

# Health Economic Implications for Wound Care and Limb Preservation

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## Summary

Ulcers and the subsequent consequences are costly to the health care system. Prevention of ulcers is important in all diabetic patients. Once an ulcer occurs, it must be treated quickly and aggressively to prevent amputation. One option for limb preservation is the use of negative pressure wound therapy to promote faster healing, get patients out of the hospital faster, and reduce overall costs.

## Key Points

- Every diabetic foot that becomes infected or requires amputation is a huge cost to the health care system.
- Early aggressive intervention of wounds is needed to prevent worsening of the wound and amputation.
- Amputation avoidance programs should include a risk stratification system allows quick access to care, aggressive management of ulcers and infections, a multidisciplinary care team, and a patient-centered education program for chronic patients.
- Calculating wound area reduction during the early weeks of therapy is a good benchmark for eventual wound healing.
- Compared with moist dressings, negative pressure wound therapy has been shown to heal wounds faster, reduce total length of hospitalization, and reduce total wound treatment costs.

HEALTH CARE PROVIDERS AND INSURERS need to be concerned about wound care and limb preservation because every 30 seconds a limb is lost somewhere in the world to diabetes. More than 100,000 amputations happened in the U.S. last year secondary to diabetics alone. Forty to 70 percent of all lower extremity amputations are related to diabetes.<sup>3,4</sup> The majority of amputations (85 percent) are preceded by foot ulcers. Fifteen percent of all patients with diabetes will develop an ulcer during their lifetime. Infected diabetic foot wounds account for up to 25 percent of all diabetes related hospital admissions.<sup>1,2</sup>

The U.S. ranks number one in the incidence of amputations per 1000 patients with diabetes.<sup>5</sup> One reason for this may be the availability of surgical expertise at virtually every hospital in the country. Unfortunately, wound care centers that aggressively treat wounds are not as widely available. Although the number of patients with diabetes is increasing, the amputation incidence decreased

from 1999 to 2003 (Exhibit 1).<sup>6</sup>

Exhibit 2 illustrates the causal factors leading to limb loss.<sup>7</sup> The most common factors that initiate the downward spiral to amputation are microtrauma, ulceration, and faulty wound healing. The major final triggers for an amputation are infection and gangrene. Between 49 percent and 85 percent of all amputations can be prevented.

Preventing amputations is important because of the consequences of this procedure. The five-year mortality rate after a diabetes-related lower leg amputation is high. One series found that at five years, only 25 percent of patients with diabetes who had a lower extremity amputation were still alive.<sup>8</sup>

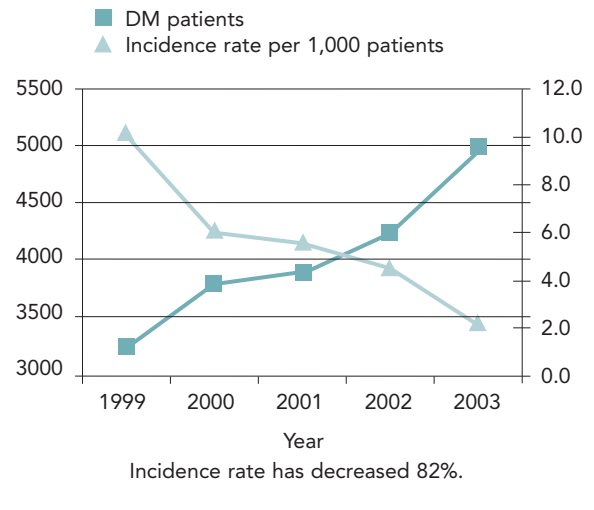
Every diabetic foot that becomes infected or requires amputation is a huge cost to the health care system. An uncomplicated diabetic foot ulcer is estimated to cost \$8,000 to treat. If the ulcer becomes infected, the costs increase to \$17,000. If an amputation is required to resolve the ulcer, the costs soar to \$45,000.<sup>9,10</sup> Lower-extremity ulcers cost the

Medicare system over \$1.5 billion annually.<sup>11</sup> Medicare expenditures for lower-extremity ulcer patients are on average 3 times higher than those for Medicare patients in general (\$15,309 vs. \$5,226).

With regard to the cost of chronic wound care, ulcer costs increase as wound severity increases.<sup>12</sup> Deeper wounds require more resource intensive care. Additionally, infected wounds cost more to treat than non-infected wounds.<sup>13</sup> Osteomyelitis is the most costly infectious event. Hospitalization accounts for the majority of healthcare costs in patients with lower extremity ulcers (70 percent to 80 percent).<sup>14</sup> An analysis of Medicare data showed the major contributors to cost of lower extremity ulcers is hospitalization (74 percent), outpatient care (10.9 percent), home health care (11.4 percent), and hospice care (4 percent).<sup>11</sup> Antibiotic costs are minor compared to care of infected wounds not properly treated initially. Treatment decisions should not be based upon antibiotic cost, but on the antimicrobial coverage and likely infecting organisms. Debridement, a cornerstone of wound care, is effective in preventing and managing infection, and improves wound closure.<sup>15</sup> It does not add considerably to the cost of care (\$7,104 vs. \$6,278 average yearly cost in patient receiving debridement vs. no debridement).<sup>11</sup> Early aggressive intervention of infected wounds with debridement and antibiotics will be most beneficial.

The goals in diabetic care are to prevent ulcers from developing and to heal wounds that do develop quickly while avoiding infections, deeper ulcers, and amputations. Any wound care intervention that could

**Exhibit 1: Annual Incidence Rate of Diabetic Lower-Extremity Amputations and Total Number of Diagnosed Diabetic Patients from 1999-2003**



prevent even a small percentage of wounds from progressing to the stage at which inpatient care is required may have a favorable cost effect. An amputation avoidance program should include a stratification system for risk level that allows quick access to care, aggressive management of ulcers and infections, a multidisciplinary care team, and a patient-centered education program for chronic patients.

Several types of economic studies have been developed to assess costs of treatment. Cost-minimization, cost-effectiveness, cost-utility and cost-benefit studies

**Exhibit 2: Frequency of Causal Factors Present in Lower Extremity Amputation Cases**

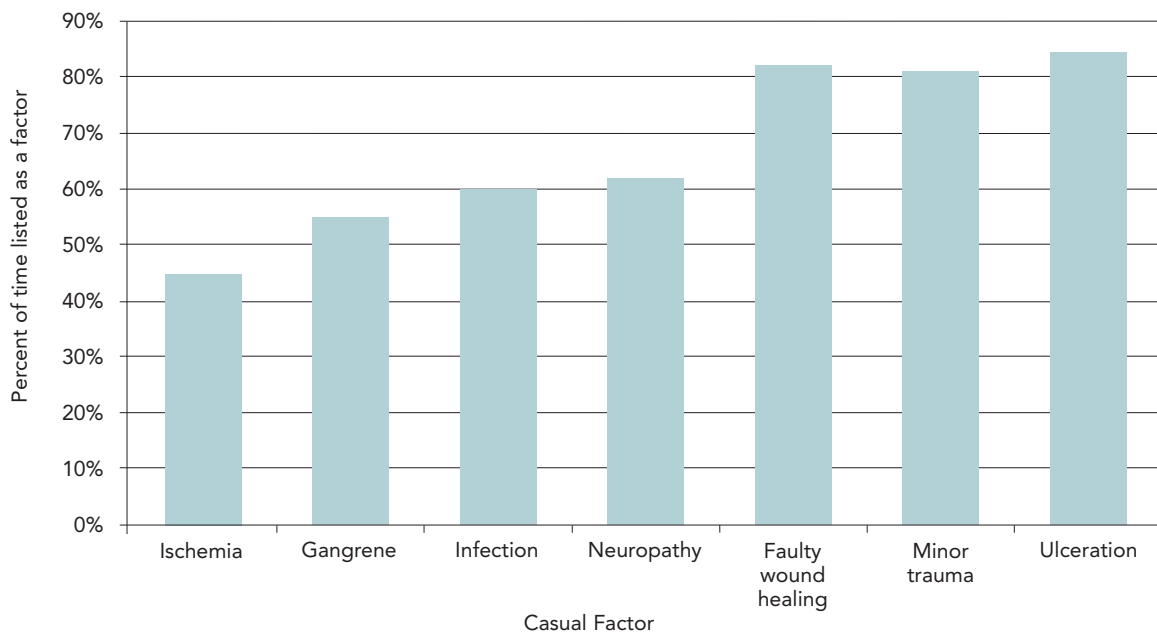


Exhibit 3: Probability of Healing Based on One-Week Wound Progression

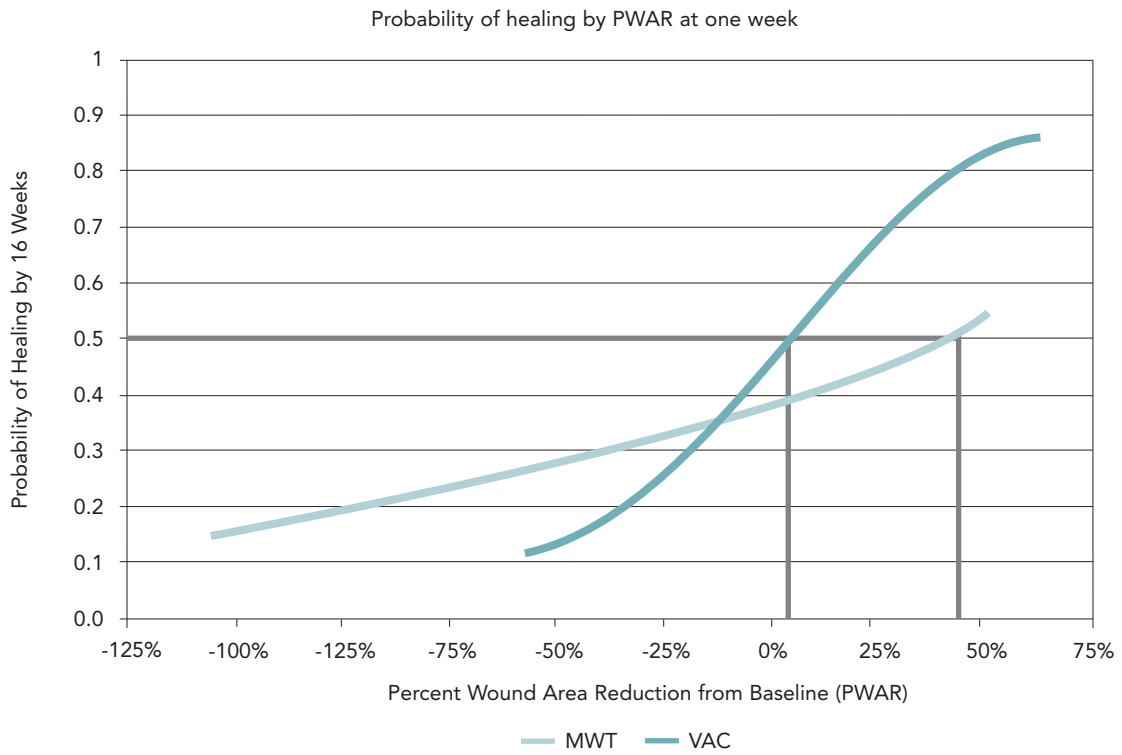
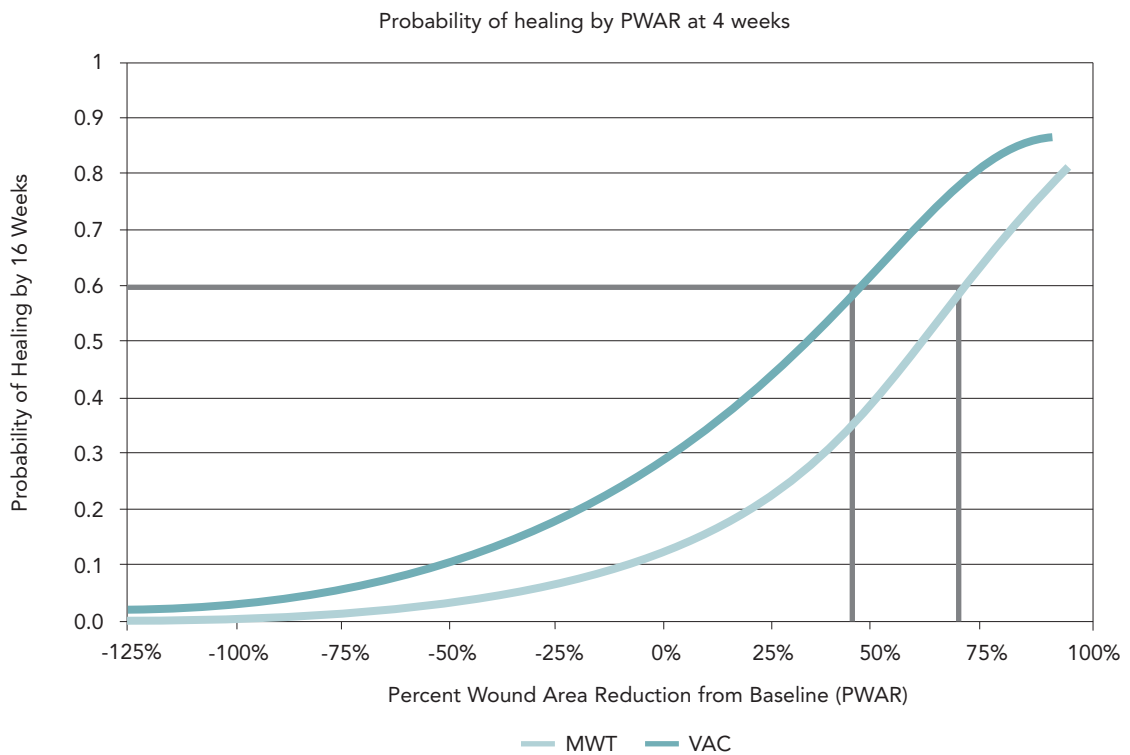


Exhibit 4: Probability of Healing Based on Four-Week Wound Progression



all examine different aspects of disease or treatment costs. These types of studies are being used to demonstrate the benefits of various wound care regimens in achieving appropriate outcomes. Some of the outcomes being examined by these studies are time to healing, time to reoccurrence (i.e., reulceration), avoidance of infection, length of hospital stay, survival, death, and amputation. Minimizing total costs while preserve limbs is the ultimate goal in wound care. A study by Ortegon and colleagues is an example of a cost-effectiveness study in wound care.<sup>16</sup> Guideline-based care (optimal foot care and good glycemic control) in patients with diabetes improved survival and quality-adjusted survival and decreased foot complications.<sup>16</sup>

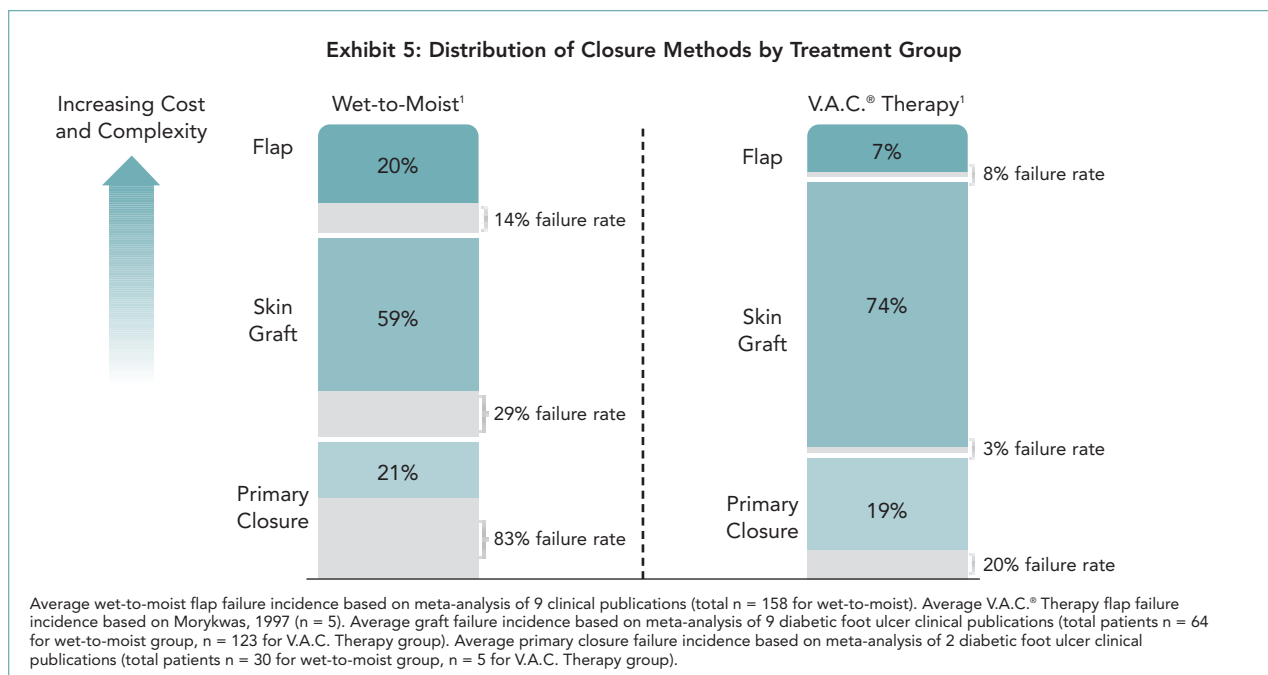
Negative pressure wound therapy (NPWT) is one of the wound treatments which has been examined in economic studies. A 16-week multi-center, randomized controlled trial in patients with partial foot amputation wounds compared NPWT (V.A.C.<sup>®</sup> Therapy<sup>™</sup>) or traditional moist dressing (alginates, hydrocolloids, foams, or hydrogels).<sup>17</sup> Data were analyzed using a time-to-event strategy with Kaplan-Meier estimates. Seventy-seven percent of the patients achieved a 50 percent wound area reduction. Patients treated with V.A.C. therapy achieved 50 percent closure at twenty-nine days as compared to 42 days for traditional moist wound healing. The V.A.C. patients were almost one and a half times more likely to achieve wound closure during the 16-week treatment period.

Another 16-week randomized clinical trial of 162 patients compared outcomes associated with NPWT

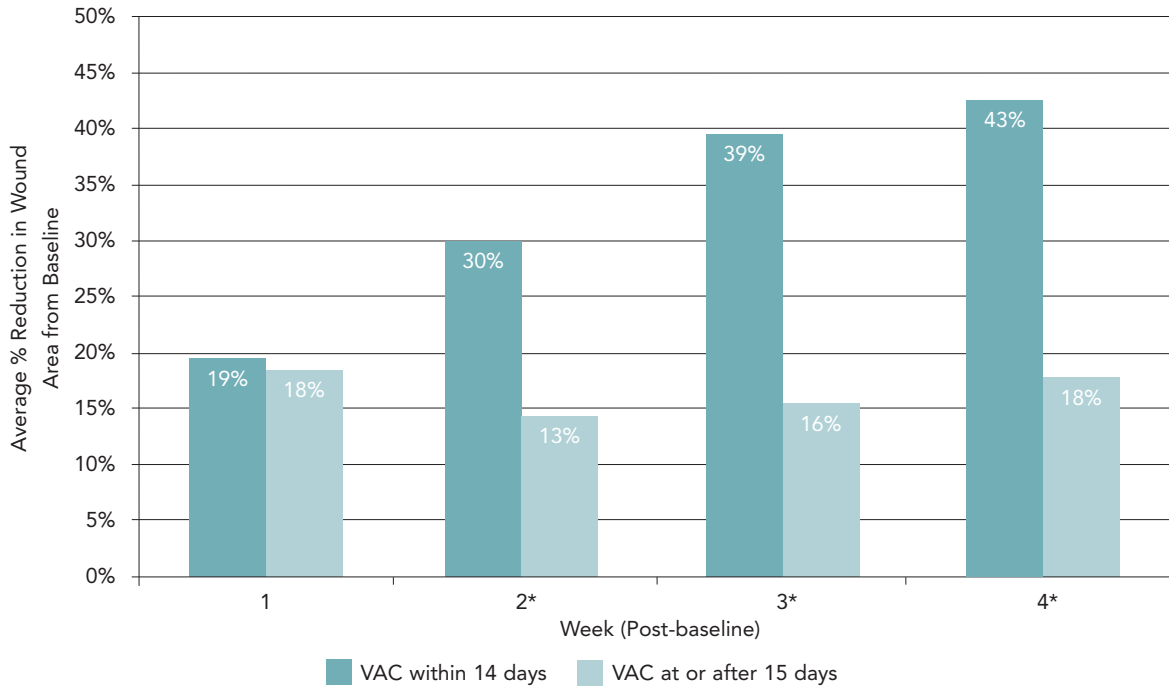
delivered through the V.A.C. Therapy System (n=77) versus standard moist wound therapy (n=85).<sup>18</sup> These patients had a non-ischemic diabetic wound followed by a partial foot amputation. One and four-week regression models included 153 and 129 of the patients, respectively. This study found that early changes in percent wound area reduction were predictive of final healing at 16 weeks. Patients who achieved at least a 15 percent reduction of their wound area at one week or 60 percent by week four had a 68 percent or 78 percent probability, respectively, of achieving closure. If they did not achieve these percentage area reductions, the probability of closing was only 31 percent and 30 percent. Patients receiving V.A.C. therapy were two and one half times more likely to achieve a 15 percent reduction at one week and a 60 percent reduction at one month as compared to moist wound healing therapy. The results of this study suggest clinicians could calculate the percent reduction in an area as early as one week in order to predict the likelihood of wound closing.

A study by Sheehan in 2003 found similar results. This study found that reducing the area by four weeks was predictive of final wound healing.<sup>19</sup> Another study found that a 10 to 15 percent reduction in wound area each week was a good benchmark for healing.<sup>20</sup>

A plot of the one-week healing trajectories comparing V.A.C. therapy with moist dressings is shown in Exhibit 3. To have a 50 percent probability of healing by sixteen weeks, VAC patients have to achieve 7 percent closure at week one, while the moist wound healing patients have to achieve 37.5 percent at week



**Exhibit 6: Differences in Percent Wound Reduction Over Time with Early vs. Late Initiation of NPWT (V.A.C. Therapy®)**



\* Indicates p<0.05 from a two-sample t-test. Please note that the sample sizes decrease over time due to patient's healing, being discharged and missing data.

**Exhibit 7: Early vs. Late Initiation of NPWT (V.A.C.® Therapy)**

Variable	V.A.C. Early Mean Values	V.A.C. Late Mean Values	P-value
Percent wound area change (3 weeks)	38.8%	16.2%	0.04
Days until 50% reduction in wound area	22.0	34.2	0.002
Total length of treatment (days)	25.1	31.6	0.116
Total length of stay (days)	35.4	56.4	<0.0001
Total wound care treatment costs	\$3,194.36	\$4,182.13	0.08

one. At four weeks on the same healing trajectories, the V.A.C. patients would require a 45 percent area of reduction and the non-V.A.C. patients 68 percent, to have the same 60 percent probability of healing by sixteen weeks (Exhibit 4).

In a meta-analysis of studies, treatment with NPWT resulted in lower failure rates for primary closure, skin grafts, and surgical flaps than moist dressings (Exhibit 5).<sup>21</sup> Comparing the levels of surgical intervention required to close wounds, the analysis showed that patients treated with moist dressing required more complex surgeries to close

their wounds versus those that were treated with NPWT. Costs increase as complexity of the surgical procedures required to close the wound increase. Failure rates of the procedure also factor into the total cost.

Using Health Care Utilization Project (HCUP) operating room charges, converted to cost using CMS cost-to-charge ratio (45 percent), NPWT resulted in \$4,323 in costs and moist dressing cost \$5,225.<sup>21</sup> There is a potential savings of \$902 per patient with the use of NPWT. The biggest cost difference is in the length of stay. The average length of

### Patient Example



Day 14 in acute hospital;  
refused amputation;  
referred to LTAC.



Day 28 after 2 weeks of  
V.A.C.



Day 54; discharged home,  
ambulating with dry dressing  
and no home.

Female admitted to the hospital with diabetic ulcers present for an unknown period of time. At the time of admission she had an abscess and infection. Treatment started with debridement in the operating room, daily whirlpool, and enzymatic debridement. After two weeks of inpatient care, amputation was recommended but she refused. Her daughter stated the mother would not be able to live independently with an amputation. She was transferred to a long-term acute care program with an organized wound care program. She was treated with V.A.C. therapy and a skin graft. When discharged at day 57, she went home with dry dressings, no home health care, and was set up with a podiatrist for regular foot follow-up. In the four years since, she has not been readmitted for another wound.

stay for the moist group was 15.8 days.<sup>21</sup> For the NPWT group, it was 11.3 days.<sup>21</sup> Saving 4.5 days of hospital stay is estimated to save \$6,000.

Frykberg and colleagues used retrospective amputation claims data to compare NPWT versus traditional wound therapies in reducing the incidence of lower extremity amputations in patients with diabetic foot ulcers.<sup>22</sup> Amputation incidences with NPWT versus traditional therapy were 35 percent lower in the Medicare sample (10.8 percent versus 16.6 percent,  $p=.0077$ ) and 34 percent lower in the commercial payer sample (14.1 percent versus 21.4 percent,  $p=.0951$ ). In the traditional treatment groups, more severe wounds had a higher incidence of amputation. The same increasing trend was not seen in the NPWT groups. The authors concluded that patients with diabetic wounds treated with V.A.C. therapy had a lower incidence of amputation than those undergoing traditional wound therapy.

In an unpublished retrospective analysis from a long term acute care setting, records of 241 patients treated with NPWT (V.A.C. Therapy<sup>®</sup>) were examined to identify if timing of therapy initiation made a difference in outcomes and costs. The majority of these patients had diabetes. The patient records were divided into those who had early therapy (within first 14 days of admission) and late therapy. A significant difference in percent wound reduction was seen at weeks two, three, and four post-baseline with early NPWT (Exhibit 6). A multiple regression model, controlling for severity of the wound as well as the initial size, showed that starting V.A.C. within the first 14 days was associated with a reduction of 22 days in

total length of stay. In a long-term acute care hospital, a decrease in length of stay of 22 days would result in enormous cost savings. Starting patients on NPWT (V.A.C.<sup>®</sup> Therapy) within 14 days of admission was associated with significant differences in percent area change at 3 weeks, fewer days until 50 percent reduction in wound area (35 percent reduction), reduction in total length of stay (38 percent reduction), and reduced total wound treatment costs (\$987.77) (Exhibit 7).

### Conclusion

Cost drivers in wound care are ulceration, infection, hospitalization, and amputation. Prevention is important and cost-effective. Once wounds occur, quick aggressive treatment makes a difference in outcomes. It is clinically and economically beneficial to prevent and aggressively treat ulceration and infection. This keeps patients from needing hospitalization and amputation. Using negative pressure wound therapy is one way to cost effectively manage wounds. **JMCM**

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