

# COST EFFECTIVENESS IN WOUND HEALING

## THE ECONOMIC ASSESSMENT OF ADVANCED WOUND CARE PRODUCTS: FROM RESEARCH THEORY TO PRACTICE

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### INTRODUCTION

Chronic wounds are a significant health problem around the world. Ulcers reduce quality of life and may lead to infections, pain, and death. While prevention of chronic wounds should be the primary goal, over the past decade, new adjunctive therapies have become available.<sup>1</sup> For pressure ulcers, for example, these therapies include applying electric and electromagnetic energy,<sup>2</sup> external negative pressure,<sup>3</sup> wound normothermia,<sup>4,5</sup> low air loss beds,<sup>6</sup> various dressings,<sup>7</sup> skin substitutes,<sup>8</sup> and growth factors.<sup>9</sup>

#### ***Regulators and payers want value for money for new products***

While these products offer exciting opportunities for doctors and patients, there remain economic issues that require attention. Purchasers want proof of value. Among the specific topics that need further clarification are the processes and criteria that payers use to consider, adopt and finance new wound care treatments. For example, should the federal government pay for these technologies? Should insurance companies have a list of acceptable wound care products that are deemed to be cost-effective? The choices health insurers make regarding new technologies may depend on how health economists - often working on behalf of the health insurers - conduct economic analyses of new wound care technologies.

The goal of this article is to present an overview of how health economists perceive economic analyses of new technologies such as advanced wound care products. This guide is intended as a roadmap to highlight the research methods. Although cost-effectiveness analysis is a specific type of economic evaluation, the term is commonly used (sometimes mistakenly) to refer to all types of economic evaluation in health care.

The application of economics to medical practice does not necessarily mean that less money should be spent, but rather that the use of resources might be more efficient. At some point, the extra money spent for small improvements in quality of medical care is not worthwhile. Economic study of wound care treatment aims to identify appropriate practice, because money misspent could have been devoted to medical care that would achieve greater benefit (e.g., vaccinations), or to some other meaningful social purpose (e.g., elementary school education). Since, there are not enough resources to provide all the medical care technically possible or that patients might prefer to receive, difficult trade-offs and choices will occur.

Healthcare systems, regardless of their financing and delivery systems, then must employ a number of mechanisms to ration these finite healthcare resources. This is because health care is different than consumer goods, which rely on the marketplace to get allocated optimally.

Table 1.

#### How is health care different from consumer goods?

- ?? suppliers may influence demand (i.e., new surgeon in town)
- ?? patients are not cost-conscious
- ?? patients are shielded from true cost of their healthcare (benefits are non-taxable)
- ?? uncertainty in the services needed to treat pts
- ?? information is lacking on what works (need outcomes research)

In analyzing the economics of chronic wound care, three different dimensions can be considered.

#### 1. *Types of analysis.*

There are three main types of analysis:

- Cost-identification
- Cost-effectiveness
- Cost-benefit

#### 2. *Points of view.*

An analysis may take the following points of view:

- Society
- Patient
- Payer (usually the insurance company)
- Health care provider

#### 3. *Types of costs.*

A variety of cost types may be included in a health economic analysis:

- Direct medical costs
- Direct nonmedical costs
- Indirect morbidity and mortality costs
- Intangible costs

This theoretical framework and the tools of analysis presented can be applied to all new technologies. The incremental cost-effectiveness ratio is defined as:

$$\text{Incremental cost-effectiveness ratio} = (C2 - C1) / (E2 - E1)$$

Where C2 and E2 are the cost and effectiveness of the new intervention being evaluated, and C1 and E1 are the cost and effectiveness of the standard therapy.

The take home message is that the cost-effectiveness of new technologies requires clinical effectiveness, is relative and incremental to the standard of care, can quantify the additional cost and the additional benefit, but not whether the treatment is 'worth it'.

Ideally, for example, the economic analysis, can then be used by decision-makers at the local treatment facilities or by national policy experts to make informed coverage decisions. Cost-effectiveness analysis is only one of many sources for informed decision making.

## **TYPES OF ECONOMIC ANALYSIS**

### ***Cost-identification analysis***

Cost-identification analysis simply asks the question, 'What is the cost?' By calculating the cost of having a particular type of treatment, or the medical services used to treat a disease once it occurs, the cost of alternative ways of providing care (i.e., with or without new wound care treatments) can be determined. Cost-identification analysis is sometimes referred to as 'cost-minimization analysis' because it is usually used to identify the lowest cost of different available diagnostic or therapeutic strategies. Cost-identification analysis assumes that the outcomes of the strategies are considered equivalent, so the goal is to find the least expensive way of achieving the outcome.

As useful as cost-identification analysis may be in determining the cost of medical care or the financial burden of disease, it is lacking in that it does not evaluate what these expenditures bring in terms of gains in health outcomes. Thus, cost-identification analysis can guide medical practice only if a service has both lower cost, and better or equal outcomes than its alternative.

### ***Cost-effectiveness analysis***

Cost-effectiveness analysis, on the other hand, incorporates both cost and effect.<sup>10</sup> It measures the net cost of providing a service (expenditures minus savings) as well as the outcomes obtained. Outcomes are reported in a single unit of measurement (e.g., quality-adjusted life-years). The advantage of cost-effectiveness analysis is that it considers the possibility of improved outcomes in exchange for the use of more resources.

Quality-adjusted life-years include a length of time component (e.g., one year) and a quality of life component (i.e., utility).<sup>11</sup> For example, one quality-adjusted life-year for an individual in perfect health (with a utility = 1.0) for one year (QALY=1) is considered equivalent to two years in a health state with utility = 0.5 (QALY=1). Quality adjusted life years gained is depicted in Figure 1, with a hypothetical intervention that improves survival and quality of life.

### **Figure 1. Quality adjusted life years gained.**

With the evaluation of any new wound care product for clinical use, two questions must be answered. First, is the therapy effective in improving clinically meaningful outcomes? If the answer is yes, the second question is: are those improved outcomes or extra benefits worth whatever extra costs they entail? Four possibilities exist:

### **Figure 2.**

Very importantly, no medical intervention can be considered 'cost-effective' in isolation but must be compared with the standard of care. Decisions based on cost-effectiveness are always relative to the alternative choices, which may include non-medical expenditures (e.g., education).

### ***Cost-benefit analysis***

Cost-benefit analysis, the third level of economic assessment of clinical practice, forces an explicit decision about whether the cost is worth the benefit by measuring both in dollar terms. Because translating value of health care (e.g., less pain and suffering a patient might experience) is tricky, cost-benefit studies are done less often.

### **PERSPECTIVE OF ANALYSIS**

Costs, outcomes, and benefits can be analyzed from different points of view - the patient, the provider, the payer, or society as a whole. The cost of a medical service (e.g., an advanced wound care product) to the payer (e.g., an insurance company in the United States) equals the percentage of charges actually paid by the payer. However, the relevant cost to the patient is the out of pocket expense (not covered by insurance) plus other costs (e.g., loss of time at work) incurred due to having to take time off to get the test. The cost of advanced wound care products from society's point of view is the total cost of all the different components of society, or the result of society having given up the opportunity to use those resources for some other purpose. For researchers, costs are usually assessed from a societal perspective.

### **TYPES OF COSTS**

***Direct costs*** are expenditures for medical or non-medical products and services. The types of direct medical costs that are usually included are those of hospitalization, drugs, physician's fees, laboratory tests, radiological procedures, rehabilitation, durable medical equipment, and long-term care. Substantial portions of direct costs are for nonmedical services (e.g., transportation and lodging if a patient has to travel to obtain the genetic test).

***Indirect costs*** are those that occur because of loss of life or livelihood and may result from morbidity or mortality. Indirect morbidity costs may occur because of being absent from work, because of a decreased earning ability when working, or because of long-term disability that necessitates a change in type of work.

***Intangible costs*** represent another category of costs and, like indirect costs, are difficult to measure. These are the costs of pain, suffering, grief, and the other non-financial outcomes of disease and medical care.

### **DISCOUNTING - A COST TODAY IS NOT EQUIVALENT TO A COST IN THE FUTURE**

Even after inflation has been taken into account, a cost or an outcome today is not equivalent in value to the same cost or outcome in the future. Since people prefer to have something today instead of having it in the future, a future value must be discounted (typically at 3-7% per year) to the present. For chronic wound care treatments, time costs may be relevant as the length of treatment increases.

## A SENSITIVITY ANALYSIS IS ALSO REQUIRED

Sensitivity analyses are necessary to evaluate the impact of changing key variables.<sup>12</sup> The ranges of estimates for each parameter usually encompass the ranges reported in the clinical trials or the published literature. Probabilistic sensitivity analysis is particularly helpful in considering uncertainties in all probabilities, utilities, and costs simultaneously.<sup>13</sup>

## CONCLUSION

Economic evaluation is a useful conceptual framework to support evidence-based healthcare. Nevertheless, the actual use of economic evaluations in actual decision-making process is unclear. This may be in part due to data interpretation issues including comparison of the clinical trial population to the patients under consideration for treatment with the therapy, translation of the costs reported to the costs relevant to the perspective of the decision-maker, and translation of the clinical outcome measures to outcomes relevant to the length of treatment being proposed by the practitioner.

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