

# Health Economics of Wound Care and Limb Preservation: Beyond Clinical Evidence

Costs are important in clinical decision making when there is no gold standard.

BY VICKIE R. DRIVER, DPM, MS

Talking about *medical economics* is a difficult issue for practitioners to discuss because we feel uncomfortable thinking about money and health care together.<sup>1</sup> It is very important that we understand, however, how economics affects our practice of medicine. The term *pharmacoeconomics* comes from a compilation of the sciences. The term is used by scientists in the fields of economics, epidemiology, pharmacy, medicine and the social sciences. Since the 1990s — due to rising health care costs and finite resources — we have been pressured to determine the actual value of health expenditure.

The study of wound care economics includes evidence, guidelines and existing knowledge. Work from Reiber<sup>2</sup> suggests that an uncomplicated wound might cost about \$8,000 to treat. Taking a limb may cost about \$45,000, and furthermore, the price tag for treating an infected diabetic foot ulcer might be about \$17,000.

Going back 16 years, Pecoraro<sup>3</sup> talked about the causal pathway. This has changed over time and with the large number of diabetic patients increasing every year, along with new modalities such as gene therapy and the like, showing that the triggers change. We have new literature, new ideas, new costs and new assessments.

## QUALITY OF LIFE

At 5 years post-below-the-knee and above-the-knee

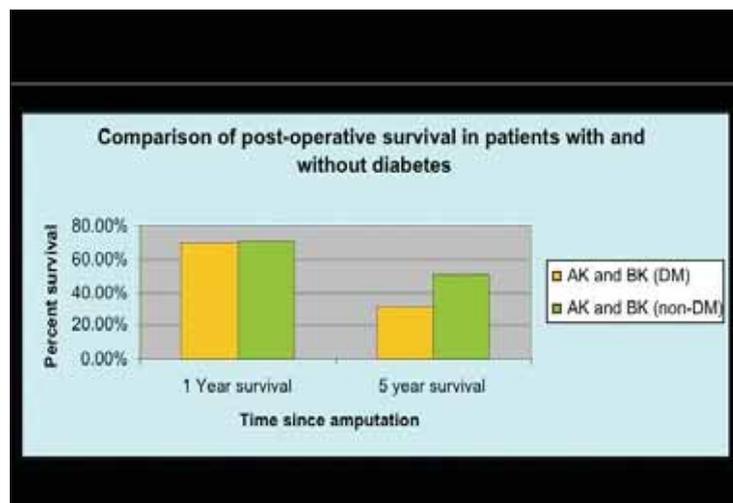


Figure 1. The quality-of-life data for patients 5 years after amputation is not good.

amputations, there is a 72% chance that a patient will die (Figure 1).<sup>4</sup> How much did it cost to keep those alive that are still living, and how much will it cost to keep all of these patients alive 5 years postamputation? This is important information for us to have. Literature from the Centers for Disease Control and Prevention<sup>5</sup> and the American Diabetes Association reveals that diabetes is on the rise, and amputations seem to be following close behind.

We have come a long way, in that we have developed stratification systems for risk levels to quickly assess the care. We now understand that diabetic foot ulcers, and especially infections, are a medical emergency. We have

put multispecialty teams in place, and we discuss their necessity and their cost effectiveness, and we also have organized a patient-centered, focused system.

### COST AND COST-EFFECTIVENESS

Costs and cost-effectiveness are important when the therapeutic need outweighs the available resources. Costs are also important in clinical decision making when there is no gold standard. In diabetic foot treatment — and in diabetes care in general — there are far too few gold standards.

Economic analysis is used for decision making by the government, health care plans and physician groups, as well as you and I. We need economic analysis and cost-effectiveness information because the care of lower-extremity ulcers is a huge cost issue.<sup>6</sup> In 1995, disease-attributable Medicare spending for all lower-extremity ulcer patients was \$1.45 billion.

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There are four different types of costs that we should be familiar with in terms of economic evaluation. These include the measures of cost itself, measures of benefit, surrogate measures and cost and effectiveness.

We have to understand the difference between the types of cost. In practice, we talk about whether or not our care is cost effective, but we really want *cost savings*. This means that we are saving limbs, saving lives and helping patients be more productive.

When we study the evidence related to costs and cost-effectiveness, it is important to realize that there are many ways to evaluate the literature. We must know if authors are talking about models of care or actual patients. Of course, not all studies are equal, and *efficacy* does not equal *effectiveness*. A clinical trial is efficacious; once you bring that product, treatment or drug into your clinic, then you can determine if it is effective.

### PERSPECTIVE OF ANALYSIS

There are various perspectives to consider when determining cost-effectiveness. We care mostly about

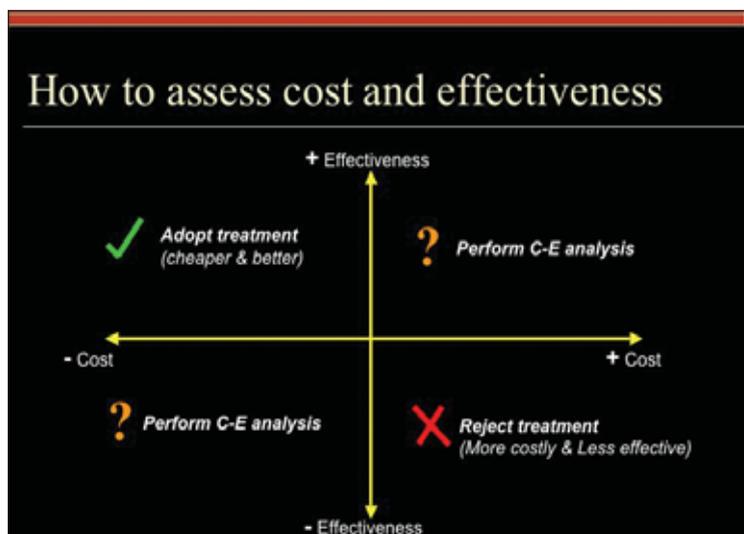


Figure 2. Use a basic cost and effectiveness chart. This is the tool that is used by administrators in medicine.

society's perspective, but its voice is low. Unfortunately, the third-party payer's voice is loud, and we hear very little from the patient and their family. Measures of benefit must be taken into account when we determine cost. Things to consider are time to healing, time to reoccurrence of infection or ulceration and time to reoccurrence of the second-digit amputation. We seek to avoid infection and keep patients alive and productive.

Statisticians speak about measures of benefit in terms of utilities and surrogate endpoints. We talk about Q-TWIST or quality-adjusted time without symptoms of disease or toxicity of treatment. This, as well as quality-adjusted life years (QALY), wound-healing velocity and limb preservation are benefits that will be measured as we move toward pay for performance.

Other considerations in terms of benefit go beyond wound healing as complete wound healing may not always be a realistic endpoint. Wound closure is important, but it is a very limited window through which to view efficacy. There are factors such as subtle changes in the wound environment and gene expression. With regard to limb preservation, we consider how distal we can go with surgery, and can we preserve functional anatomy and articulation?

### AT WHAT COST?

Multidisciplinary centers worldwide may have fewer amputations, but the cost must be considered. We have the ability to perform more distal amputations, which preserve function, but at what costs to the patient in time, energy and money? We must look to surrogate markers that are very important in all other areas of medicine.

For example, Margolis<sup>7</sup> work shows us an endpoint of

## Cost Generation in Wound Care

- Settings of care:
  - Hospital (surgical & non-surgical)
  - Outpatient / clinic
  - Home (self) / Home (healthcare professionals)
- Components of direct cost of care:
  - Medications
  - Supplies / dressings
  - Physicians
  - Nurses / staff

Figure 3. The cost generation in wound care is made up of care and the direct costs of care.

## What is Cost Effectiveness?

- Cost effectiveness is the ratio of the marginal cost to the marginal effectiveness:

$$\frac{\Delta \text{Cost (A-B)}}{\Delta \text{Effectiveness (A-B)}}$$

Figure 4. This equation is used by Medicare, hospitals and statisticians.

early change in wound size that we should consider. After 4 weeks of care, the percentage change in area can be used to predict 76% of the time those that may or may not heal. Other surrogates in wound healing are wound velocity, gene expression and necrotic/granular tissue/epithelial changes. This is very important as we look to drugs, procedures and therapies, as well as in developing clinical trials.

### MEASURES OF COST

Measures of cost are:

- Direct costs. Hospitalization, doctor, medication, nursing care, dressings and supplies.
- Indirect costs. Lost work and lost productivity.
- Intangible costs. Pain, lost companionship. Secondary depression and suffering.
- Fixed cost versus variable cost.

All of these costs must be measured to come up with a complete analysis. Remember that cost does not equal charge does not equal reimbursement.

One way to make sense of this is to use a basic cost and

effectiveness chart (Figure 2). In medicine, this is the tool that is used by administrators. The cost generation in wound care is made up of settings of care and the direct costs of care (Figure 3). Ulcer costs increase as the severity increases, and also not surprisingly, infected wounds cost more than noninfected wounds.<sup>8</sup>

Work by Harrington and Girod<sup>6,9</sup> has shown that hospitalization accounts for the majority of health care costs (70% to 80%). Other contributors to the cost of lower-extremity ulcers are outpatient care at 10.9%, home health care 11.4% and hospice care 4%.<sup>6</sup>

But cost is not everything. Limb preservations may be cost-effective in the long term, although the direct costs of amputation may be less than failed revascularization plus amputation or prolonged hospitalization for infection, then amputation. This is very difficult to measure. Figure 4 is the equation used by Medicare, hospitals and statisticians. Figure 5 puts these terms into real events, using the Q-TWIST.

A cost-effectiveness prevention article by Ortegon et al<sup>10</sup> used a Markov mathematical model applied to Medicare patients in 13 states. The study tested optimal foot care and intensive glycemic control. Optimal foot care consisted of protective foot care, patient and staff continuing education, foot inspec-

tions, identification of high-risk patients, treatment of nonulcerative lesions and a multidisciplinary approach to existing ulcer treatment. The investigators looked at survival, QALY and decreased foot complications using this guidelines-based care.

They found that if you combine optimal foot care and intensive glycemic control, it costs <\$25,000 annually per QALY, intensive glycemic control alone cost \$32,057 per QALY and optimal foot care alone cost anywhere from \$12,169 to \$220,100 depending on the success rate. For <\$25,000, we can treat the underlying infection, we can prevent ulceration, infection, hospitalization and amputation. Additionally, literature by Tennvall<sup>11</sup> found that an intensified prevention strategy is cost-saving in all high-risk patients.

Also cost-effective is debridement. It improves wound closure, it does not add considerably to the cost of care (<\$1,000 annually), it is the cornerstone of wound care, and it is effective in preventing and managing infection.<sup>6,12</sup>

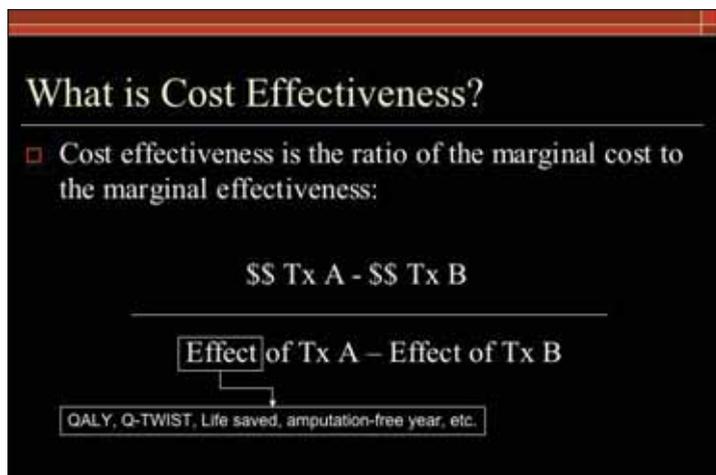


Figure 5. This takes the equation and puts the terms into real events using Q-TWIST.

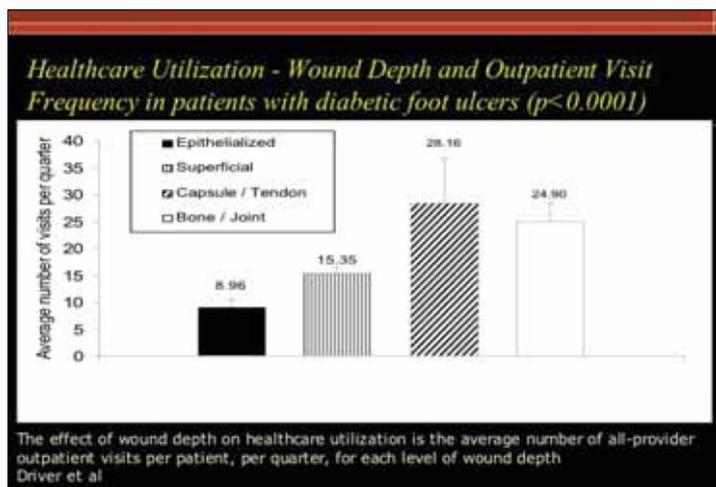


Figure 6. As the wound progresses, health care resource utilization soars.

The cost of treating an infected ulcer is greater than that of an uninfected ulcer. It costs about \$775.00 per month to care for an uninfected ulcer, >\$2,000 per month for an ulcer with cellulitis, and almost \$4,000 per month for an ulcer with osteomyelitis.<sup>8</sup> These are important data to present if you are trying to get certain agents on a formulary. Adding to this is my work at an army-based hospital, which found that hospitalizations involving osteomyelitis were 2.5 times as expensive as those with no infection.<sup>13</sup>

We also looked at wound depth and outpatient visits (Figure 6). It is no surprise that as the wound progresses health care resource utilization soars. These issues have to be looked at for many reasons, especially cost-effectiveness. Wound depth and the rate of hospitalization follows along a similar pattern. Interventions and preven-

tion are most cost-effective in high-risk patients if ulcers and amputations are reduced by 25%.<sup>11</sup>

**BETTER EDUCATION AND THE FUTURE**

In order to make our care and the use of new advances in technology cost-effective, we need better education. We have to understand that when we talk to patients about preventing a callus, for example, that is different than when they have just lost a toe and you are telling them what they are up against next.

The next-generation studies we are going to look to for information are going to be detailed clinical trials. We must integrate data from multiple sources, such as epidemiological/observational trials, billing and reimbursement, and electronic medical records. Putting them all together will help us understand the big picture. ■

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