

**PRESSURE ULCER
PREDICTIVE STUDY
Long Term Case Study - 12 Months**

Outcomes

180 new patients were selected from 4 facility sites to follow and record outcomes for pressure ulcer development. Of the original 180 patients, 50 were released from the study due to attrition, leaving 130 net patient outcomes. These results were scored against the 835 patient training data with the following results:

From the 130 patients, using 10-fold cross validation data from 835 data set obtained clinically relevant results of NPV (95.59%); PPV (98.39%), sensitivity (95.31%), specificity (98.48%), percent accurately classified (96.92%) for pressure ulcer prediction for the 130 patients.

These results were statistically higher than would have been anticipated given the parameters of predictors in the training data. Further analysis of outcomes reveals the reasons for this phenomenon:

1. Although the 835 patient data was collected from 12 facility sites representing 10 separate acuity levels, where as The 130 patients in the long term study case were selected almost exclusively from long term care sub acute facility sites.
2. Data fitted – The long term care data subset represents 10.2% of the overall population for the 835 patients. Long term care data subset was 88% of the overall population for the 130 patient model. All long term care facilities in this subset had an overall pressure ulcer incidence of 21% to as much as 43%. This represents a higher incidence in this model than in the 835 patient set. Additionally, these patients fit the classic, traditional profile of at-risk patients, i.e., prolonged compromised health issues compounded with comorbid conditions such as end-of-life, neurologic and deteriorating mobility. This produces better accuracy in the smaller 130-patient model.
3. 130 population had 44% history of pressure ulcers versus a 13% history of pressure ulcers in the 835 training data population.

Conclusion

Research is ongoing, and the complexity of multiple variable entanglement demonstrates a need for even more specific predictive models to be created to express the variables cleanly through progressive model development and algorithm optimization. Results demonstrate a need to break down patient populations into separate acuity groups to develop more specific variables relevant to their needs.

With repeatable validation in large prospective series, these models could then be implemented in clinical setting for improved patient selection based on a patient's individual medical profile and specifically tailored to the level and breadth of their clinical acuity, which would lead to better quality of care for patients and optimization of resource allocation for healthcare facilities.

OVERVIEW	
Breakdown	Totals
Initial patients followed in group - no wounds	180
Patient attrition from initial group	50
Patients left from initial group - no wounds	130
Number of patients developed pressure ulcers from initial group of 130	64
Number of facilities	4
Acuity levels	2
Number of risk assess questions	37
Percent of questions used from original risk assess in training data	19.5%
Number of medical categories	16

MODEL RESULTS

Predictive model was applied to 130 patients in a long term case study.

These 130 patients were not part of the model training data. On these patients the model had:

**Accuracy 96.92%
Misclassified 3.08%**

RISK ASSESSMENT QUESTIONS		
Category	# of Questions	% of Total
General Info (Vital Signs)	8	22%
Cognitive	2	5.4%
Mobility/Ambulation	7	19%
Nutrition/Hydration	2	5.4%
Incontinence/Moisture	4	11%
General Medical	14	38%
TOTAL	37	

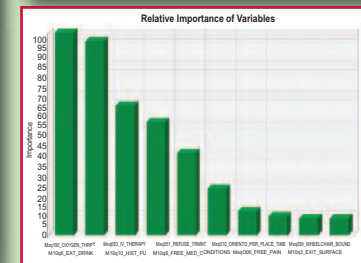
MODEL RESULTS	
Scored Date of 130 Patients	% Values
Sensitivity	95.31%
Specificity	98.48%
Positive Predictive Value (PPV)	98.39%
Negative Predictive Value (NPV)	95.59%
Percent Accurately Classified	96.92%
False Positive Rate	1.52%
False Negative Rate	4.69%

CONFUSION MATRIX

LONG TERM CASE STUDY OUTCOMES			
		Predicted Category	Predicted Category
		0	1
Actual	0:	65	1
Actual	1:	3	61

MODEL ACCURACY

LONG TERM CASE STUDY OUTCOMES			
Category	# of Patients	Misclassified	Percentage
No Ulcer	66	1	1.52%
Ulcer	64	3	4.69%
Total	130	4	3.08%



Utilizing Predictive Models for Evaluation of a Patient Medical Profile to Predict an Individual Pressure Ulcer Risk Assessment

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History of Problem

According to the Centers for Medicare and Medicaid, industry experts, government agencies, healthcare advocacy groups, and various research institutions:

- 1 million people develop pressure ulcers every year
- Total annual cost for treating pressure ulcers in the US is estimated between 1.3 billion and \$11 billion.
- 2.5 million patients being treated for pressure ulcers in US acute care facilities annually
- Pressure ulcer incidence rates vary considerably by clinical setting — ranging from:
 - 0.4 percent to 38 percent in acute care
 - 2.2 percent to 23.9 percent in long-term care
 - 0 percent to 17 percent in home care
- Pressure ulcers can increase a patient's acuity and hospital stay, and cause an estimated 60,000 patient deaths annually from related complications

Complexity of Problem

Considering the depth, breadth and enormous number of dynamic variables in play in medical situations where patients' health is compromised by one or more factors, and where pressure ulcers are concerned, the complexity of sorting through all the variables is daunting. Data information collected has multiple attributes and is obtained from multiple data sources across several facility sites with several acuity levels and within multiple time series. This study focuses on how multi-source, multi-attribute information about pressure ulcers is integrated and how the data information for the situation was fitted, and hence a solution can be extrapolated. This approach can assess the patient's individual medical situation through integrating obtained information and analyzing all related data sources.

In practice, clinical judgment exercised by a clinician in the choice of treatment for an individual patient is based to an extent on theoretical considerations derived from an understanding of the nature of the illness. But it is based also on an appreciation of statistical information about diagnosis, treatment and prognosis acquired either through personal experience or through medical education. The important argument is whether such information should be stored in a rather informal way in the clinician's mind, or whether it should be collected and reported in a systemic way. No clinician – no matter how thorough and intelligent they may be – has the ability to acquire by personal experience, enough factual information over the entire range of medicine to be able to do what can be done with technology and statistical models. And it is partly by the collection, analysis and reporting of statistical information that a common body of knowledge is built and solidified. The truth is that the amount of on-hand knowledge needed in order to deliver appropriate care and treatment has become so vast that even highly specialized clinicians have trouble keeping current with new information germane to their professional area of focus.

Former Secretary of the Department of Health and Human Resources Tommy Thompson stated the problem succinctly in 2003: "One of our challenges is the explosion of new knowledge resulting from research, which has surpassed the ability of individual practitioners to absorb and apply it while actually delivering care. This knowledge is only as useful as the ability of a provider to remember it when it really matters."8 In other words, no matter how good a physician or clinician is, the vast expanse of medical knowledge is just not readily available at bedside. At a first glance, many studies and projects initiated, funded, endorsed and encouraged by the government appear to have been fairly fruitful, as evidenced in the abundance of research and burgeoning technology. Many hospitals, in particular, boast wonderful new electronic data transfer methods and highly technological methods of treatment. But there is still that difficult gaping chasm that needs to be bridged: Bring it to the point of care; those few face-to-face minutes where a clinician needs to quickly use all available medical information to make a critical determination of the direction of care for their patient who is counting on them to do it right.

Harnessing all this data for instant care planning and on-the-spot diagnosis will take a Herculean effort and all the muscle of today's latest technology. Too much information, too much data, and no reasonable way to deliver answers to the bedside of the patient in a manageable, quick and accurate way is still a considerable problem. Compounding this care delivery issue are the following issues inherent to healthcare:

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|--|--|---|--|
| <p>Patient factors:</p> <ol style="list-style-type: none"> 1. Ever changing patient status 2. Varying clinical settings 3. Patient acuity complexity | <p>Personnel factors:</p> <ol style="list-style-type: none"> 1. Level of clinical expertise 2. Flux of individual clinician judgment (subjective observation) 3. Staffing shortages 4. High turnover rates 5. Increasing workloads | <p>Facility factors:</p> <ol style="list-style-type: none"> 1. Mushrooming cost of care 2. Shrinking finances 3. Lack of standardized continuum of care across healthcare acuity spectrum | <p>Technology factors:</p> <ol style="list-style-type: none"> 1. Limited access to clinical informatics 2. Limited understanding of how to use new technology |
|--|--|---|--|

Even the vast amounts of data being collected through the healthcare system -- which could provide facilities with some pathway to reaching out ahead of the problems with accurate risk assessments and preventative care -- is falling short in application. If clinicians don't have sensitive enough assessment tools, they cannot accurately assess a patient's care/treatment needs in a timely manner, resulting in a failure to match up patient acuity levels with accurate reimbursement. This is the very essence of the healthcare crisis.

Existing risk assessment tools are inadequate because they only use sums ($V1 + V2 + V3 = Sv$) of the variable without taking into account the interaction of all the variables and how their weights factor in to the outcome of the Sum ($V1*V2*V3*V4*V5*V6, ... = Sv$) in part because they were developed years ago and do not utilize current technology. These tools have many limitations, including the following:

1. They usually weight each risk factor equally, when in fact certain responses are far more predictive of risk.
2. They do not capture resident history, e.g., the cumulative effects of chronic conditions and diagnoses that contribute to risk.
3. They fail to weigh interactions of smaller risk factors that add up to high risk.
4. They fail to account for non-linear relationships between predictors and outcomes.

In this time of diminishing healthcare dollars available to apply to each healthcare need, precision tuning of the system that officiates that process – the risk assessment – is critical. When it comes to accurately matching acuity levels with reimbursement dollars, the healthcare industry is in need of an instant, point-of-care, highly specific and sensitive risk assessment.

Utilizing Predictive Models for Evaluation of a Patient Medical Profile to Predict an Individual Pressure Ulcer Risk Assessment

GATHERING DATA Training Data 835 Patients

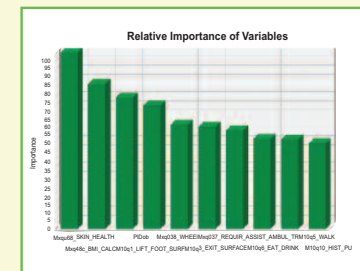
Objective

The objective of this study is the exploration of progressive predictive model development for optimizing accuracy of a pressure ulcer risk assessment. Data collected was utilized for generation of training data from predictive models (PM) using a large representative healthcare population. Training data was collected and then utilized to evaluate subset individual medical profiles (records) for determining risk for developing a pressure ulcer (PU).

Methodology

Expert medical information already has several strong clinical indicators that currently trigger preventative care plans. Data was collected using a comprehensive spectrum of variables (questions) developed from this established knowledge. Clinicopathological data that was tracked was divided into categories: demographics, mobility, nutrition, continence, cognition and general medical. This data was collected across a population of 835 subjects. Subjects resided in 10 subset healthcare facility types: Long Term Care, Sub acute Care, Bariatric Hospital, Assisted Living, Post Acute Care, Wound Care Clinic, and Hospice. Study subjects were formally consented into the research, subjects were followed, and outcomes were charted under the 2-year approval of the Western Institutional Review Board.

RISK ASSESSMENT QUESTIONS		
Category	# of Questions	% of Total
General Info (Vital Signs)	8	4.2%
General Info (Demographics)	20	10.6%
Cognitive	12	6.4%
Mobility/Ambulation	13	6.9%
Nutrition/Hydration	14	7.5%
Incontinence/Moisture	12	6.5%
General Medical Subcategories		
Integumentary	9	4.8%
Cardio	17	9%
Respiratory	7	3.7%
Gastrointestinal	6	3.2%
Genitourinary	5	2.6%
Musculoskeletal	16	8.5%
Neurologic	21	11.1%
Endocrine	5	2.6%
Hematology	7	3.7%
Medications	17	9%
TOTAL Gen. Med. Category	110	58.2%



DATA	
Breakdown	Totals
Patients	835
Acuity Levels	7
Number of Facilities	11
Number of Risk Assess Questions	189
Number of Wound Assess Questions	27
Number of Medical Categories	16
Number Wound Differential Categories	4

WOUND ASSESSMENT QUESTIONS		
Category	# of Questions	% of Total
Wound Location	2	7.4%
Wound Description	16	59.3%
Suspected DTI	6	22.2%
Closed Wound	3	11.1%
TOTAL Gen. Med. Category	27	100%

FACILITIES		
Acuity Levels	# of Patients	% of Patients
Long Term Care	85 (10.2%)	90 (69.23%)
Sub Acute Care	104 (12.5%)	40 (30.8%)
Bariatric Center	39 (4.5%)	0
Assisted Living	128 (15.3%)	0
Post Acute Care	312 (37.4%)	0
Wound Clinic	34 (4.1%)	0
Hospice	133 (15.9%)	0
TOTAL	835	130

MODEL DEVELOPMENT Ulcer Probability Predictive Model

Predictive Modeling

Modeling is a comparatively new area of activity involving the marriage of ideas from various disciplines, and is an essential and inseparable part of all scientific activity. Any system starts with a problem domain and a conceptual model of how to execute a solution.

Scientific modeling is the process of generating abstract, conceptual, graphical and or mathematical models in a logical rubric designed to direct an acceptable outcome. Science offers a growing collection of methods, techniques and theory about all kinds of specialized scientific modeling, many of which can be applied to medical situations.

Ideally these refined models will be implemented into a system that will give clinicians the freedom and confidence to authorize treatment to their individual patient needs under the art of medicine, as well as satisfy the implementation of data with the powerful application of mathematics/statistics. The solution may lie in enhanced risk tools in the form of an intelligent system that allows clinicians the freedom to apply their considerable skills in combination with the power of accurate and current predictive models.

Accurate and quick clinical application of data could be a powerful tool and could result in measurable improvement in the quality of life, the length of life, lower mortality rates and lower and more precise and relevant reimbursement costs to the government.

Finally, where the individual patient is concerned, validation in large prospective series, these models could then be implemented in clinical setting for improved patient selection based on a patient's individual medical profile and specifically tailored to the level and breadth of their clinical acuity, which would lead to better quality of care for patients and optimization of resource allocation for healthcare facilities.

Predictive models for this study were composed from the 835 patient data. Training data was created and fitted to a random subset of 180 patients, from which 30 patient subjects were released from the study, leaving 130 patient subjects with results. These 130 patients were from four facility populations, three longterm care and one sub acute care, for data validation.

Predictive models created were built with the aim of examining negative predictive value (NPV), positive predictor value (PPV), sensitivity and specificity. The 10-fold cross-validation of predictors in the 835 patient population obtained results of: NPV (88.39% - 97.59%); PPV (79.94% - 98.78%), sensitivity (82.83% - 97.59%), specificity (86.28% - 99.20%), with percentages reflective of validation data and training data respectively.

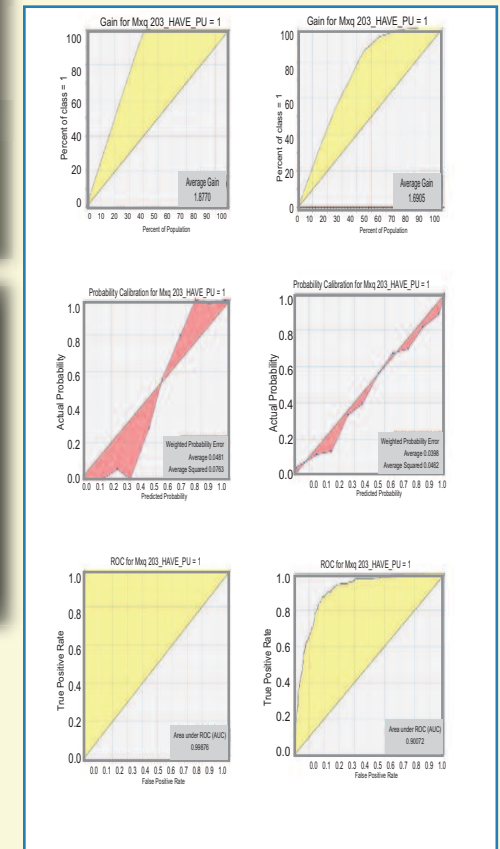
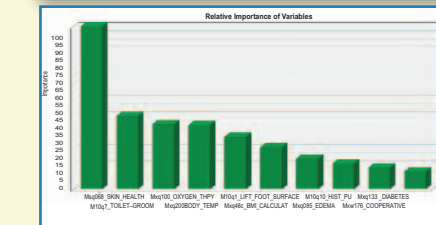
MODEL ACCURACY			
TRAINING DATA			
Category	# of Patients	Misclassified	Percentage
No Ulcer	503	4	0.79%
Ulcer	332	8	2.41%
Total	835	12	1.44%
10-Fold CROSS-VALIDATION DATA			
Category	# of Patients	Misclassified	Percentage
No Ulcer	503	69	13.72%
Ulcer	332	57	17.17%
Total	835	126	15.10%

DATA	
Training Data	Values
Sensitivity	97.59%
Specificity	99.20%
Geometric mean of sensitivity & specificity	98.39%
Positive Predictive Value (PPV)	98.78%
Negative Predictive Value (NPV)	98.42%
Geometric mean of PPV & NPV	98.60%
Avg. weighted probability error	0.048128

Cross-Validation Data	Values
Sensitivity	82.83%
Specificity	86.28%
Geometric mean of sensitivity & specificity	84.54%
Positive Predictive Value (PPV)	79.94%
Negative Predictive Value (NPV)	88.39%
Geometric mean of PPV & NPV	84.06%
Avg. weighted probability error	0.066895

CONFUSION MATRIX			
TRAINING DATA			
		Predicted Category 0	Predicted Category 1
Actual	0:	499 (59.76%)	4 (0.48%)
	1:	8 (0.96%)	324 (38.80%)
VALIDATION DATA			
		Predicted Category 0	Predicted Category 1
Actual	0:	434 (51.98%)	69 (8.26%)
	1:	57 (6.84%)	275 (32.94%)

MODELS	
Predictive Model Development	
Problem Domain: Does patient develop pressure ulcer	
Processes Utilized	
<ul style="list-style-type: none"> Data was fitted Statistic relationship to target Expert knowledge of problem Ran over 350 various predictive models Found over 60 viable predictive models to problem domain solution Lift/Gain was analyzed Progressive predictive models 	
Predictive Models Explored	
<ul style="list-style-type: none"> Decision Trees TreeBoost Decision Tree Forests Multilayer Perceptron Neural Networks Probabilistic Neural Networks Support Vector Machine (SVM) Concept Model Linear Regression 	



REFERENCES

[1] Institute for Healthcare Improvement (IHI), "Relieve the Pressure and Reduce Harm", <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethethePressureandReduceHarm.htm> [2] Lyder CH. "Pressure ulcer prevention and management" JAMA 2003;289(2)223-226. [3] Jie Lu a, Xiaowei Yang a,b, Guangquan Zhang: Support vector machine-based multi-source multi-attribute information integration for situation assessment; Expert Systems with Applications 34 (2008) 1333-1340 [4] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), governmental policies and procedures for pressure ulcer identification, treatment and reporting. November 12, 2004 Transmittal #4, Appendix PP, Tag 314, Tag 309, Current Guidelines to Surveyors, CMS requires 483.25 © Pressure Sore. [5] The National Pressure Ulcer Advisory Panel (NPUAP) nationally recognized panel of experts who serve as the authoritative voice for improved patient outcomes in pressure ulcer prevention and treatment through public policy, education and research. [6] Braden Scale; "Prevention Plus" The purpose of Prevention Plus, LLC, is to provide services and products related to the Braden Scale for Predicting Pressure Sore Risk© and evidence-based programs of pressure ulcer prevention. [7] Christie Teigland, Richard Gardiner, Hailing Li, Colene Byrne; "Clinical Informatics and Its Usefulness for Assessing Risk and Preventing Falls and Pressure Ulcers in Nursing Home Environments"; March 2007, AHRQ[8] Brandeis, G., Berlowitz D., Hossain M., Morris J. Pressure Ulcers: The Minimum Data Set and the Resident Assessment Protocol, Advances in Wound Care; Nov/Dec 1995, Vol. 8 No. 6 [9] P. Armitage, Geoffrey Berry, J. N. S. Matthews: Statistical Methods in Medical Research, Published by Blackwell Publishing, 2001, p1,2.