AN ACTUARIAL REPORT ON THE COST EFFECTIVENESS OF A NEW MEDICAL TECHNOLOGY

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It would be difficult to overstate the concern today in the United States regarding health care costs. The January 1991 issue of the Conference Board[1] reported on the results of the Board's latest Chief Executive Opinion survey covering nearly 600 top U.S. companies. Asked to rate the future burden of present problems, the number one concern of top CEO's was health care costs.

New medical technology is often cited as a contributing factor to increasing health care costs. In a 1990 report to the National Committee for Quality Health Care, [2] the forces driving health care spending were examined in detail. In a section reviewing the impact of new medical technology, the report cited an analysis of American Hospital Association data that concluded half the increase in real hospital costs derive from new technology. [3]

In such an environment, a report of a new medical technology demonstrating cost reduction as well as substantial improvement in patient care is extremely noteworthy. Such a report has been published by Itoh et al. (Goldwater Memorial Hospital, New York City) in the February 1991 issue of Decubitus, The Journal of Skin Ulcers.[4]

The medical problem studied was pressure ulcers, a pervasive health problem, particularly among the elderly in nursing homes (an ever-increasing number as the population ages) and among severely, chronically debilitated patients, e.g., spinal cord injuries.

Pressure ulcers are commonly classified in four stages as follows:

Stage I: Nonresolving reddened area with no break in skin;

Stage II: Reddened area with superficial skin break;

Stage III: Open area extended beyond epidermis to subcutaneous tissue with or without necrosis;

Stage IV: Deep open area exposing muscle, fascia, or bone.

A chronic pressure ulcer can progress to Stage IV and eventually cause death.

Estimates of the extent of the problem vary, but all indicate pressure ulcers are a significant health care problem and expense. For hospitalized patients various authors have estimated a prevalence of pressure ulcers ranging from 3% to 11%.[6,7,8] In other studies, approximately one quarter of residents admitted to the nursing home from an acute care hospital[9] and one third admitted to a chronic care hospital[10] had a pressure ulcer. In an analysis of 51 nursing homes in 11 states covering all geographic regions of the country for the years 1984-85, Brandeis et al. reported 11.3% possessed a Stage II through Stage IV pressure ulcer. Further, for those admitted to the nursing home without a pressure ulcer, the one year incidence of developing a pressure ulcer was 13.2%. This increased to 21.6% by two years of nursing home stay.[11]

The International Association for Enterostomal therapy (IAET), a 2,200-member association consisting of ET nurses specializing in treatment of pressure ulcers, has stated that over 500,000 people in nursing homes are at risk to develop a pressure ulcer and that almost 60,000 people die each year from pressure ulcers.[12]

It is difficult to calculate the total patient cost attributable to pressure ulcers. The consensus statement of the National Pressure Ulcer Advisory Panel estimated a range of $2,000 to $30,000.5 Some estimates range as high as $86,000 per patient.[13] Slow-healing or non-healing ulcers require a prolonged hospital stay, and the patient may develop complications, including infection and secondary disability. Morbidity and mortality of this condition is high.11 The magnitude of the problem is in the billions of dollars annually, with the IAET citing costs as high as $10 billion.

The impact for insurance companies is most significant in two areas. One is the emerging new insurance product, Long-Term Care, a coverage that emphasizes nursing home care. The already overburdened Medicare program is not able to take on nursing home expenses. Long-Term Care policies have, therefore, been perceived by a number of legislators as a possible solution to this growing problem facing the country's aging population. The number of bills recently introduced to provide tax-preferred status for benefits from these policies provides a barometer for gauging the concern and interest over this issue.[14] The second area of significance for insurance companies is medical management of catastrophic claims such as spinal cord injury and cerebrovascular accidents.

Itoh reported[4] on treatment of pressure ulcers with pulsed, high-frequency, high-peak-power electromagnetic energy (Diapulse). This therapy has recently been described by the Food and Drug Administration as a segment of "Emerging Electromagnetic Medicine."[15] Experimental and clinical applications of this energy are reported in the literature as providing a safe and effective method of aiding soft tissue healing,[16-20] reduction of edema,[21-24] absorption of hematoma,[25,26] reduction of inflammation,[27-29] nerve[30-34] and spinal cord regeneration,[35-39] and improving peripheral vasculature.[40-42]

Based on the literature and a report[43] that Diapulse was beneficial in the treatment of superficial and deep pressure ulcers

which had failed to heal, the authors undertook the present study of Stage II and III pressure ulcers which were demonstrably slow to heal or failed to heal with conventional treatment.

Diapulse technology produces pulsed high-frequency high-peak-power electromagnetic energy, and operates on an assigned FCC medical frequency of 27.12 MHz. The energy is delivered in 65 micro-second bursts at six settings of 80 to 600 pulses per second with a wattage range from 293 to 975 peak watts in six steps. Energy is induced through a 9-inch-diameter drum-shaped treatment head, placed in contact with the area to be treated. Treatment is completely safe, non-invasive, and can be applied through clothing and surgical dressings.

Patients with Stage II ulcers unhealed within 3 to 12 weeks and those with Stage III ulcers unhealed within 8 to 168 weeks by conventional methods were included in the study. When Diapulse was added to conventional therapy during the 9-month study, all 22 ulcers healed. All Stage II ulcers healed in one to six weeks (mean: 2.33) and all Stage III ulcers healed in one to 22 weeks (mean: 8.85).

The primary diagnoses of the patients were as follows:

Primary Diagnosis	Stage II	Stage III	Total
Cerebrovascular Accident	3	4	7
Multiple Sclerosis	3	2	5
Organic Brain Syndrome	2	2	4
Spinal Cord Tumor	0	2	2
Diabetes Mellitus	1	1	2
Spinal Cord Injury	0	1	1
Spinal Stenosis	0	1	1
	9	13	22

Individual Results are summarized in the tables below:

		Conventional Treatment Status		DIAPULSE and Conventional Treatment	
	Stage II Age	Duration (weeks)	Ulcer Size (cm^2)	Duration (weeks)	Status
	79	3	3.00	4	Healed
	56	3	2.25	1	Healed
	56	3	15.00	3	Healed
	52	8	1.00	1	Healed
	77	12	1.00	1	Healed
	86	12	7.50	6	Healed
	86	12	7.50	3	Healed
	60	12	6.75	1	Healed
	81	9	6.00	1	Healed
Mean	70.33	8.22	5.56	2.33	
SD	12.6	3.94	4.18	1.70	

		Conventional Treatment Status		DIAPULSE and Conventional Treatment	
	Stage III Age	Duration (weeks)	Ulcer Size (cm^2)	Duration (weeks)	Status
	82	52	0.15	1	Healed
	49	168	1.00	7	Healed
	56	16	0.09	6	Healed
	57	10	4.50	6	Healed
	61	52	0.25	22	Healed
	93	14	1.00	3	Healed
	79	24	17.50	8	Healed
	79	34	28.00	13	Healed
	91	12	5.60	6	Healed
	65	44	40.00	21	Healed
	70	8	1.00	7	Healed
	72	8	9.00	10	Healed
	52	8	6.00	5	Healed
Mean	69.7	34.62	8.78	8.85	
SD	14.0	41.71	11.96	6.09	

It should be emphasized that patient selection was limited to chronic ulcers without any sign of healing, or ulcers of short duration that were deteriorating rapidly with conventional treatment. Not only was complete healing effected in all cases, but many cases of long-term standing were healed in a very short time, e.g., a Stage III ulcer unhealed for 168 weeks healed in 7 weeks and another Stage III ulcer unhealed for 52 weeks healed in 1 week. Many of the Stage II ulcers were healed in 1 week.

To put these results in perspective, Brandeis et al. reported on a much more favorable patient group (all admissions to nursing homes) and still only saw 54.5% of Stage II pressure ulcers healed in 13 weeks.[11]

Itoh et al. reported that a thorough review of the literature produced no evidence of complete healing of Stage II ulcers in a mean average of 2.33 weeks and Stage III ulcers in a mean average of 8.85 weeks. They readily attributed their results to the addition of Diapulse therapy.

What is perhaps most important for the insurance industry, however, is the cost analysis presented in the *Decubitus* paper. Indeed, the authors, fully aware of the health care cost crisis in the New York City hospital system, appeared to be as excited about the cost-savings implications of this therapy as they were over improved patient care.

The cost analysis compared the direct costs of conventional treatment ($229.53 per week) per ulcer with the cost of conventional plus Diapulse treatment ($331.03 per week) per ulcer. The authors noted that Stage II ulcers were on average treated conventionally for 8.22 weeks x 229.53 per week = $1,886.74.

They then compared the 2.33 weeks (conventional plus Diapulse) x 331.03 per week = $771.30.

Similarly for Stage III ulcers the comparative cost per ulcer is:

34.62 weeks x $229.53 per week = $7,946.33;

8.85 weeks x $331.03 per week = $2,929.62.

The authors totaled up the savings for all 22 ulcers and observed a savings of $65,217.23 in this small 9-month study with one Diapulse unit.

Of course, these savings are enormously understated. The ulcers had not healed when Diapulse therapy was introduced. Thus, the cost for Diapulse and conventional is accurate, but the cost for conventional only has an artificial cut off date, i.e., the day Diapulse therapy started.

If we were to simply add the mean healing time with Diapulse and conventional to the conventional cost, assuming that the ulcers would have healed by that time (an assumption clearly unwarranted) the savings would increase from $65,217.23 to $96,437.90.

The ulcer population in the Itoh (Goldwater Memorial Hospital) study is, as pointed out earlier, biased toward non-healing ulcers. It is instructive to compare the mean healing time with Diapulse to the natural history of pressure ulcers in general. The assumption here, that Diapulse plus conventional therapy will heal a normal pressure ulcer in the same time frame (2.33 weeks, Stage II; 8.85 weeks, Stage III) should be conservative because these ulcers are by definition more amenable to healing. The Brandeis paper[11] provides the statistics for the following analysis:

Natural History of Pressure Ulcers (n = 1,626)
% Healed in T weeks

	T = 13	T = 26	T = 52	T = 104	Non-healing	TOTAL
Stage II	54.5	19.4	12.8	10.6	2.7	100%
Stage III	31.5	27.4	19.9	18.7	2.5	100%

To calculate an approximation of average healing time by stage, we can make the reasonably conservative assumption that healing within each time period occurs at a uniform rate. Thus, the 54.5% of Stage II ulcers that were healed at the end of 13 weeks are assumed to have healed on average at the midpoint, i.e., 6.5 weeks. The 19.4% of Stage II ulcers that were not healed at 13 weeks, but were healed at 26 weeks, are assumed to have healed on average at the midpoint, 19.5 weeks. A similar calculation is done for T = 52 and T = 104. For those Stage II ulcers not healed at 104 weeks (2.7%), we can conservatively use 104 weeks as the average healing time. The same method is applied for Stage III ulcers.

Thus, the approximate average healing time by Stage is:

Stage II = (6.5 wks x .545) + (19.5 wks x .194) + (39 wks x .128) + (78 wks x .106) + (104 wks x .027) = 23.4 wks.

Stage III = (6.5 wks x .315) + (19.5 wks x .274) + (39 wks x .199) + (78 wks x .187) + (104 wks x .025) = 32.3 wks.

Using the Goldwater costs, the savings by Stage per ulcer would be:

Stage II = (23.4 wks x $229.53) - (2.33 x $331.03) = $4,600.

Stage III = (32.3 wks x $229.53) - (8.85 wks x $331.03) = $4,484.

If we apply a $4,500 savings per ulcer to the estimated prevalence of nursing home residents, the annual U.S. savings are approximately $2.25 billion. These savings do not reflect ancillary savings that would derive from reduced mortality and morbidity. In the latter case, more than 50,000 lower extremity amputations are performed on diabetics each year at an estimated cost of $500 million as a result of chronic non-healing wounds.[44]

The Diapulse technology probably falls into what the Health Insurance Association of America classifies as Underevaluated Health Care Technology.[45] For those insurance companies entering the Long Term Care marketplace, further evaluation of the cost savings potential of Diapulse would appear to offer a possible advantage over the competition. For those companies involved in managed care of high cost claims, secondary morbidity costs may be minimized by addition of Diapulse technology to conventional therapy.

The emergence of electromagnetic medicine may offer cost savings opportunities in other areas that have been somewhat refractory to therapeutic approaches devised to date. Widespread industry review, including investigation and evaluation of this new therapeutic modality, may prove to be a worthwhile cost containment strategy.

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