infected wounds are the cause for 15 to 20 percent of diabetes-related hospital admissions.

Diabetic ulcers present an opportunity for disease management but have been ignored or inadequately addressed by health plans. Diabetic ulcers are common, costly, easy to identify, and frequently recurrent but are preventable and treatable. Diabetic foot ulcers are an orphaned issue because no one group of health professionals is responsible for the care. Care ends up being provided by whoever has the passion to deal with the issue in a particular community. This may be an internal medicine physician, orthopedic surgeon, vascular surgeon, nurse, physical therapist, or podiatrist. It may also be a multi-specialty effort. Groups that use a systematic, evidence-

based approach are likely to be the most effective.

Many times, administrators and even physicians are unaware that foot complications are avoidable or that tools for prevention exist. If a health plan has an ulcer prevention program, many times the wrong population of patients with diabetes is targeted. Not all patients with diabetes need ulcer prevention.

There are two disease management opportunities for managed care – prevention of ulcers and treatment of acute complications. The target population for prevention can be identified using risk factors for diabetic foot ulcers and amputation for risk stratification. Exhibit 2 lists the local and global risk factors.⁹ Of the local risk factors, neuropathy, previous history of ulcer or amputation, and peripheral vascular disease (PVD) are the most important. The local risk factors are better predictors of the target population for prevention interventions rather than global risk factors. Diabetic foot risk classification using local factors predicts outcomes (Exhibit 3).¹⁰ In one study, patients with PVD, ulcer history, or amputation history (20 percent of the population) accounted for 70 percent of the ulcers and amputations and 90 percent of the hospitalizations.¹⁰ Patients with diabetes and the three major predictive risk factors are the ones

Exhibit 1: Amputation Incidence in Blacks, Hispanics, Whites
(per 10,000 diabetics)

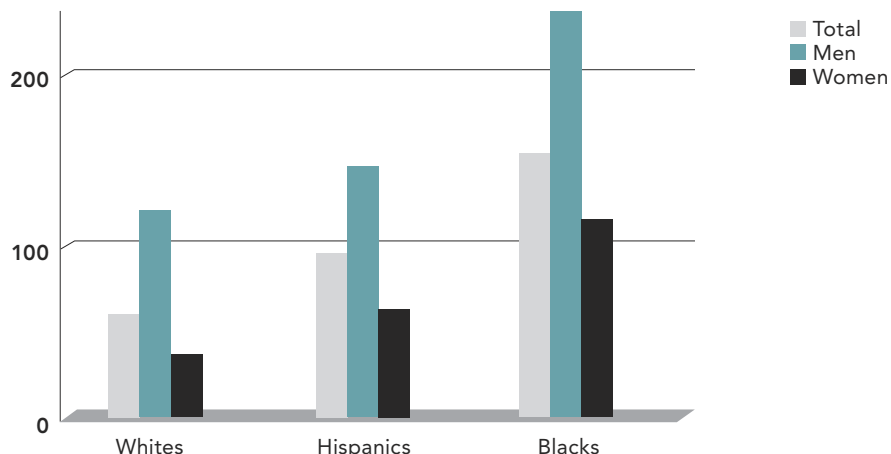


Exhibit 2: Risk Factors: Foot Ulcers - Amputations

Local Risk Factors	Global Risk Factors
History of ulcer-amputation	Male gender
Sensory Neuropathy	Diabetes > 10 years
PVD	Poor vision
Abnormal Biomechanics • limited joint mobility • structural deformity • plantar foot pressure	Increasing age
	Glycemic control >9%
	Nephropathy
	Retinopathy

who should be targeted for intervention. Patients with a history of ulcer or amputation can usually be readily identified from claims databases. It is more difficult to identify PVD or neuropathy because of coding differences or lack of coding.

Standard prevention of foot ulcers includes regular foot care, patient education, and therapeutic shoes and insoles. Exhibit 4 shows the interventions that are recommended for various risk categories. Regular podiatric care has been shown to reduce the number of deep and infected ulcers. Studies of multispecialty, high-risk foot programs show significant reductions in ulcerations, amputations, hospitalizations, and length of stay (Exhibit 5).¹¹⁻¹³

There are no good published data to indicate that

Exhibit 3: Diabetic Foot Risk Classification Incidence of Complications (yearly incidence)

N=1,666	Ulcer	Amputation	Hospitalization
1.No disease	2.0%	0	0
2.Neuropathy	4.5%	0	1.0%
3.Neuropathy + deformity	3.0%	0.7%	1.8%
4.PVD	13.8%	3.7%	15.9%
5.Ulcer history	31.7%	2.2%	8.2%
6. Amp history	32.2%	21.0%	50%

Exhibit 4: Treatment Recommendations based on Diabetic Foot Risk Classification

	Shoes-insoles	Others
Risk Group 0	None	Yearly evaluation
Risk Group 1 Neuropathy	Correctly fit shoes & OTC insoles	Education
Risk Group 2 PVD	Inlay depth OTC vs. custom	Intensive education, frequent care
Risk Group 3 History Pathology	Shoes +/- modifications Custom insole	+ Temperature monitoring

Exhibit 5: High Risk Foot Program Outcomes

Author	Journal	Outcomes
Patout	Diabetes Care 2000	49% ↓ ulceration 79% ↓ amputation 89% ↓ admissions
Cherry	Diabetes Tech Therap 2002	32% ↓ admissions 34% ↓ ER visits 49% ↓ outpatient visits
Lavery	Diabetes Research Clin Pract 2005	52% ↓ amputation 38% ↓ admissions 28% ↓ length of stay

70% ↓ in skilled nursing facility

education changes foot outcomes. A lot of the diabetic foot education involves self-care practices but patients may have difficulty doing this. Visual impairment, limited lower extremity joint mobility, and obesity can prevent the patient from examining and caring for his or her feet.¹⁴

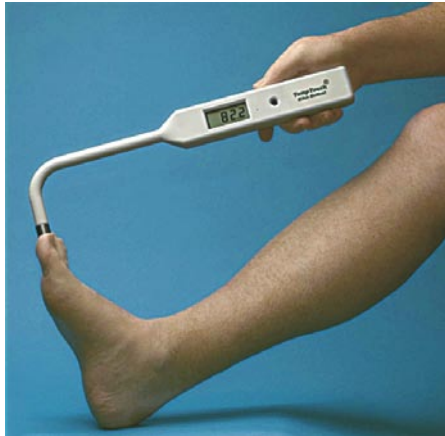
Therapeutic shoes can reduce ulceration rates but even when patients see podiatrists and have custom shoes they will have ulcers.³ Fewer than 3 percent of eligible patients receive therapeutic shoes or insoles. The process of getting these covered by Medicare is cumbersome and not well understood by primary care.

Some interesting products and processes for prevention are under study. Some include foot fat pad augmentation, computer generated shoes and insoles, computer activity monitors, shear-reducing insoles, and temperature monitoring. In a pilot study, the shear reducing insoles reduced shear forces significantly and reduced the incidence of ulceration.¹⁵ Temperature monitoring is a self-monitoring tool, like a glucose meter, that identifies areas

of inflammation at an early stage before tissue injury occurs (Exhibit 6). Studies with these devices have shown reduced risk of ulceration.^{16,17} A study on a temperature device that compared the device to visual inspection, found that visual inspection (with a mirror or by a family member) was not effective in identifying early damage. By the time the patient could identify damaged areas there was already ulceration. The patients in the temperature monitoring device group who did develop an ulcer were found to be noncompliant with monitoring greater than 50 percent of the time. The number needing treatment with home temperature monitoring to prevent an ulcer is 4 to 7 percent, which compares very favorably with preventative measures used in other diseases. The next generation of this device is a scale like device that scans the foot temperature and transmits data to a provider.

The prevention process for diabetic foot ulcers is low-tech. The time to realize effect is short and this is an overlooked opportunity in managed care. An

Exhibit 6: Temperature Monitoring Device



impact on clinical outcomes can be seen quickly. Approximately half of all ulcers could be prevented with someone paying attention to the patient's foot and prescribing therapeutic shoes and insoles.

Acute complications of diabetic foot ulcers can be expensive, thus treatment of these ulcers is an appropriate disease management target. There are groups of wound care specialists around the country that use evidence medicine to provide care. Man-

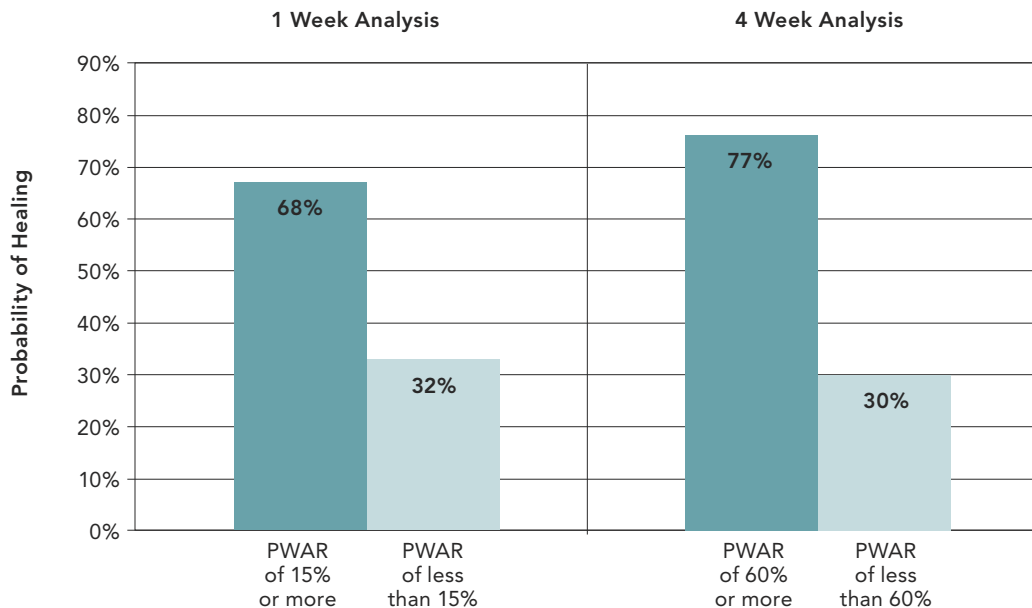
aged care plans should seek out these specialists for managing their most difficult patients.

There is a role for advanced products like negative pressure wound therapy in treating wounds. Patients with a history of poor healing, exposed tendon or bone, or large tissue defects should receive treatment with advanced products as a first line of therapy. Early response to therapy has been studied as a predictor of which patients will heal. Wound area reduction (15 percent or greater and 60 percent or greater at one and four weeks of therapy, respectively) is predictive of ulcer response at 16 weeks (Exhibit 7).¹⁰ One advanced therapy, negative pressure wound therapy with V.A.C., has been shown to increase the rate of complete skin closure, decrease the wound area, and decrease the number of secondary amputations.¹⁸ In addition, a cost analysis comparing V.A.C. with moist dressings found that overall costs were significantly reduced with V.A.C. therapy (Exhibit 8).¹⁹

Conclusion

The issue of diabetic foot ulcers is overlooked as a disease management opportunity. The prevention process is low-tech and the time to realize impact on clinical outcomes is short. Prevention programs should target patients with the major risk factors for ulceration - neuropathy, previous history of ulcer or amputation, and peripheral vascular disease. If

Exhibit 7: Percent Wound Area Reduction Predicts Healing



PWAR, percent wound area reduction

Exhibit 8: Average Treatment Cost per Procedure/Patient

Patient Group	Average Cost per Patient V.A.C.® Therapy	Average Cost per Patient MWT	Difference
Achieved Complete Healing	\$25,954	\$38,806	\$12,852
Patients Treated >8 wks	\$27,270	\$36,096	\$8,826
All Patients Treated	\$26,972	\$36,887	\$9,988

an ulcer occurs, treatment should include advanced therapies such as negative pressure wound therapy in those patients with poor healing, exposed tendon or bone, or large tissue defects. **JMCM**

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