

A Nursing and Rehabilitation Center in New Jersey: Expected Value of Remedy™ Skincare Products and Remedy/Restore® Briefs in an At-Risk Resident Population for Pressure Ulcer and Incontinence-Associated Dermatitis Prevention

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Expected Value of Remedy Skincare Products and
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for Pressure Ulcer and Incontinence-Associated Dermatitis Prevention

OBJECTIVES:

To quantify the importance in pressure ulcer incidence, incontinence-acquired dermatitis and pressure ulcer costs at a long-term care facility when they use Remedy skincare products and Remedy/Restore Briefs line with Remedy Skin Repair Cream.

STUDY DESIGN:

- Retrospective cohort study
- Subjects were randomly selected from a sub population that triggered quality indicators for incontinence and/or pressure ulcers
- Pre period was 2003, 2004 and one half of 2005
- 2006-2007 was the official Post period
- Charts and MDS data for both periods were reviewed
- Pressure ulcer incidence was collected for each quarter
- The at-risk profile for each resident was calculated with EQUIP for Quality®
- No significant difference in risk was found in the Pre and Post populations
- Analysis of all data and expected value model was created

FINDINGS:

- Remedy skincare products, Remedy/Restore adult briefs and regular in-service education correlated with a decrease in pressure ulcer incidence from 17 percent to 0 percent, where it has remained into 2008.
- The incidence rate for incontinence-associated dermatitis reduced from 30 percent to 0.04 percent during the study period.
- Savings are estimated at an average \$861.00 per resident at-risk for pressure ulcers over their length of stay in the nursing home. This considers all at-risk residents whether they acquire a pressure ulcer or not. Savings are produced from reduction in nosocomial pressure ulcers and incontinence-associated dermatitis treatment. Savings come from reduced labor, medications, medical products etc. used in their resolution.

Executive Summary

Pressure ulcers (PU) in nursing homes represent a significant problem for residents in terms of morbidity, pain and reduced quality of life.¹⁻⁵ They represent a major cost to the facility in terms of treatment, regulatory fines and potential litigation.⁶⁻⁹

At Meridian Nursing and Rehabilitation Center, the incidence of pressure ulcers and incontinence-associated dermatitis was high throughout 2003, 2004 and first quarter 2005. The facility was placing everyone at risk on daily rental, low-air-loss beds, expecting to alleviate the problem through pressure relief. However, over 50% of the residents were incontinent and the incidence of incontinence-associated dermatitis was over 30%. Nurses were using a variety of generic, low-cost skincare products and incontinence briefs without consideration for a systematic procedure for application and sizing of the products, respectively.

In December 2004, the director of nursing switched from high-cost daily rental beds to low-air-loss replacement mattresses from Medline Industries, Inc., Mundelein, Illinois. In June 2005, a decision was made to change from using generic skincare products to a Remedy skincare regimen (Medline Industries, Inc.). Further change came in February 2006 with the switch from generic briefs to Remedy/Restore disposable briefs (Medline Industries, Inc.). Product introductions, training and in-service were provided to the nursing staff on when and how to apply and use the products.

Throughout this observation period, there were no significant changes in nursing staff. The facility and staff practiced evidence-based pressure ulcer prevention as required by the Agency for Healthcare Research and Quality. The only changes included lower-cost replacement mattresses, skincare products and incontinence briefs.

A change from the daily rental beds to low-air-loss mattress replacements realized a savings for the facility. However, the pressure ulcer incidence remained the same. A significant drop in pressure ulcers occurred when Remedy skincare products replaced the generic line of skincare products in June 2005. The pressure ulcer incidence rate went from 17 percent to 0 percent and it has remained at that level into 2008. The incidence rate for incontinence-associated dermatitis changed from over 30 percent to 0.04 percent after February 2006. This facility continues to realize a positive return on investment and maintains a below average rating on the national and state levels for pressure ulcer incidence.

The expected value for implementing Remedy skin care and Restore briefs into the facility is an \$861.00 gain per at-risk resident. The expected savings that could have been realized if the facility was using Remedy and Remedy/Restore prior to June 2005 is estimated at \$685,584.00. The pressure ulcer incidence rate went from 17 percent to 0 percent and it has remained at that level into 2008. The incidence rate for incontinence-associated dermatitis changed from over 30 percent to 0.04 percent, as recognized by the nursing staff, after February 2006.

OBJECTIVES:

To compare nursing home residents with respect to the incidence of nursing home-acquired pressure ulcers and to examine the expected value of Remedy skincare products and Remedy/Restore disposable briefs in preventing such wounds. Secondly, observational outcomes are evaluated alongside pressure ulcer data to determine the additive benefit from a reduction in incontinence-associated dermatitis.

METHODS AND SETTING

Design: A retrospective cohort study conducted between 2003 and 2007. A decision model is used to determine expected value of Remedy and Remedy/Restore disposable briefs implemented after June 2005 compared with pre-implementation outcomes.

Setting: A Medicare/Medicaid-certified skilled nursing facility in New Jersey with 137 bed capacity.

INTERVENTIONS

Prior to June 2005, Meridian Skilled Nursing and Rehabilitation Center was using various skincare products and generic disposable briefs (Tena® Classics) to manage incontinent residents (Pre-Implementation Group (Pre)). After June 2005, the facility began using a Remedy skincare regimen followed by Remedy/Restore disposable briefs exclusively for managing incontinence (Post Implementation Group (Post)).

Remedy features potent antioxidants and other ingredients to help nourish the skin on the

cellular level. The basis for Remedy is Olivamine®, a patented molecular composition that helps revitalize the cell membranes and restores cells to a healthy state. Olivamine is a proprietary blend of antioxidants; amino acids and their cofactors, vitamins B₆ and B₃ and methylsulfonylmethane (MSM). All Remedy products contain Olivamine. Remedy/Restore® disposable briefs have 100 percent breathable side panels. Improved airflow not only keeps residents more comfortable, it also helps to reduce skin irritation. Advanced skin nourishment is built right into every Remedy/Restore disposable brief. That's because each brief's inner liner is coated with Medline's Remedy™ Skin Repair Cream. This exclusive, all-natural cream helps provide protection against moisture. Restore skin-safe closures with "grab anywhere" technology allow for the best possible fit and also reduce waste. Anti-leak cuffs perform up to 20 percent better than standard cuffs, which help to protect clothing, bedding, etc. The cloth-like outer cover is comfortable against skin, helping to minimize irritation and rashes.

Data Collection

The Director of Nursing provided access to the facility Minimum Data Set (MDS), under confidentiality, to randomly select a sample of residents from 2003 to the end of 2007. This was to allow a comparison of resident characteristics and risk for pressure ulcers during the Pre and Post periods. The director provided the research team with quarterly nursing home-acquired pressure ulcer incidence rate statistics from April 2003 to January 2008. Dates for switching from daily rental low-air-loss beds to low-air-loss replacement mattresses and

implementation of Remedy and Remedy/Restore briefs were provided by the facility.

MEASUREMENTS

Minimum Data Set: The MDS was used to compare resident characteristics during the Pre and Post periods for characteristics that may put one group at more risk of pressure ulcers than the other. The first assessment at admission is used to ascertain a risk profile. Certain characteristics have been defined from the MDS that put an individual at more risk than others. They are:

Resident characteristics and risk factors	MDS v2.0*	Risk Adjusted Odds Ratio
History of Pressure Ulcer (risk increases as number and highest stage increases)		2.0+
Comatose	B1	1.7
Male	AA2	1.3
Age:		
- 65 – 89 years		1.4
- 90 years or older		1.8
Rarely or Never Able to Make Self Understood	C4	1.7
Bed mobility: limited assistance through total dependence	G1AA	1.4
Transfer: limited assistance through total dependence	G1BA	2.0
Other person wheeled	G5C	1.4
Bedfast all or most of time	G6A	1.8
Bowel incontinence	H1A	1.4
Catheter or Ostomy	H3D or H3I	1.6
Diabetes, Peripheral vascular disease, or Missing limb	I1A, I1J, or I1N	1.3
Multiple sclerosis or Paraplegia	I1W or I1X	2.2
Clostridium difficile	I2B	1.3
Edema	J1G	1.3
End-stage disease, resident not expected to live more than 6 months	J5C	2.2
Previous cured ulcer or current wound, skin tear, or stasis ulcer	M2B, M3, M4E, or M6F	1.6

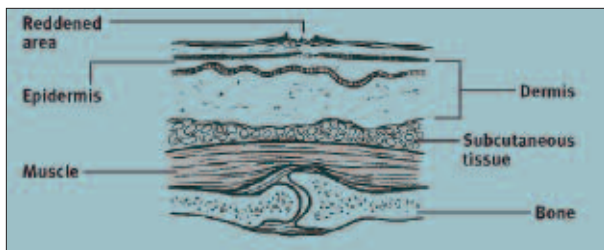
Source: Minimum Data Set (MDS) data for all New York State Nursing Homes 2005 – 2006; analysis provided by New York State Association of Homes and Services for the Aging (NYAHS)A/EQUIP for Quality® under CMS DUA #08591 and NYS DUA#15407.

Using the above criteria and a proprietary formula from EQUIP for Quality, we compared the risk profile of residents before and after implementation of Remedy and Remedy/Restore. The EQUIP for Quality Measures (EQUIP) system is an adjunct to recording Minimum Data Set assessments for their Medicare population.¹⁰ The EQUIP system provides detailed reports on pressure ulcer risk, probability of pressure ulceration and the incidence and prevalence of pressure ulcers in a skilled nursing facility. In fact, some experts state that the predictive validity of determining pressure ulcer risk in the skilled nursing

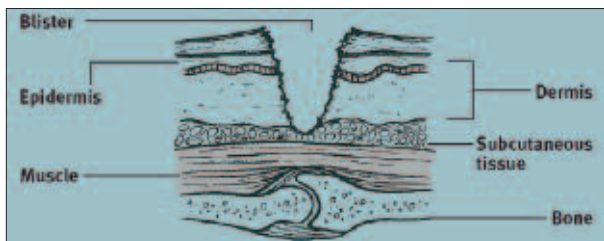
population, based on MDS factors, is more predictive than the Braden Scale for Predicting Pressure Sore Risk.¹⁰ A sub-analysis of incontinence prevalence was completed to compare the exposure to fecal and urinary problems. A chi-square statistic is used to compare differences in overall pressure ulcer risk and prevalence of incontinence. An independent t-test is used to compare equality of means for age.

Pressure Ulcer Incidence Rates: Quarterly incidence rates of nursing home-acquired pressure ulcers were calculated by the director of nursing and his staff. Incidence rate is calculated by the number of at-risk residents who developed a pressure ulcer during the time period for Pre and Post implementation of Remedy and Remedy/Restore.

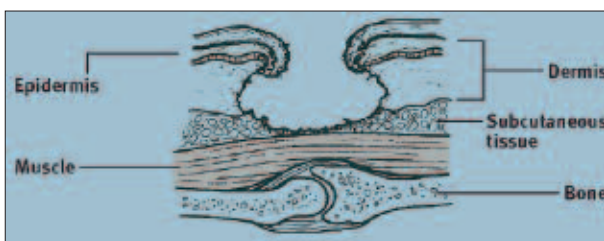
Pressure Ulcer Severity and Costs: The costs of treating pressure ulcers vary greatly, depending on ulcer severity and patient co-morbidities, with an average cost reportedly ranging from \$500 to \$90,000 per ulcer episode.^{11, 12} Pressure ulcer treatment costs are highly variable within and between facilities and residents respectively. In this study, we used pressure ulcer treatment data compiled from patient charts in a skilled nursing facility equivalent to the New Jersey facility and secondary sources to estimate the mean costs of pressure ulcer treatment within the site. The costs were determined by pressure ulcer staging (National Pressure Ulcer Advisory Panel Recommendations, NPUAP) and location of the pressure ulcer:



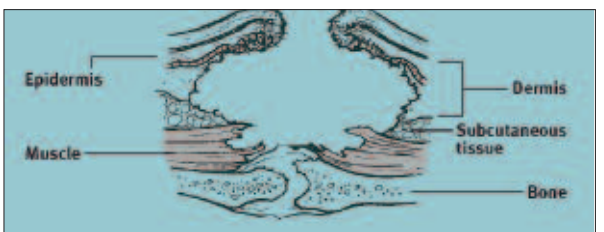
Stage 1:



Stage 2:



Stage 3:



Stage 4:

Costs of treatment included modern wound care treatments, nursing time, pressure redistribution costs (above the normal threshold), dietician time, physical therapy and nutritional supplements.

Decision Analysis: Decision analysis is the application of explicit, quantitative methods to analyzing decisions under conditions of uncertainty. Decision analysis allows clinicians to compare the expected consequences of pursuing different strategies. A simple decision tree, probabilities from the cohort evaluations and costs of pressure ulcer treatment will determine the expected value of the

Remedy and Remedy/Restore implementation with pre-implementation.

Statistical distributions were used in the economic model to help determine the expected value comparing Pre and Post cohorts. A repeated sampling from the values gives a mean estimate of the costs for treatment.

Retrospective Observations by Clinical Staff:

A roundtable discussion with staff nurses who manage incontinent patients and treat for complications was completed as part of the investigation. All nurses have observed the outcome of incontinence-associated dermatitis through Pre and Post periods.

Data Analysis

Cohort Average Age

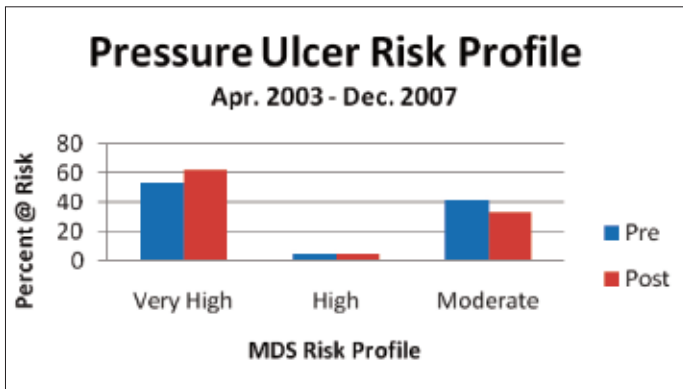
The average age of each cohort is 81.17 and 83.48 for the Pre and Post, respectively. There are no significant differences in age. (Table 1)

Table 1

Cohort	Sample Size	Mean	Standard Deviation	Significance
Pre	111	81.17	11.61	P = 0.058
Post	189	83.48	9.12	

Pressure Ulcer Risk Profile: The resident risk for pressure ulcers is statistically equivalent between the pre and post residents ($\chi^2=2.456, DF=2, p=0.293$). (Table 2)

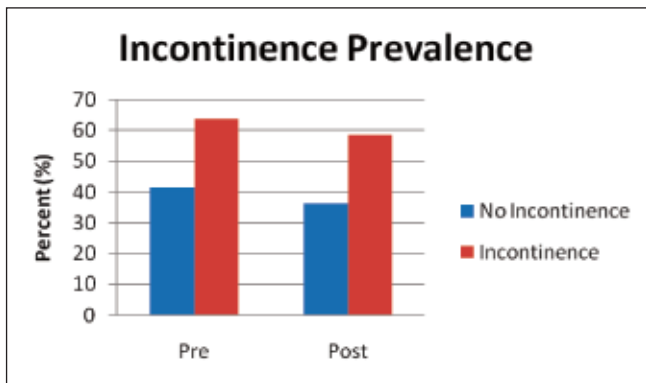
Table 2



Incontinence Prevalence: There is no significant difference between the prevalence of incontinence in either period of time ($\chi^2=.841, DF=1, p=0.359$). There were 46.8% and 48.2% of the incontinent residents in the Pre and Post periods, respectively, who have frequent (daily) bladder and or bowel episodes.

There is a very high prevalence rate for incontinence from 2003 to 2007, making it a significant burden on resources and costs. (Figure 1)

Figure 1



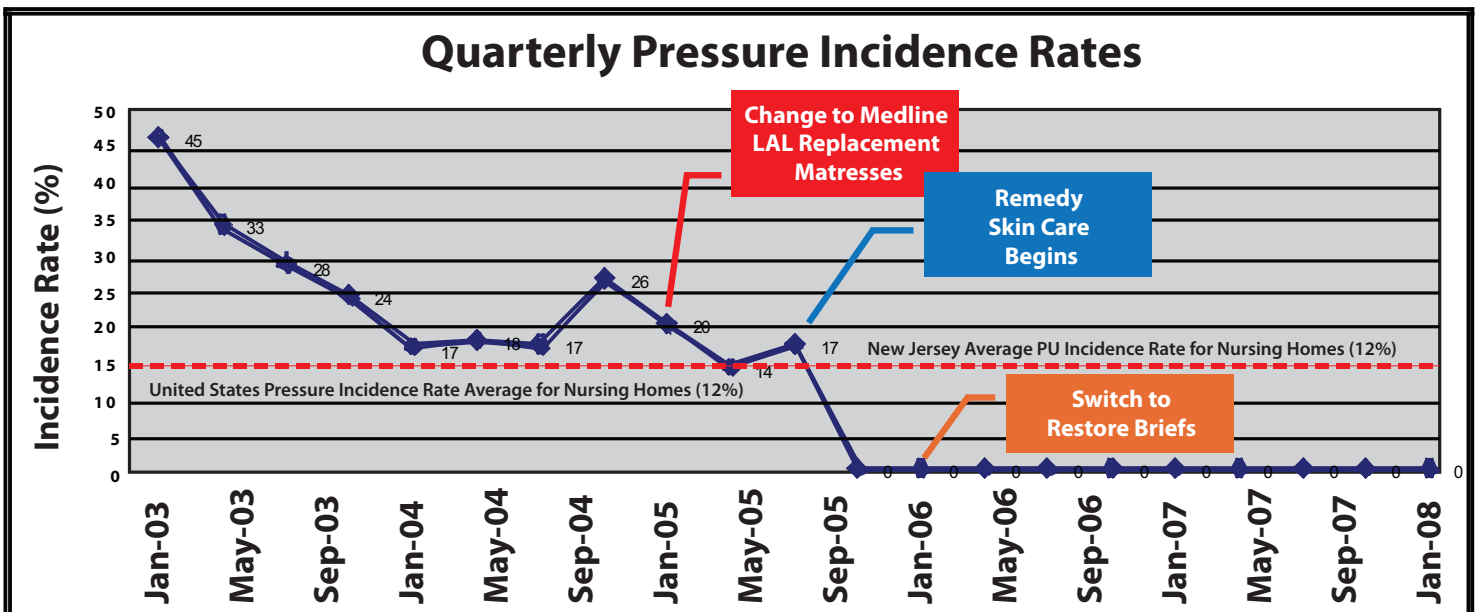
Pressure Ulcer Severity: A review of the MDS database realizes a chance of 39% that a pressure ulcer will form as a Stage 1 and 61% for greater than or equal to a Stage 2 when they have occurred in the New Jersey facility.

Cost of Pressure Ulcers: A normal distribution of costs for nursing home residents was determined from another study with nursing home residents. A sample of nursing home residents with pressure ulcers was used to evaluate the labor, pressure redistribution, dressing supplies, medications, nutritionals and skincare products consumed in treatment through healing or discharge from care. The distributions were developed using Best Fit software. (Figures 3 and 4)

Pressure Ulcer Incidence Rates

(Nursing Home Acquired): A time series analysis is provided to evaluate the incidence of pressure ulcers pre- and post-implementation of Remedy and Remedy/Restore. (Figure 2) There is a significant drop in the incidence rate after June 2005, when Remedy and subsequently Remedy/Restore briefs were placed in the clinical protocol. There were no changes in staffing or other components of preventative care.

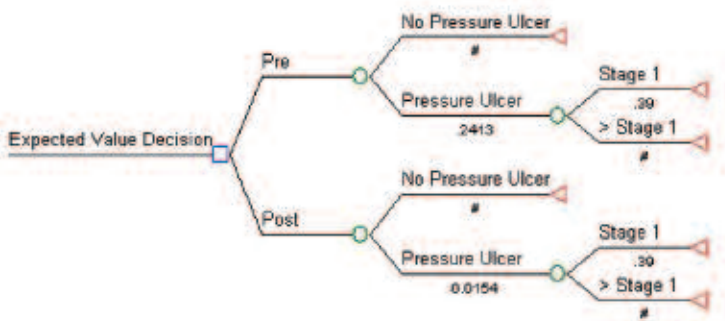
Figure 2



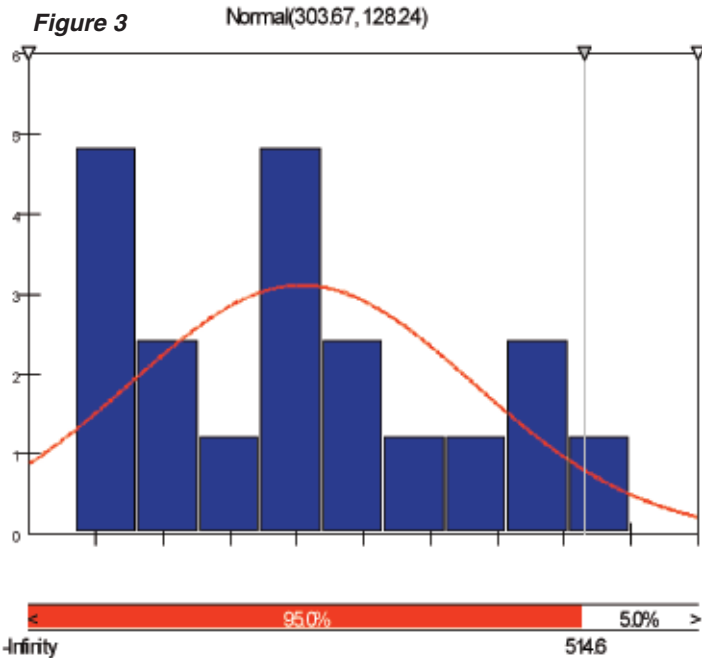
costing of IAD treatment in the facility revealed an approximate cost of \$102.00 for the resolution of the skin condition with Remedy skin repair, antifungal therapy, supplies and nursing labor.

Expected Value Analysis:

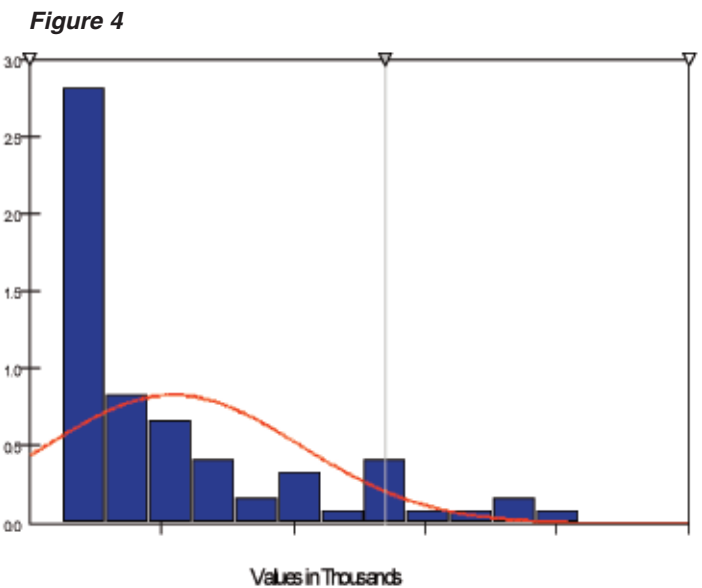
A. Reduction in Pressure Ulcer Treatment Costs:
 The expected value calculated from the decision analysis results in an \$828.00 gain per at-risk resident after implementing the Remedy skincare regimen and Remedy/Restore disposable briefs. This is expected savings, per at-risk resident, during their length of stay at Meridian Nursing and Rehabilitation Center from reduced labor, pressure redistribution, dressing supplies, medications, skincare products and nutritional supplements necessary for treating pressure ulcers. All treatment costs in the model represent labor and resources for the year 2007. The pressure ulcer model used is below:



Basic Pressure Ulcer Treatment Model



Skilled Nursing Facility Average Total Costs per Resident for Treatment of Stage 1 Pressure Ulcers (Normal Distribution)



Skilled Nursing Facility Total Costs for Treatment > Stage 1 Pressure Ulcers (Normal Distribution)

Retrospective Observational Analysis:

Nursing staff revealed their observations of incontinence-associated dermatitis (IAD) outcomes in a roundtable discussion. Prior to using Remedy and Remedy/Restore, one out of every three residents developed IAD. After June 2005, the rate of IAD dropped to one out of every 25 incontinent residents. This represents a significant change in outcome. A

The expected savings from reduced pressure ulcer treatment costs that could have been realized if the facility was using Remedy and Remedy/Restore prior to June 2005 is \$685,584.00. (Table 3)

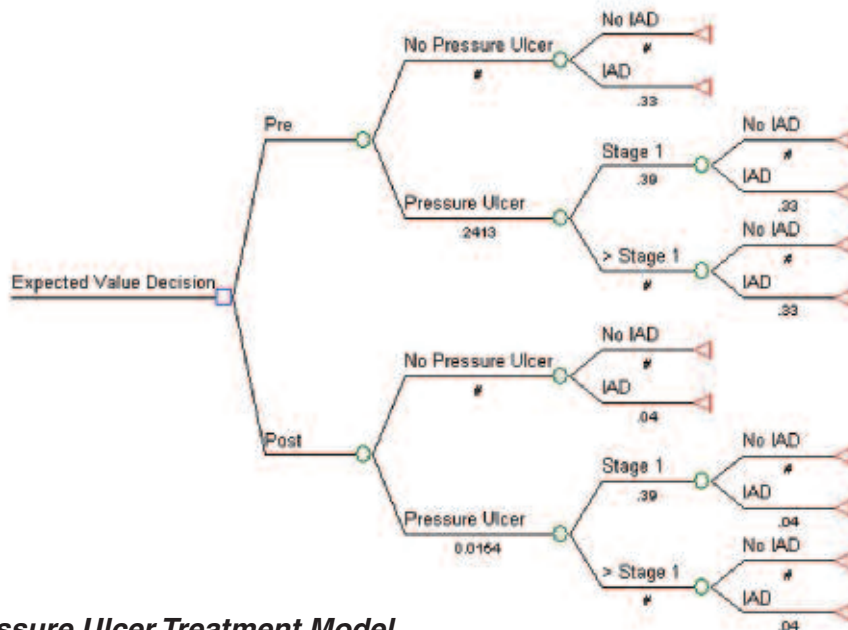
Table 3

	Apr 2003	July 2003	Oct 2003	Jan 2004	Apr 2004	July 2004	Oct 2004	Jan 2005	Apr 2005	Jul 2005
At-Risk Residents	79	84	89	76	85	83	81	91	101	59
X \$828.00	\$65,412	\$69,552	\$73,692	\$62,928	\$70,380	\$68,724	\$67,068	\$75,348	\$83,628	\$48,852
Total Expected Savings That Could Have Been Realized in Pressure Ulcer Treatment Costs										\$685,584

Cost Summary

B. Reduction in Incontinence-Associated Dermatitis:

IAD probabilities and treatment costs for Pre and Post periods were added to the pressure ulcer model to determine the benefit (gain) from a reduction in IAD as an additive effect to the expected value of pressure ulcers. The effect considers a reduction in IAD treatment costs related to at-risk residents but more so for incontinence. The addition to the model is below:



Expanded Pressure Ulcer Treatment Model

The expected value, considering treatment reductions from IAD, added a further gain of \$33.00 per at-risk resident to the expected value of \$828.00 for pressure ulcers alone. The gain is now \$861.00 per at-risk resident. (Table 4)

Table 4

	Apr 2003	July 2003	Oct 2003	Jan 2004	Apr 2004	July 2004	Oct 2004	Jan 2005	Apr 2005	Jul 2005
At-Risk Residents	79	84	89	76	85	83	81	91	101	59
X \$861.00	\$68,019	\$72,324	\$76,629	\$65,436	\$73,185	\$71,463	\$69,741	\$78,351	\$86,961	\$50,799
Total Expected Savings That Could Have Been Realized in Pressure Ulcer Treatment and IAD Costs										\$712,908

Expanded Cost Summary to Include IAD

Summary

Clearly, the nursing home has reduced the cost of treating nosocomial pressure ulcers after June 2005 as they have not occurred in any at-risk residents admitted to the facility since then. The correlation between entries of Remedy skincare therapy and Remedy/Restore briefs with pressure ulcer reduction is high, especially when their introduction was the only change made within the clinical prevention protocol over as many years evaluated. However, there was a change in pressure reduction mattresses from daily rental low-air-loss beds to purchasing replacement low-air-loss mattresses from Medline Industries, Inc. The change was made around December 2004. The incidence of pressure ulcers remained the same over the subsequent two quarters, giving indication that pressure reduction was not a factor for reducing the incidence rate. All at-risk residents had pressure relief using maximum types of pressure reduction systems. It does indicate that low-air-loss replacement mattresses would be more cost-effective than daily rental low-air-loss beds as an adjunct to pressure ulcer prevention.

We investigated the differences in risk for the cohorts studied and found no significant differences in resident variables that would predispose each group to higher or lower incidence rates. There was a high prevalence of incontinent patients, especially residents with daily episodes of bowel and bladder problems. The facility was already using pressure redistribution technology as an adjunct to preventing pressure ulcers. Clinical practice guidelines for care and prevention were followed by the institution. Everything being equal from the clinical guideline perspective, the obvious conclusion is that the resident's skin from consistent incontinence episodes was not being effectively managed with current products.

The main factor for pressure ulcer reduction in this evaluation was skin care using Remedy product therapy that highlights a silicone-based dermal nourishing emollient skin care regimen (SBDNE). In previous clinical research, the ability of this range of products to ameliorate skin conditions, for example in lymphedema-affected skin, ichthyotic skin and skin affected by poor lower limb circulation has been reported.¹³⁻¹⁵ The specialized nutrients, for example, modulate biochemical abnormalities associated with pruritus.¹³ The mechanism through which the SBDNE line prevents pressure ulcer formation is yet to be confirmed, though the capacity of the product range to keep skin moist and hydrated may have a major contributor effect.¹⁶ Local episodes of perfusion blockage and reperfusion are known to lead to an exuberant presence of reactive oxygen species and free radicals, which lead to below-the-surface tissue damage that might "open out" to pressure ulcer episodes.¹⁷⁻²⁰ It is possible that the antioxidant nature of potent anti-oxidative ingredients such as hydroxytyrosol prevent such reactive molecular species-related damage to tissue, leading to a lowering of pressure ulcer conditions and rates. In addition, the role of dimethyl sulfoxide (DMSO) in wound healing and as an anti-inflammatory drug has been probed.²¹ The SBDNE range contains methylsulfonylmethane, a close chemical relative to DMSO, and it is possible that a similar anti-inflammatory role, leading to pressure ulcer reduction, may be played by the methylsulfonylmethane molecule.

The Remedy/Restore disposable briefs were purchased by the facility starting in February 2006 (eight months after Remedy implementation). Because the pressure ulcer incidence rate was already zero, it was difficult to establish the correlation of the product with pressure ulcer reduction. The cumulative effect of Remedy skincare and the briefs appears to provide a solid combination in keeping the pressure ulcer

incidence rate and IAD prevalence rate consistently down in the facility. More work is necessary to determine the exact financial benefit that Remedy/Restore briefs add to the outcomes.

The expected value comparing Pre and Post periods of skincare and incontinence management gives a gain of \$861.00 per resident admitted to the facility and at-risk of pressure ulceration after June 2005.

The savings realized by the New Jersey center has allowed hiring of new nurses and implementation of special educational programs.

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