



The cost-effectiveness of prevention strategies for pressure ulcers in long-term care homes in Ontario: Projections of the Ontario Pressure Ulcer Model

FINAL REPORT

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Contents

ACKNOWLEDGEMENTS	I		
CONTENTS	I		
LIST OF ABBREVIATIONS	III		
LIST OF ABBREVIATIONS (CONTINUED)	IV		
EXECUTIVE SUMMARY	V		
BACKGROUND.....	v		
OBJECTIVES	v		
METHODS.....	v		
RESULTS	vi		
<i>Strategies supported by high quality evidence.</i>	<i>vi</i>		
<i>Strategies supported by moderate quality evidence</i>	<i>vii</i>		
<i>Strategies supported by low quality evidence.</i>	<i>vii</i>		
CONCLUSION.....	viii		
CHAPTER 1: INTRODUCTION.....	1		
CHAPTER 2: NATURAL HISTORY MODEL OF PRESSURE ULCER.....	3		
INTRODUCTION	3		
METHODS.....	3		
<i>Model Population</i>	3		
<i>Outcome Measures</i>	3		
<i>Model structure</i>	3		
<i>Data Sources</i>	7		
<i>Model parameters</i>	8		
<i>Model calibration</i>	11		
<i>Model predictions</i>	11		
RESULTS	12		
CHAPTER 3: STANDARD CARE	18		
INTRODUCTION	18		
METHODS.....	18		
RESULTS	18		
<i>Size and type of facility</i>	18		
<i>Staffing ratios</i>	19		
<i>Wound care teams</i>	19		
<i>Mattresses</i>	19		
<i>Repositioning programs</i>	19		
<i>Nutritional supplements</i>	20		
<i>Incontinence care</i>	20		
<i>Wound care protocols</i>	20		
<i>Pressure Ulcer Statistics</i>	20		
CHAPTER 4: STRATEGY IDENTIFICATION...21			
INTRODUCTION	21		
METHODS.....	21		
<i>Registered nurse time increase</i>	21		
RESULTS	22		
<i>Strategy 1: Alternative Foam (AF) mattress</i> ...22			
<i>Strategy 2: AF mattress and 4-hourly turning/repositioning schedules</i>22			
<i>Strategy 3: Nutritional supplementation</i>26			
<i>Strategy 4: Skin care protocols for urinary/fecal incontinence</i>	26		
<i>Strategy 5: Registered nurse time increase</i>26			
CHAPTER 5: COSTING	32		
INTRODUCTION	32		
STANDARD CARE.....	32		
<i>MDS cohort and risk stratification</i>	32		
<i>Nursing and personal care</i>	32		
<i>Physician visits</i>	33		
<i>Emergency Department (ED) visits</i>	33		
<i>Drug, laboratory and diagnostics</i>	33		
<i>Hospitalizations</i>	34		
<i>Summary</i>	34		
STRATEGY 1: ALTERNATIVE FOAM MATTRESS	38		
<i>Standard care</i>	38		
<i>Intervention</i>	38		
<i>Resource use and costs</i>	38		
STRATEGY 2: ALTERNATIVE FOAM MATTRESS AND 4-HOURLY TURNING/REPOSITIONING	38		
<i>Standard care</i>	38		
<i>Intervention</i>	39		
<i>Resource use and costs</i>	39		
STRATEGY 3: NUTRITIONAL SUPPLEMENTATION	39		
<i>Background</i>	39		
<i>Standard care</i>	39		
<i>Supplements currently in use</i>	40		
<i>Intervention</i>	40		
<i>Resource use and costs</i>	41		
STRATEGY 4: SKIN CARE PROTOCOLS FOR INCONTINENCE CARE	43		
<i>Standard care</i>	43		
<i>Intervention</i>	43		
<i>Resource use and costs</i>	43		
STRATEGY 5: REGISTERED NURSE TIME INCREASE	44		

<i>Background</i>	44	<i>Univariate sensitivity analysis</i>	59
<i>Staffing</i>	44	<i>Probabilistic sensitivity analysis</i>	59
<i>Nursing hours per resident per day</i>	45	SUMMARY.....	60
<i>Standard care</i>	45	CHAPTER 8: BUDGET AND HEALTH	
<i>Intervention</i>	45	IMPACT ANALYSIS.....	68
<i>Resource use and costs</i>	45	INTRODUCTION.....	68
CHAPTER 6: HEALTH-RELATED QUALITY		METHODS.....	68
OF LIFE.....	48	<i>STEP 1: Estimate the number of residents in</i>	
INTRODUCTION.....	48	<i>long-term care homes in Ontario</i>	69
METHODS.....	48	<i>STEP 2: Estimate the proportion of LTC</i>	
<i>Setting and population</i>	48	<i>residents targeted by each strategy</i>	69
<i>Data sources</i>	48	<i>STEP 3: Estimate the implementation budget</i>	
<i>Risk of pressure ulcer</i>	49	<i>for each of the prevention strategies</i>	70
RESULTS.....	49	<i>STEP 4: Estimate the total cost for each</i>	
DISCUSSION.....	49	<i>strategy</i>	71
CHAPTER 7: COST-EFFECTIVENESS AND		<i>STEP 5: Estimate the total cost in the absence</i>	
COST-UTILITY ANALYSIS.....	51	<i>of pressure ulcer for each strategy</i>	71
INTRODUCTION.....	51	<i>STEP 6: Estimate the pressure ulcer -related</i>	
METHODS.....	51	<i>cost for each strategy</i>	71
<i>Perspective</i>	51	<i>STEP 7: Estimate the pressure ulcer -related</i>	
<i>Time horizon</i>	51	<i>health impact for each strategy</i>	71
<i>Comparators</i>	51	RESULTS.....	71
<i>Target population</i>	51	<i>Health impact analysis</i>	71
<i>Outcome measures</i>	51	<i>Budget impact analysis</i>	72
<i>Model parameters</i>	52	CHAPTER 9: DISCUSSION.....	77
<i>Utility</i>	52	REFERENCES.....	80
<i>Modeling</i>	53	APPENDIX A:.....	86
<i>Analysis</i>	53	<i>National Pressure Ulcer Advisory Panel</i>	
<i>Expected value calculation</i>	53	<i>(NPUAP) revised classification of pressure</i>	
<i>One-way sensitivity analysis</i>	53	<i>ulcer stage</i>	86
<i>Probabilistic sensitivity analysis</i>	56	APPENDIX B:.....	87
<i>Cost-effectiveness acceptability curve</i>	56	<i>Search strategy identifying articles relevant to</i>	
RESULTS.....	56	<i>staffing ratios/time</i>	87
<i>Health outcomes</i>	56		
<i>Costs and Cost-Effectiveness</i>	59		
<i>Scenario-based sensitivity analysis</i>	59		

List of Abbreviations

ADL	Activities of Daily Living	HINF	High Intensity Needs Fund
AF	alternate foam	HRPD	hours per resident per day
AHCPR	Panel for the Prediction and Prevention of Pressure Ulcers in Adults	HRQOL	health-related quality of life
		HUI	Health Utilities Index
BIA	budget impact analysis	ICER	incremental cost-effectiveness ratio
CAD	Canadian dollars		
CAET	Canadian Association of Enterostomal Therapists	LHIN	Local Health Integration Network
		LPN	licensed practical nurse
CAP	Clinical Assessment Protocol	LTC	long-term care
CEA	cost-effectiveness analysis	LY	life year
CI	confidence intervals	MAS	Medical Advisory Secretariat
CIHI-DAD	Canadian Institute of Health Information Hospital Discharge Abstracts Database	MDS	Minimum Data Set
		MDS-HSI	Minimum Data Set Health Status Index
CMI	case mix index		
DAD	Discharge Abstract Database	MOHLTC	Ministry of Health and Long-Term Care
DOC	Director of Care		
		NBM	Net Monetary Benefit
ED	emergency department	NPUAP	North American National Pressure Ulcer Advisory Panel
EPUAP	European Pressure Ulcer Advisory Panel		
		NPULS	National Pressure Ulcer Long-Term Care Study
ET	enterostomal therapist		
GTA	Greater Toronto Area	OD	odds ratio

List of Abbreviations (continued)

OHIP	Ontario Health Insurance Plan	THETA	Toronto Health Economics and Technology Assessment Collaborative
OLTCA	Ontario Long Term Care Association		
ONS	oral nutritional supplementation	VE	viscoelastic foam
		WTP	willingness-to-pay
OPUM	Ontario Pressure Ulcer Model		
OSCAR	Online, Survey, Certification, and Reporting System		
PSW	personal support worker		
PRPD	per resident per day		
PU	pressure ulcer		
QALY	quality-adjusted life year		
RAS	Risk Assessment Scale		
RCT	randomized controlled trial		
RN	registered nurse		
RNAO	Registered Nurses Association of Ontario		
RPN	registered practical nurse		
RPNAO	Registered Practical Nurses Association of Ontario		
RR	relative risk		
SD	standard deviation		

Executive Summary

Background

Pressure ulcers (PUs), commonly known as bedsores, are lesions caused by many factors such as unrelieved pressure over bony prominences, friction, humidity, and shearing forces to any part of the body. PUs are common among residents of long-term care (LTC) homes in Ontario.

Although treatable if found early, PUs can become life-threatening, and in rare instances, lead to fatal infections. PUs impose a significant health and economic burden, costing the Canadian health care system approximately \$2.1 billion annually.

In Ontario, it is estimated that approximately 57,000 (62%) residents of 613 LTC homes are at risk of developing PUs. While several prevention strategies are available, the cost-effectiveness of potential strategies is unclear.

This report was prepared to advise the Ontario Ministry of Health and Long-Term Care (MOHLTC) through the Medical Advisory Secretariat (MAS) on the cost-effectiveness of provincial implementation of pressure ulcer (PU) prevention strategies. The report was prepared in conjunction with a systematic review of PU prevention strategies undertaken by MAS.

Objectives

- To examine the economic attractiveness of evidence-based prevention strategies to reduce the burden of PUs in Ontario.
- To estimate the budget impact and other health system implications related to the

implementation of cost-effective prevention strategies for PUs.

Methods

Decision analytic modeling was used to address the objectives. The study required developing a natural history model of PUs, assessing current standard care, determining evidence-based best practice interventions, and estimating the cost and health impact of moving from current to best preventive care practice for PUs in LTC homes in Ontario. Specific inputs to the decision model included:

1. A 52-state Markov model of the natural history of PU in LTC residents using clinical insight derived from an expert panel, literature review, and epidemiologic data describing the natural history of PUs in 91 Ontario LTC homes housing 18,891 residents.
2. A survey of selected LTC homes in Ontario was conducted in order to determine current standard care.
3. Data on the efficacy of selected prevention and treatment strategies were obtained from the systematic review by MAS.

The following prevention strategies for PU were compared to standard care:

STRATEGY 1: Alternate foam (AF) mattress: replacing standard mattresses with an AF mattress only where such mattresses are not currently in use. Currently, 46% of the LTC residents in Ontario are already using AF mattresses. Thus, AF mattresses are targeted to 54% of LTC residents using standard mattresses in Ontario.

STRATEGY 2: AF mattress and 4-hourly turning/repositioning: replacing standard mattresses with an AF mattress and introducing a 4-hourly turning/repositioning program among LTC residents with mobility deficits who are at high risk of developing PUs and not currently on a 4-hourly turning/repositioning schedule. As noted for strategy 1, 46% of beds in LTC homes in Ontario are already equipped with AF mattresses, and as a result, the proportion of residents targeted for AF mattresses is 54%. The proportion of immobile residents at high risk of developing PUs is approximately 62% and among these residents, the proportion and turning frequency according to current standard care are uncertain. Preliminary data suggest that up to 75% of these residents need to be targeted to receive turning/repositioning.

STRATEGY 3: Nutritional supplementation: daily multinutrient supplementation among LTC residents with nutritional deficits who are at high risk of developing PUs not currently receiving nutritional supplements. The proportion of malnourished residents at high risk for developing PUs is 9.7%, and currently 40% of these residents are receiving nutritional supplementation. The proportion of malnourished residents at high risk of PU targeted by this strategy is 60%.

STRATEGY 4: Skin care protocol for incontinence: daily skin assessment and use of skin cleansers and barrier creams for residents with urinary or fecal incontinence who are at high risk of developing PUs and not receiving skin care for incontinence. The proportion of residents with urinary or fecal incontinence is 72%, and currently 50% are treated with a skin care protocol. The proportion of residents with urinary or fecal incontinence targeted by this strategy is 50%.

STRATEGY 5: Registered nurse (RN) staff time increase (RN time increase): an additional 20 minutes (from 0.27 hours to 0.58 hours) per

resident per day (PRPD) of RN time for residents who are at high risk of developing PUs. The proportion of residents in LTC homes that are at high risk for developing PUs is 62%, and currently none of these residents receives 0.58 hours of RN time per day. The proportion of residents at high risk for developing PUs targeted by this strategy is 100%.

The clinical effects of prevention strategies, lifetime costs, cost-effectiveness, and cost-utility of each strategy were estimated.

An economic and health impact model was developed in order to estimate the 5-year budget and health consequences of using strategies for preventing PUs in all residents of LTC homes in Ontario, Canada.

Results

Strategies supported by high quality evidence

The AF mattress strategy showed a reduction in the incidence of new PUs by 69%, based on data from four randomized controlled trials (RCTs). Compared to standard care, this strategy increases average lifetime costs by \$80 per person (Canadian dollars, discounted) and increases quality-adjusted life years (QALYs) by 0.0127 per person (discounted) (Table I). This strategy is economically attractive, with an incremental cost of \$6,328 per quality adjusted life year gained. Implementing this strategy for 48,600 eligible residents would cost approximately \$22 million in the first year (i.e., one time implementation cost for this strategy for an estimated average life-span of 7 years per AF mattress) (Table I). Although not cost saving overall, it is associated with estimated PU-related savings of 17.3 million per year, averting approximately 3,000 cases of new PUs, and 173 QALY gains each year.

Strategies supported by moderate quality evidence

The AF mattress and turning/repositioning 4-hourly strategy reduces new PUs by 79%, based on data from one RCT. Compared to standard care, this strategy also increases the average lifetime costs by \$74 per person (discounted) and increases QALYs by 0.0142 per person (discounted) (Table I). Implementing this strategy for 48,600 eligible residents would cost approximately \$22 million in the first year. (i.e., the same implementation cost as for AF mattress alone). This strategy reduces PU incidence by 79%. It is also an attractive strategy relative to standard care, and is associated with PU-related cost savings of \$19.7 million per year, preventing approximately 3,300 cases of new PUs and increasing 192 QALYs each year. It could become a dominant strategy (i.e., health gains and cost saving) if staffing time reduction associated with the 4 hourly turning / repositioning schedule is realized. This realization is however contingent upon better understanding of current turning frequency in current practice.

Nutritional supplementation for residents at high risk of PU with nutritional deficits reduces new PUs by 16%, based on data from four RCTs. Compared to standard care, this strategy increases average lifetime costs by \$194 per person (discounted) and increases QALYs by 0.0002 per person (discounted) (Table I). Implementing this strategy for 3,000 eligible residents would cost approximately \$9.4 million per year.

Strategies supported by low quality evidence

Skin care protocols for residents at high risk of PU with fecal/urinary incontinence reduce new PUs by 64%, based on data from one study. Compared to standard care, this strategy increases average lifetime costs by \$1,329 per person (discounted) and increases QALYs by 0.0046 per person (discounted) (Table I). Implementing this strategy for 20,000 eligible residents would cost approximately \$65 million per year.

Increased RN time for residents at high risk of PUs reduces new PUs by 84% based on data from a large cohort study including 1,300 residents from the US. Compared to standard care, this strategy also increases average lifetime costs by \$4,448 per person (discounted) and increases QALYs by 0.0165 per person (discounted) (Table I). Implementing this strategy for 56,000 eligible residents would cost approximately \$198 million per year.

All prevention strategies reduced the burden of disease associated with PU, with the greatest reductions observed with the RN time increase strategy and the AF mattress and 4-hourly turning/repositioning strategy compared to standard care. With these strategies, the lifetime risk of PU was reduced by approximately 25-30% in relative terms and 13-15% in absolute terms, from approximately 50% to approximately 36%.

In pairwise comparisons with standard care, AF mattress (with or without 4-hourly turning/repositioning protocols) strategies were shown to be economically attractive although not cost saving. In one-way sensitivity analysis across the plausible ranges of input variables, only AF and 4-hourly turning/repositioning strategy was considered dominant over standard care for producing lower costs and higher benefits.

In multi-way (probabilistic) sensitivity analysis, the certainty that AF mattress (with or without turning/repositioning) strategies were economically attractive was moderate (approximately 65%). It was highly unlikely that any of the remaining strategies would be economically attractive.

Conclusion

The clinical evidence and cost-effectiveness data suggests that some of the prevention strategies considered above lead to substantial improvement in health compared to standard care in LTC homes across Ontario. The prevention strategies with AF mattresses with or without 4-hourly turning/repositioning were somewhat attractive, and were supported by moderate to high quality evidence. These two strategies are economically attractive at an incremental cost-effectiveness ratio (ICER) below \$50,000 per QALY gained. In addition, they were associated with lower implementation costs compared to other alternatives. Nutritional supplementation, skin care protocol, and RN time increase strategies cannot be considered cost-effective under the conventional threshold of \$50,000 per QALY.

The clinical and economic evidence supports implementation of AF mattresses in LTC homes in Ontario. Reducing the frequency of turning to 4 hourly intervals, in conjunction with implementation of AF mattresses also appears to be economically attractive, but significant uncertainty remains regarding the clinical equivalence of 2-hourly and 4-hourly turning in high risk groups. However, because of the potential for very significant impacts on labor requirements for long-term care facilities (i.e., potential cost savings, or potential allocation of work-time to other effective interventions), this strategy should be evaluated in future research studies.

Table I. Summary of economic evaluation of prevention strategies for pressure ulcers in Long-Term Care homes in Ontario

Analysis	Description	Strategies (incremental, relative to standard care)					
		Standard care	AF mattress	AF mattress+4-hourly turning/repositioning	Nutritional supplementation	Skin care protocol	RN time increase
	Targeted residents	90,158	48,686	48,686	3,019	20,123	55,898
Clinical Outcomes	Lifetime probability of PU	50.00%	-11.23%	-12.52%	-0.06%	-3.84%	-15.36%
	Lifetime probability of chronic PU	31.46%	-7.68%	-8.70%	-0.04%	-3.01%	-11.10%
	Lifetime probability of PU-related local infection	12.67%	-2.82%	-3.20%	0.00%	-1.32%	-4.66%
	Lifetime probability of PU-related systemic infection	9.37%	-2.15%	-2.47%	-0.01%	-1.00%	-3.60%
CEA	LYs gained per resident*	3.4263	0.0154	0.0174	0.0002	0.0059	0.0213
	QALYs gained per resident*	1.3540	0.0127	0.0142	0.0002	0.0046	0.0165
	Incremental lifetime cost per resident**	\$153,148	\$80	\$74	\$194	\$1,329	\$4,448
	ICER (\$/QALY gained)	-	\$6,328	\$5,234	\$1,186,022	\$287,133	\$269,202
BIA	PU cases (averted)	11,739	-2,984	-3,381	-54	-1,379	-4,517
	QALYs gained	35,629	173	192	3	60	211
	Total care budget (increase)†	\$4,029,876,226	\$4,565,375	\$2,160,648	\$9,104,257	\$57,222,261	\$171,129,173
	PU-related budget (saved)§	\$77,603,322	-\$17,343,112	-\$19,747,839	-\$267,061	-\$7,531,713	-\$26,709,773
	Implementation cost‡	\$0	\$21,908,486	\$21,908,486	\$9,371,319	\$64,753,973	\$197,838,946

*LYs/QALYs gained per resident for each alternative relative to standard care, discounted at 5%. ** Incremental costs per resident for each alternative relative to standard care. Positive value indicates increase in cost. †Estimated annual total health care cost (total budget impact) relative to standard care. §Estimated PU-related health care cost (PU-related budget impact) relative to standard care. ‡Estimated annual cost for implementing prevention strategies.

AF, alternate foam; RN, registered nurse; PU, pressure ulcer; CEA, cost-effectiveness analysis; LYs, life years; QALYs, quality-adjusted life years; ICER, incremental cost-effectiveness ratio; BIA, budget impact analysis.

Chapter 1: Introduction

Pressure ulcers (PUs) are common in a variety of health care settings. A pressure ulcer (PU) is defined as an area of localized damage to the skin and underlying tissue due to pressure, shear, or friction.¹ They usually occur over bony prominences and are common in the elderly, the very ill, patients who are neurologically compromised, and in individuals with conditions that are associated with immobility.

It is estimated that 1.3 million to 3 million adults in the US have a PU.^{2,3} In Canada, the prevalence of PUs is estimated to be 30% in long-term care (LTC) settings, 25% in acute care settings, and 15% in community care settings.⁴ The overall prevalence for PUs across all health care settings is estimated to be 26%.⁴ The incidence of PUs varies, ranging from 2.2% to 23.9% in LTC settings, 0.4% to 38.0% in hospital settings, and 0% to 17% in community care settings.⁵

Among LTC residents, PU is considered a serious and costly health condition.^{6,7} Although treatable if found early, PUs can become life-threatening, and in rare instances, lead to fatal infections. If left untreated, PUs are associated with adverse health outcomes and high treatment costs.⁸ It could delay functional recovery, impair quality of life, and cause complications that require hospitalization with prolonged length of stay,^{9,10} as well as a two-fold increased risk of death.¹¹

The cost of healing a PU is likely high because it often involves a multitude of prolonged complex treatments and hospitalization. Once a PU reaches stage III or IV, it may take as long as six months to heal. Some PUs may not be healable because of existing co-morbidities and may require ongoing treatment and care.^{9,10} In the US, costs to heal each ulcer is estimated at \$500

to \$40,000.^{2,3} An average hospitalization cost for treatment of PUs is estimated at \$38,000,¹² and the estimated aggregate cost is \$11 billion per year.¹³ Treating a single PU could cost as much as \$70,000.¹² In a Canadian study, Allen & Houghton (2004)¹⁴ estimated that the total cost for 3-month care of a person with a stage III PU in the community was \$27,500 per patient.

PUs also have a significant financial impact on various health care systems. In the US, the expenditures for treating PUs have been estimated at \$11 billion per year.¹³ In the UK in 1992, PUs cost the average health district approximately £300,000 to £750,000 (\$420,000 to \$1,050,000 (CAD)) per year.¹⁵ In the Canadian health care system, PUs cost approximately \$2.1 billion annually.⁴

Comprehensive health policy models have been used to evaluate the relative effectiveness and cost-effectiveness of health interventions. When there is a multitude of management strategies, no single empirical study can simultaneously evaluate all. By integrating epidemiologic and standard practice data, the use of health policy models can assist in decision-making, highlight where better data are needed, identify factors most likely to influence outcomes, and provide insight into the potential cost-effectiveness of different strategies.¹⁶ Applications include cardiovascular models,^{17,18} cervical cancer models,^{16,19} and prostate cancer models,²⁰ among others.

Existing models evaluating the cost-effectiveness of prevention strategies for PUs are limited in scope (e.g., short time horizon)²¹ or specific to the strategy under study.²² Both health policy makers and clinical professionals need health economic evaluations on the prevention of PU to formulate policy and shape

clinical guidelines. A platform is needed to simultaneously evaluate a number of prevention strategies. The Toronto Health Economics and Technology Assessment Collaborative (THETA) was approached to develop such a platform to address broad policy questions.

The purpose of this report is to advise the Ontario Ministry of Health and Long Term Care (MOHLTC) through the Medical Advisory Secretariat (MAS) on the cost-effectiveness of provincial implementation of PU prevention strategies, with several objectives:

examine the economic attractiveness of evidence-based prevention strategies to reduce the burden of PUs in Ontario; and

estimate the budget impact and other health system implications related to the implementation of cost-effective prevention strategies for PUs.

This report was prepared as a companion document to a systematic review of PU prevention strategies undertaken by MAS. Additionally, this report describes the development and validation of a PU model that linked to population-based data in Ontario.

Chapter 2: Natural history model of pressure ulcer

Introduction

This chapter describes the development of the Ontario Pressure Ulcer Model (OPUM) to inform health policy regarding PU prevention in Ontario. Its linkage to the population-based Minimum Data Set (MDS) for LTC homes in Ontario²³ and the Canadian Institute of Health Information Hospital Discharge Abstracts Database (CIHI-DAD), and the process of model calibration are described.

Methods

Model Population

The model population was the average cohort of LTC residents in Ontario, Canada. The mean age of the cohort was 83.6 years, 70% were females, and the average life expectancy was approximately three years after admission to a LTC home. These data are based on the observed MDS data detailed under the “model parameters” section.

Outcome Measures

The following outcome measures were used to assess the clinical impact of different modifications in the natural history of PU: (1) the prevalence of PU; (2) the lifetime probability of developing co-morbidities that placed residents at high risk for PU; (3) the lifetime probability of developing a PU; (4) the average number of PUs; (5) the lifetime probability of chronic PUs; (6) the lifetime probability of PU-related local infection; (7) the lifetime

probability of PU-related systemic infection; and (8) the lifetime probability of PU-related death.

Model structure

The model (Figure 2.1) was structured to be consistent with current biologic and clinical understanding of the development and management of PUs.^{24,25} A 52-state Markov model was used to simulate the natural history of PUs among LTC residents in Ontario according to underlying risk related to external (e.g., pressure, friction, shear force and moisture) and internal (e.g. nutrition deficiency, immobility and incontinence) factors. The natural history of disease was modeled as a series of transitions among mutually exclusive health states. The cycle length was one week. Health states were defined by: (1) underlying risk for PU (low or high risk); (2) PU stage, using a current classification system (stages I-IV);²⁶ (3) PU characteristics other than stage (healable, chronic or healed wound); (4) PU-related complications (local or systemic infection and death); and (5) location of patient (LTC or hospital). The model was implemented in TreeAge Pro 2008 software (Treeage Software, Williamstown, MA, USA).

Underlying risk for pressure ulcer

Each week (i.e., one cycle), LTC residents could develop PU according to their time-dependent risk status (Figure 2.1). This was assumed to change if any of their risk factors were altered or being modified. For example, the best practice guidelines for nursing in Ontario recommend that interventions be based on intrinsic and

extrinsic risk factors identified by a risk assessment tool, such as Braden's categories of sensory perception, mobility, activity, moisture, nutrition, friction and shear.²⁷ The prevalence of deficiencies or restrictions in mobility, Activities of Daily Living (ADL), nutrition and continence among high-risk residents were monitored in the model to facilitate the evaluation of targeted interventions (e.g., skin care protocols for incontinence care,^{28,29} nutritional supplementation³⁰). Details of the derivation of risk stratification for LTC residents are described below under the "model parameters" section.

Pressure ulcer stage

There are different systems for staging a PU based on severity, surface area and depth of the ulcer, the tissues affected, and presence or absence of necrosis, exudate, or slough. The most commonly used systems for PU staging are the North American National Pressure Ulcer Advisory Panel (NPUAP) classification system³¹ and the European Pressure Ulcer Advisory Panel (EPUAP) classification system. A stage I PU usually refers to a change in the skin without breakage. Stage II refers to a shallow ulcer with partial loss of skin thickness. Stages III and IV are considered advanced ulcers with full loss of skin thickness, affecting tissues beneath the dermis. In early 2007, a new category was added to the NPUAP to represent damage of underlying soft tissues while the skin remains intact.²⁶

The model thus explicitly represents PU stage using the NPUAP classification system (Figure 2.1),³¹ which captures many important characteristics of PU, particularly those related to depth of the PU and involvement of underlying tissues. However, this staging system does not capture all clinically relevant aspects of PUs. For example, stage I PU has intact skin but

there may be pressure-related injury to subcutaneous tissue under intact skin. These ulcers may have the appearance of a bruise and potentially herald the subsequent development of a stage III or IV PU.³²

Further, the model does not use the staging system in reverse order to indicate healing since in a healing ulcer, the tissue lost is generally not regenerated but is replaced with granulation tissue and ultimately scar tissue³¹ (Figure 2.1). Hence, healing is modeled as a transition from a PU stage to the "healed" stage. A full description of the PU stages is provided in Appendix A.

Healability

Factors that may make a PU healable or chronic are considered in the model.³³ Healable PUs are generally treatable; their surrounding blood supply is adequate and coexisting conditions or drugs do not prevent healing.³³ Within a time period sufficient for the determination of healability (e.g., a threshold of 12 weeks), a PU could start the healing process in which granulation, contraction and re-epithelialization continue to improve until complete skin closure occurs. This assumption was made based on the mean healing time of 13 weeks for stage II PU.⁶ Provisions were also made for some PUs to progress quickly to late stage (e.g., "bottom-up" damage) and others to gradually develop skin and tissue damage, potentially as a result of excessive moisture due to incontinence (i.e., "top-down" damage). PUs unable to heal within a predefined threshold were deemed chronic. Chronic PU could remain at the same stage or progress to a later stage but could not heal during the simulation (Figure 2.1).

PU-related complications: local and systemic infections

In the model, local infection could occur with stage II or higher PUs and generally be treated and cleared with topical anti-microbial preparations³⁴ (Figure 2.1). Prolonged presence of local infection in stages III-IV increases bacterial burden in the wound. If untreated, its systemic dissemination could result in sepsis; progression may lead to multi-organ failure and even death.

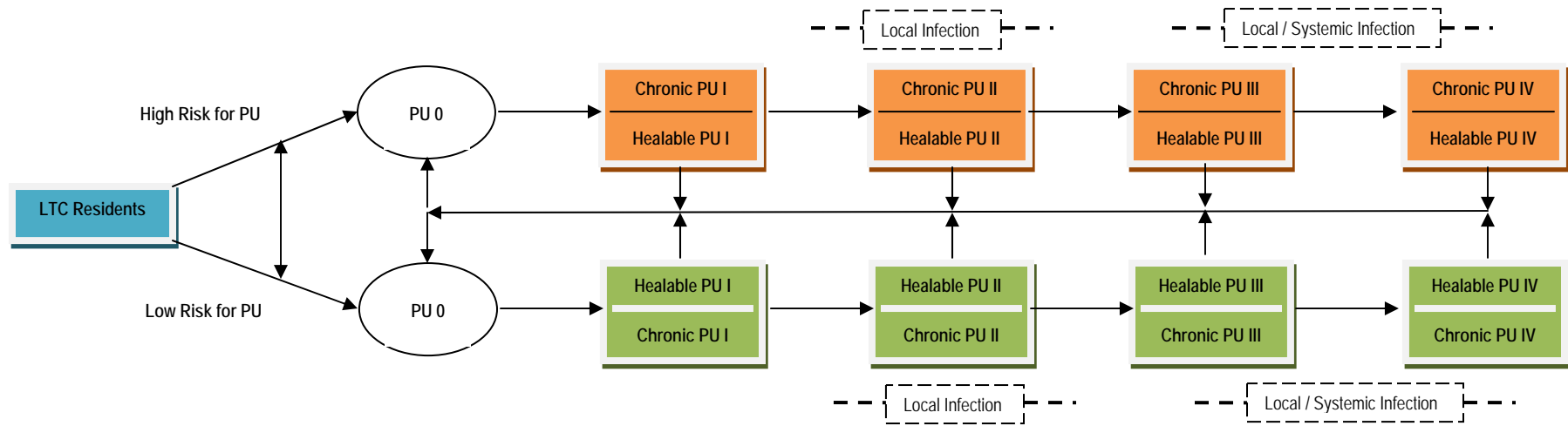


Figure 2.1. Model structure

LTC, long-term care; PU, pressure ulcer

Competing risk

At each cycle of the simulation, residents were also considered at risk of hospitalization or death due to causes unrelated to PU.

Location

The model represents outcomes of a prevalent population residing in LTC homes in Ontario in 2008. However, residents in LTC homes may require short-term care in acute hospital settings, either for treatment of PU, or for an unrelated cause. The model represents transitions between LTC and acute care.

Data Sources

The model used three sources of data (Table 2.1): the population-based MDS (Canadian version 2.0) for LTC homes in Ontario;²³ the Canadian Institute of Health Information – Hospital Discharge Abstract Database (CIHI-DAD); and published literature to inform the description and parameterization of the natural history of PU. Records obtained from the MDS for the study cohort were linked to the CIHI-DAD using unique identification numbers in order to obtain in-hospital mortality data. The data linkage and related data analyses were performed by a data analyst at the MAS, the Ontario MOHLTC.

Minimum Data Set: The MDS is an assessment instrument that highlights issues related to functional status and quality of life for individuals in geriatric settings. It thus provides a common language for assessing health status, care needs, and preferences.³⁵ The MDS is comprised of two parts. The first is designed to collect standardized information on a broad range of variables including cognition,

communication, ADL, instrumental ADL, continence, nutrition and hydration, skin conditions, and other aspects of functioning, and services. The second part consists of 30 problem-focused Clinical Assessment Protocol (CAP) areas. Responses to selected assessment items are incorporated into CAP triggers, algorithms that indicate whether the person has a problem, risk factor or potential for improved function in a specific CAP area. CAPs potentially relevant to PU include functional performance (e.g., domains related to ADL rehabilitation, instrumental ADL, and institutional risk), mental health (e.g., cognition), bladder management (e.g., urinary incontinence) and health problems / syndromes (e.g., dehydration, nutrition and PUs). The MDS has passed critical tests for both inter-rater reliability and validity in multiple trials.³⁶⁻³⁸

The Ontario implementation of the MDS began in 2004, and by 2007 included approximately 91 LTC homes (out of 613 homes in Ontario) housing a cohort of 18,325 residents. Residents were assessed upon admission and at 3-month intervals, or when significant changes in health status occurred. The cohort had a mean follow-up of 12 months when residents had on average 4 assessments.

Canadian Institute of Health Information Hospital Discharge Abstracts Database:

CIHI-DAD uses well validated and reliable instruments for hospital discharge abstracts data collection.³⁹ This yielded data pertaining to inpatient hospitalization: sex, date of birth, date of hospital admission, admitting institution, and the primary diagnosis for hospitalization, among others.³⁹

Published literature: Other data relating to mean healing time, relative risk (RR) of death of high versus low risk for PU, death due to PU-related sepsis were obtained using targeted literature searches.

Model parameters

Model parameters are reported in Table 2.2.

Demographic characteristics

Age and gender of the LTC cohort were obtained from the MDS. The mean age of the LTC cohort was 83.6 years, and the majority (69%) of the cohort were female.

Table 2.1. Data sources

Data type	Data components	Data source
Demographics	Age, gender and co-morbidities	MDS
Risk of PU	17-item risk assessment scale and change in risk over time	MDS
Natural history of PU	Incidence of PU, chronic PU, healing, PU-related local and systemic infections	MDS
Other	Mean healing time, relative risk of death of high versus low risk for PU, death due to PU-related sepsis	Literature
Competing risk	Death in LTC and hospitalization	MDS
	Death in hospital	CIHI-DAD
Model calibration	Prevalence	MDS

Note: Most data components were stratified by age and risk.

LTC, long-term care; MDS, Minimum Data Set; CIHI-DAD, Canadian Institute of Health Information-Hospital Discharge Abstracts Database; PU, pressure ulcer.

Risk of pressure ulcer

More than 100 risk factors for PUs have been identified in the literature, such as unrelieved pressure over bony prominences, friction, humidity and shearing forces to any part of the body. Some physiologic risk factors include diabetes mellitus, peripheral vascular disease, cerebrovascular disease, sepsis, and hypotension. It has been hypothesized that these physiological factors place people at risk because of impairment of the microcirculatory system.⁴⁰

Using a validated risk-adjustment scale,⁴¹ LTC residents were divided into two risk strata: low and high risk for PU. The scale included information about specific diagnoses, functional status, nutritional status, physical examination findings and demographic characteristics. It was developed to predict the development of PU stage II to IV (residents with stage I ulcers were considered PU-free). Seventeen data elements necessary to classify risk status, including severe ADL restriction, nutritional deficiency indicated by weight loss, and incontinence were available

from the MDS. Published coefficients were used to reconstruct the scale and applied to the Ontario MDS.⁴¹ Model-predicted risk of PU development was divided into deciles; residents with model-predicted risk below the third deciles were considered low risk, and those above the third deciles were considered high risk.

Changes in risk status over time were estimated using MDS data from groups of residents with at least one year of follow-up. The one-year duration was selected instead of shorter periods in order to obtain average estimates of changes over time. Specifically, the proportion of residents with low risk status at an index assessment and high risk status after one year was calculated. Similarly, the proportion of residents changing from high risk to low risk within one year was calculated.

Weekly transition rates of changes in risk status were derived using the density method.⁴² Assuming that the weekly transition rate remains constant during one year, the weekly rates were derived from the exponential reduction in the group with respect to risk status changes.⁴²

The proportions of residents at high risk of PU associated with immobility, incontinence and nutritional deficiencies were also derived.

Over half of the cohort had risk factors for the development of PU, including immobility (55% severe ADL restrictions) and urinary or fecal incontinence (72%). Approximately 62% residents were at high risk for PU upon admission. Among residents at high risk of PU, approximately 10% had nutritional deficiency. Using data from risk status change over one year period, estimates of weekly transition rates of changing risk status were derived for use in the model (Table 2.2). Each month, approximately 1.5% of the residents from a low risk status moved to a high risk status. The reverse transition was 1.6% (derived using the weekly transition rate). Other model input parameters are reported in Table 2.2.

Pressure ulcer incidence

Incidence of PU was estimated from the MDS data. It was assumed that a resident had developed a PU when he or she was without an ulcer on an index assessment and had a stage I or greater ulcer at a subsequent 3-month assessment.⁴¹ The index assessment was defined as the first assessment of each quarter of the calendar year. The outcome assessment was the assessment closest to 90 (\pm 45) days after the index date (i.e., residents must remain institutionalized for at least 45 days). A resident could contribute multiple observations to the sample as long as the 45-day requirement was met for each quarter. The outcome assessment from one quarter could then serve as the index assessment for the next quarter.

The proportion of residents developing PU over a 3-month assessment was estimated by the ratio of two factors: 1) the number of residents developing a PU over a 3-month assessment

(i.e., without an ulcer on an index assessment and had a stage I or greater ulcer at a subsequent 3-month assessment); and 2) the number of residents with no ulcer at the index assessment and completed the subsequent assessment. The proportion was then used to derive the weekly incidence estimate using the density method described above. The assumption involved in these estimates was that shorter transitions (e.g., stage 0 to I, clear, then 0 to I, or other combinations) did not occur during the interim of three months. Clearly, this assumption was not completely tenable. As such, the model did not use the exact incidence estimates. They were adjusted (calibrated) so that the projected prevalence approached the observed prevalence. Further details of model calibration are outlined below.

Similar approaches were used to derive the weekly incidence of progression from stage I to II, II to III and III to IV (i.e., with calibration). Similar approaches were also used to derive weekly rates for healing of a stage-specific PU (i.e., I to 0, II to 0, III to 0 and IV to 0; with calibration).

The age-specific incidence estimates were first derived from the MDS for the low risk group. Transition estimates for the high risk groups were calculated by multiplying the corresponding estimates for the low risk group by a relative risk (RR) estimate, also derived from the MDS. This approach, instead of using direct estimates for the high risk group, was selected to ensure a consistent distance between the risk profiles across multiple stratifications (e.g., age and stage). The RR of PU for high versus low risk residents was derived from the ratio of corresponding incidence estimates.

Other data from published literature

The mean healing time for stage-specific PU could not be estimated from the MDS data (i.e., healing status unknown within three months) and was extracted from a published study in which such data was consolidated via a summary of literature.⁶ In addition, an estimate of the rate of death due to septicaemia was obtained from a Canadian study of risk-adjusted 30-day hospital mortality.⁴³

Competing risk

Age-specific mortality and hospitalization among LTC residents were derived from the MDS stratified by risk status and presence of PU (stage II to IV). For each stratification, the weekly rate of hospitalization or mortality was defined as the ratio between the number of events of interest (e.g. hospitalization) and the total duration of exposure from all individuals fulfilling the stratified conditions. Similarly, linked data between the MDS and the CIHI-DAD was used to estimate the weekly rate of in-hospital mortality among hospitalized residents.

Model calibration

The age-specific prevalence of PU was derived from a cross-sectional sample of residents in the Ontario MDS. A first-order calibration was performed to ensure that the input incidence estimates used in the model reproduced corresponding observed prevalence estimates.⁴⁴ The projected stage-specific prevalence estimates from the average cohort at one year after admission were matched to the observed prevalence in the 80-84 year age group from the MDS cross-sectional data. The following steps were used in the calibration:

1. PU stage I to IV prevalence was sampled after 52 cycles for the 83.6-year old cohort.

2. Age-specific incidence and healing estimates were scaled (e.g., 0.5 to 1.5) in order for the input incidence data to reproduce the observed prevalence. The impact of the scaling factors on the prevalence estimates was evaluated via two-way sensitivity analyses.
3. The calibration step 2 was conducted in a step-wise fashion. First, calibration was done for developing stage I PU involving only age-specific incidence estimates for stage I. Next, the calibration was done for progressing from stage I to II. This involved scaling both age-specific incidence and healing incidence from stage I. Similarly, calibration was conducted for stages III and IV. At each stage, the values of the scaling factors were inspected from the graphical displays of the sensitivity analysis results. Values of the scaling factors were selected when the projected prevalence approached the observed prevalence.
4. The scaling factors over the entire disease pathway (Figure 2.1) were inspected to ensure the consistency of the model projection across all PU stages. Small adjustments to the scaling factors were made to make sure the calibration was robust at the locally selected values of the scaling factors.⁴⁵

Model predictions

Clinical outcomes associated with PU were predicted from the model via Monte-Carlo simulations (Table 2.4).

Results

The 6-month incidence of PU was estimated to be 4.5% and 9.3% for the low and high risk groups, respectively (derived using weekly transition probabilities from Table 2.2). The projected stage-specific prevalence was consistent with the observed prevalence (Figure 2.2). For an 83.6-year old cohort admitted to LTC, the chance of getting PUs over the residential time was predicted to be 49% (Table 2.4); the remaining life expectancy was estimated to be 3.43 years (Table 2.3).

Over a 6-month period, the model estimated that approximately 33% of the cohort would be hospitalized with an in-hospital mortality of approximately 6.6% (Table 2.3). The 6-month mortality in LTC was projected to be approximately 5%. These projections were generally consistent with observed data not used in the model (Table 2.3).

Table 2.2. Model parameters

Variable	Value	Source
Characteristics of LTC residents (mean)		
		MDS; Demographic data
Mean age (year)	83.6	
Female (%)	69	
Co-morbidities (%)		
Severe ADL restrictions	55	
Nutrition deficiency among residents at high risk of PU	9.7	
Urinary or fecal incontinence	72	
Underlying risk for PU		
		MDS
Proportion of high risk residents	62	
Weekly transition probability of low to high risk	0.0037 (0.0013, 0.0117) *	
Weekly transition probability of high to low risk	0.0043 (0.0013, 0.0173) *	
Weekly probability of worsening tissue damage		
		MDS; PU one-step worsening data
PU 0→PU I, Low risk	0.00192 (0.00168, 0.002136) *	
PU I→PU II, Low risk	0.0121 (0.0105, 0.0159) *	
PU II→PU III, Low risk	0.000544 (0.00032, 0.000944) *	
PU III→PU IV, Low risk	0.00689 (0.00455, 0.00763) *	
Relative risk for PU 0→PU I, high vs. low risk	2.12 (1.79, 2.52) *	MDS; PU incidence data
Average relative risk of 1-step worsening of PU stage (I->II, II->III, III->IV), high versus low risk	2.48 (0.45, 4.82) *	MDS; PU one-step worsening data
Healability or chronicity		
Percent of persistent PU 1 year after admission (%)	27	MDS; chronic wound
Threshold for assessing chronicity of PU I-IV (weeks)	12	Assumption based on literature ⁶

Table 2.2. Model parameters (continued)

Variable	Value	Source
Weekly probability of PU starting to heal ¹		MDS; risk-stratified healing data
PU I - Low risk	0.0507 (0.0493, 0.0522)*	
PU II - Low risk	0.0400 (0.0400, 0.0401)*	
PU III - Low risk	0.0230 (0.0175, 0.0286)*	
PU IV - Low risk	0.0169 (0.0045, 0.0031)*	
Relative risk of PU starting to heal		MDS; risk-stratified healing data
PU I – High versus low risk	0.60 (0.49, 0.98)*	
PU II – High versus low risk	0.55 (0.42, 0.72)*	
PU III – High versus low risk	0.49 (0.19, 1.00)*	
PU IV – High versus low risk	0.57 (0.22, 1.00)*	
Mean healing time until skin closure (weeks)		Bennett et al. 2004 ⁶
PU I	4	
PU II	13	
PU III	18	
PU IV	22	
Mortality		
Weekly probability of death in LTC		MDS
Low risk	0.0009 (0.0005, 0.0019)*	
High risk	0.0025 (0.0016, 0.0036)*	
Probability of death among hospitalized LTC residents (per hospitalization)		Discharge Abstract Database
Low risk	0.1349 (0.0385, 0.1746)*	
High risk	0.1663 (0.0385, 0.2316)*	
Hospitalization		
Weekly probability of hospitalization among LTC residents		MDS, hospitalization data
Low risk	0.0124 (0.0090, 0.0136)*	
High risk	0.0146 (0.0126, 0.0181)*	
Relative risk of death in high vs. low risk for PU	1.45 (1.30, 1.65)	Berlowitz et al. 1997 ⁴⁶

PU-related infection

Weekly probability of local infection among PU II	0.0101	MDS; morbidity data
Relative risk of local infection of PU III-IV vs. PU II	1.2	MDS; morbidity data
Conditional probability of sepsis given local infection	0.1429	MDS; morbidity data

*95% confidence intervals. Age-adjusted value although age-specific estimates were used in the model.

LTC, long-term care; MDS, Minimum Data Set; ADL, Activities of Daily Living; PU, pressure ulcer.

Table 2.3. Other observed versus projected data for a cohort of LTC residents aged 83.6 years

	Projected	Observed	Source
Average life expectancy (years)	3.43	3	Expert opinion[1]
Cumulative incidence over 6 months from age 83.6 yrs			
Hospitalization (%)	33.16	36.3 (visit)	M. Hillmer, 2008[2]
Mortality in hospital (%)	6.61	16.9	Tourangeau et al., 2007 ⁴⁷ [3]
Mortality in LTC (%)	4.87	7.0	M. Hillmer, 2008[2]
PU-related mortality (%)	0.02	0.02	Estimated[4]

[1] Life expectancy estimate of approximately 3 years was based on expert input, taking into account the bimodal distribution of life expectancy among LTC residents (i.e., residents with instability in health die within approximately 3-12 months after admission; residents with stable health generally live longer). [2] Unpublished data provided from a report by Hillmer et al. 2008. [3] Risk of in-hospital deaths among patients with AMI, stroke, pneumonia and septicemia. [4] The projected PU-related mortality was verified by manually calculated rate of septicemia death given MDS-derived probability estimates of local infection, MDS-derived probability of systemic infection and probability of sepsis death of 20%.⁴³

LTC, long-term care; PU, pressure ulcer; MDS, Minimum Data Set.

Table 2.4. Model predictions for standard care

	Mean (95% CI)
Lifetime probability of being at high risk for PU	78.7 (76.3, 81.4)
Lifetime probability of PU	49.2 (40.0, 57.9)
Average number of PUs per patient	1.5 (1.1, 2.0)
Lifetime probability of chronic PU	18.9 (13.8, 24.5)
Lifetime probability of PU-related local infection	10.4 (7.4, 13.8)
Lifetime probability of PU-related systemic infection	2.2 (1.2, 3.2)
Lifetime probability of PU-related death	0.8 (0.1, 1.4)

PU, pressure ulcer. CI, confidence interval.

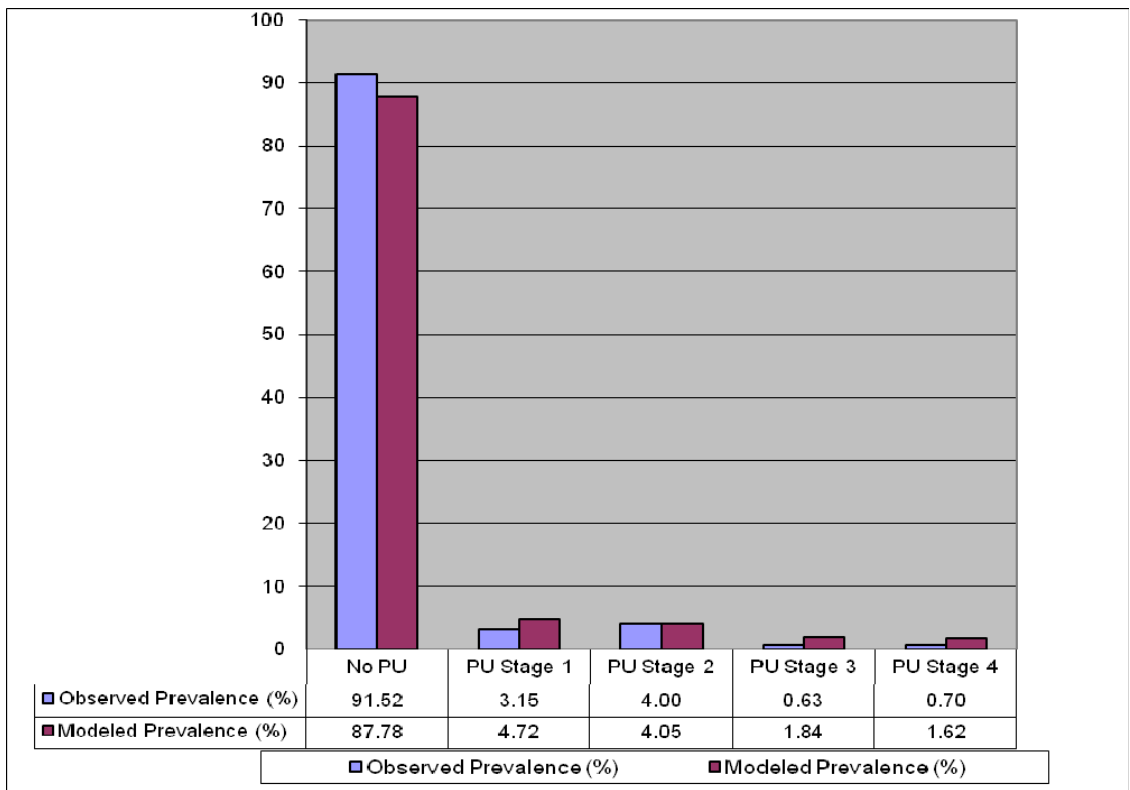


Figure 2.2. Observed versus expected prevalence of pressure ulcer for a cohort of long-term care residents aged 83.6 years one year after admission to a long-term care home

Chapter 3: Standard care

Introduction

Standard care for PU was defined as current practice in Ontario with respect to PU prevention and treatment. An electronic database housing MDS from 91 LTC homes across Ontario (see details in Chapter 2) did not consistently provide the level of detail required in areas related to the standard care of prevention and treatment of PUs. For this reason, a telephone survey was developed and administered to a random sample of LTC homes across Ontario.⁴⁸

Methods

A computer generated random number sequence selected 34 LTC homes from an online database of 613 LTC homes in Ontario, stratified by Local Health Integration Network (LHIN) to ensure geographic representation. The Director of Care (DOC) of each facility was telephoned. The facility was deemed a non-responder if no response was obtained from the DOC after 3 telephone calls.

The survey⁴⁸ was developed in consultation with clinicians with expertise in wound care (advance practice nurses, enterostomal therapists (ETs), a dermatologist, a general internist, an occupational therapist, and a dietician) and various representatives from organizations involved in LTC in Ontario (Registered Nurses Association of Ontario (RNAO, <http://www.rnao.org>), Registered Practical Nurses Association of Ontario (RPNAO, <http://www.rpnao.org>), Ontario Long Term Care Association (OLTCA, <http://www.oltca.com>), Canadian Association of Enterostomal Therapists (CAET, <http://www.caet.ca>). An

initial meeting was held with one LTC facility in the Greater Toronto Area (GTA) to pilot the survey. A final version of the survey was developed based on feedback received.

The survey⁴⁸ was conducted in April-May 2008 and addressed the following topics: 1) size and type of facility; 2) staffing ratios and salaries of registered nurses (RNs), registered practical nurses (RPNs), and personal support workers (PSWs); 3) multidisciplinary wound care teams; 4) types, numbers, and costs of mattresses in the facility; 5) repositioning programs; 6) nutritional supplements; 7) incontinence care, including rates of incontinence and types, amounts, and cost of supplies used; 8) wound care protocols; and 9) PU statistics for the previous 3-month period.

Results

Data were obtained from 26 of 34 (76%) LTC homes approached. The extent of data collected from each facility varied widely depending on the characteristics of the homes.

Size and type of facility

LTC homes ranged in size from 21 to 288 beds (mean=122, SD=69) and represented all LHINs in Ontario with the exception of the South East due to a lack of response from the facility in that region. All types of LTC homes were represented, that is, for-profit (n=17), municipal (n= 3), and non-profit (n=6).

Staffing ratios

The majority (74%) of all staff in LTC homes were PSWs, 16 % were RPNs, and 10% were RNs. These proportions remained constant across a 24-hr time period in homes surveyed. Time per patient based on staff/patient ratios in each facility were calculated for RNs, RPNs, and PSWs. A summary of current staff time per resident per day (PRPD), contrasted with recommended staff time PRPD for various staff is cited in Chapter 4 of this document.

Wound care teams

Four of 26 (15%) of LTC homes reported having a ‘wound care team’. Roles and responsibilities of these teams were loosely described but appeared to be primarily related to administrative aspects of wound care in the facility. Three homes accessed ETs on an individual, as needed basis, for stage III-IV PUs. Funding for these ET consults was via High Intensity Needs Fund (HINF) funding allocated for wound care.

DOCs often described having ‘trained in-house experts’ in wound care; however the training of these experts, usually RPNs, consisted of one-time short courses on wound care. None of the ‘in-house experts’ were certified ETs.

Mattresses

Standard mattresses, costing on average of \$225 per mattress, represent 54% of all mattresses in LTC homes. Specialty mattresses comprise 46% of all mattresses in LTC homes. Of these, 85% were High Specificity (HS) foam mattresses which cost on average \$450 per mattress. The remaining 15% of the specialty mattresses range in price from \$1,280 to \$20,000 (an average of

\$5,841 per mattress), costing a total of \$1,315,837. A total of \$2,271,162 was spent on 3,318 mattresses across the 26 homes surveyed (see further details in Chapter 4).

Of interest is the fact that 15% of these specialty mattresses account for more than half of all mattress expenditures in LTC homes surveyed. All funding for this specialty category of mattress comes directly from the MOHLTC, accessed by homes via the HINF program. In order to qualify for this funding, LTC residents must have multiple stage II, stage III or IV PUs.

LTC homes cannot access government funding currently for HS foam mattresses (\$450 per mattress), despite evidence suggesting these mattresses help to prevent PUs.⁴⁹

Repositioning programs

All homes reported attempting to reposition patients who were deemed at high risk for PU every 2 hours. However, DOCs openly admitted that this was not usually possible due to constraints on staff time.

Risk was assessed using a formal Risk Assessment Scale (RAS), typically the Braden RAS. However the frequency with which risk of PU was formally assessed varied widely. For example, two homes assessed risk of PU upon admission only. Another facility conducted risk assessment upon admission and once weekly thereafter for a period of four weeks, and quarterly thereafter, while the DOCs representing the remainder of LTC homes surveyed (n=23) could not recall frequency of formal risk assessment, suggesting that no routine frequency of administration of RASs existed.

Nutritional supplements

Twenty-four homes reported using nutritional supplements for residents with PU, 14 of which involved a dietician in this process. Only one facility reported using nutritional supplements for the prevention of PU in residents deemed at high risk for PU. The choice of nutritional supplement varied widely. DOCs commented on the high cost of supplements, a cost that was borne directly by the operating funds of the facility designated to cover all food expenses for a total of \$7 PRPD (see details in Chapter 4).

Incontinence care

All homes reported using a wide variety of disposable incontinence products. Incontinence rates cited by DOCs ranged from 65% to 90% (average=80%). Incontinence products were routinely changed 3-6 times per 24-hr period. Skin care products were used 50% of the time when providing incontinence care; soap and water were used the remaining 50% of the time. Incontinence skin care products typically consisted of a periwash product without a barrier cream. Cost per resident cited for these products varied depending on amounts used by each facility.

Wound care protocols

With the exception of one facility, all homes surveyed reported having a wound care protocol in place for PUs. Twelve homes verbally described, e-mailed, or faxed wound care

protocols for various stages of PUs. Approaches to PU care were relatively consistent across homes, with extensive use of hydrocolloid dressings for most PUs. DOCs described specialty wound care as being very costly, typically accessing HINF for products used. Detailed data related to wound care products used, or costs for these products, were not requested. However, this information would be valuable and should be obtained in future research studies.

Pressure Ulcer Statistics

All DOCs were asked for PU statistics for their facilities for the previous 3-month period. Despite 24 of 26 DOCs agreeing to e-mail or fax this information, PU statistics were only received from 5 of the 26 homes. Due to the small sample size (n=5), and inconsistencies in ways in which data were reported, these results are not included in this report.

Chapter 4: Strategy identification

Introduction

Strategies for the prevention of PUs in LTC were identified through meetings with experts in an expert panel meeting convened by MAS and through systematic literature review. Key documents, such as the Registered Nurses' Association of Ontario (RNAO) Best Practice Guideline (Assessment & Management of Stage I to IV PUs – 2007)²⁷ informed the process of strategy identification. The rationale behind PU prevention strategies relies primarily on reduction of the risk factors for developing PUs such as: external mechanical forces, limited mobility, bladder and/or bowel incontinence, poor nutritional status and limited human health care-related resources to address these issues.

The following five strategies were identified:

1. AF mattress
2. AF mattress and 4-hourly turning/repositioning schedules
3. Nutritional supplementation
4. Skin care protocols for incontinence
5. RN time increase (increasing staffing ratios/staff time in LTC homes)

Methods

A systematic literature review was performed in order to identify published studies describing the effectiveness of strategies used in LTC for the prevention of PU. Results of strategies 1-4 described in this report originate from a systematic review of PU prevention

interventions conducted by senior clinical epidemiologists within the MAS.⁵⁰ The methods of the systematic review for strategies 1-4 can be found in the MAS report.⁵⁰

A systematic review and evaluation of increasing staff time (strategy 5) was performed by THETA, and the methods of the review are described below.

Registered nurse time increase

Discussions with leading experts in the area of PU prevention attending the expert panel meeting led to a literature search for studies related to staffing patterns in LTC settings. Databases searched included Medline, Embase, Cochrane Library, and CINAHL, from January 1980 to April 2008. An experienced librarian from the University Health Network performed all searches. Keywords used in the search related to three concepts: 1) pressure ulcers 2) long-term care and 3) staffing ratios/staff time (see Appendix B).

Article selection was performed independently by two reviewers. Reviewers first assessed study titles and abstracts to select potentially relevant publications. The full-text versions of these articles were retrieved for further assessment. The reference lists of these articles were also reviewed. In addition, conversations were held with primary authors of several articles to ensure that all relevant studies had been identified. Disagreements between reviewers were resolved through discussion until consensus was reached on final article selection.

Included were all studies clearly reporting adjustments to nurse time for the prevention of

PU in comparison to standard care. As stated above, standard care was defined as non-interventional (observational) care and was comparable with current practice. Interventional and/or observational studies were included and articles published as letters to editors, commentaries, and communications were excluded. Studies were selected according to decreasing levels of evidence: meta-analysis of RCTs, RCTs, non-RCTs, pre- and post-intervention studies, prospective cohort studies, and retrospective cohort studies. In other words, although the inclusion criteria were not restricted to a specific study design, only the highest level of evidence available was included in the analysis.

The targeted population included residents of either LTC or acute care facilities aged 65 or older, at any risk level for acquiring PUs. PU was described as an area of localized damage to the skin and underlying tissue caused by external forces (e.g. pressure, shear and/or friction). Studies reporting on residents with skin damage due to diabetic and venous complications were not included in the analysis.

Results

Strategy 1: Alternative Foam (AF) mattress

Six studies were found comparing the efficacy of AF mattresses to standard mattresses for the prevention of PUs (MAS Report, 2008),⁵⁰ Principal characteristics of selected studies are presented in Table 4.1. All six studies were RCTs performed in LTC residents older than 65 years of age with limitations in mobility (i.e., due to bone fractures, extensive surgery, trauma, etc.). Follow-up ranged from 10 days to 7 months and all patients were from inpatient care units.

Data from four studies were combined. Two studies were excluded for the following reasons: Russell et al.^{50,51} included non-standard types of mattresses in the comparison group, and Berthe et al.^{50,52} did not clearly state the type of standard mattress used. Therefore, combined data resulted in a RR of 0.31 (95% confidence intervals (CI), 0.21-0.46) favouring AF mattresses (Figure 4.1). Heterogeneity of effects was not present in the combined dataset. The figure below shows the RR of PU incidence when using AF mattresses in comparison to standard mattresses.

Strategy 2: AF mattress and 4-hourly turning/repositioning schedules

Two RCTs^{53,54} were found evaluating the efficacy of patient-turning schedules in preventing PUs.⁵⁰ The study by Vanderwee et al.⁵⁴ reported a control arm not compatible with standard care. In this trial, both intervention and control groups used AF mattresses and differed in types of turning schedule. Therefore, this study was excluded from the analysis. Overall characteristics of studies evaluating the impact of turning schedules on the incidence of PUs are described in Table 4.2.

Defloor et al.⁵³ investigated the effect of four different preventive regimens involving either frequent turning on a standard mattress (2 or 3 hourly) or the use of a pressure-reducing mattress in combination with less frequent turning (4 or 6 hourly). During 28 days, four different turning schemes were used: turning every 2 h on a standard mattress (n = 65), turning every 3 h on a standard mattress (n = 65), turning every 4 h on a viscoelastic (VE) mattress (n = 67), and turning every 6 h on a VE mattress (n = 65). The incidence of grade II and higher PUs in the 4-hourly interval group was 3.0%, compared with incidence figures in the other groups varying between 14.3% and 24.1%. Thus, the estimated RR of acquiring PUs with turning every 4 hours on a VE mattress versus turning every 2 hour on a standard mattress

(identified here as standard care) was 0.21 (95% CI, 0.08-0.59). Finally, the investigators concluded that turning every 4 h on a VE mattress resulted in a significant reduction in the number of PU lesions and makes turning a feasible preventive method in terms of effort and cost.

Table 4.1. Principal characteristics of studies comparing the efficacy of alternative foam mattresses to standard mattresses in preventing pressure ulcers

Study, Year	Population	Intervention	Control	Follow up	Outcome Measures
Collier, 1996 ⁵⁵ N=99	General medical ward patients	7 types of new foam mattresses	Standard 130mm mattress	6 months	Deterioration in skin condition (none reported)
Gray & Campbell, 1994 ⁵⁶ N=170	Ortho, trauma, vascular, and medical oncology patients Waterlow score ≥ 15 No existing PU	Softfoam	Standard 130mm mattress	10 days	Incidence of PU (break in the skin= grade 2) (non reported)
Hofman, 1994 ⁵⁷ N=44	Patients with femoral neck fracture PU risk score ≥ 8	Cubed foam mattress	Standard polypropylene SG 40 mattress	2 weeks	Incidence of \geq PU grade 2 (blister formation) (Non specific grading system)
Santy, 1994 N=552	Hip fracture patients >55 years No PU stage ≥ 3 Mean Waterlow score = 25	5 types of foam mattresses	Standard 150mm mattress	2 weeks	Skin deterioration or stage 3 PU (Adapted Torrance)
Russell, 2003 ⁵¹ N=1168	Acute care, ortho & rehab patients ≥ 65 yrs Waterlow score 15-20	CONFOR-Med mattress (Vesico-elastic & polyurethane foam)	Standard hospital mattress (5 types)	8-17 days (median days in study)	Incidence of Torrance grade 2 (non-blanching erythema) or worse (Torrance Grading system)
Berthe, 2007 ⁵² N=1729	Patients from departments of Neuro, thoracic, and orthopaedic surgery and neurology, cardiology oncology-hematology No existing PU Modified EK score comparable in both groups.	Kliniplot	Standard Mattress (not described)	7 months	Development of PU stage 1 or greater. (Modified Shea scale)

PU, pressure ulcer.

Review: Pressure Ulcer Prevention
 Comparison: 01 Alternative Foam Mattresses vs. Standard Foam
 Outcome: 09 Any of skin deterioration, new ulcer, persistent or non blanching erythema, blister or worse (3)

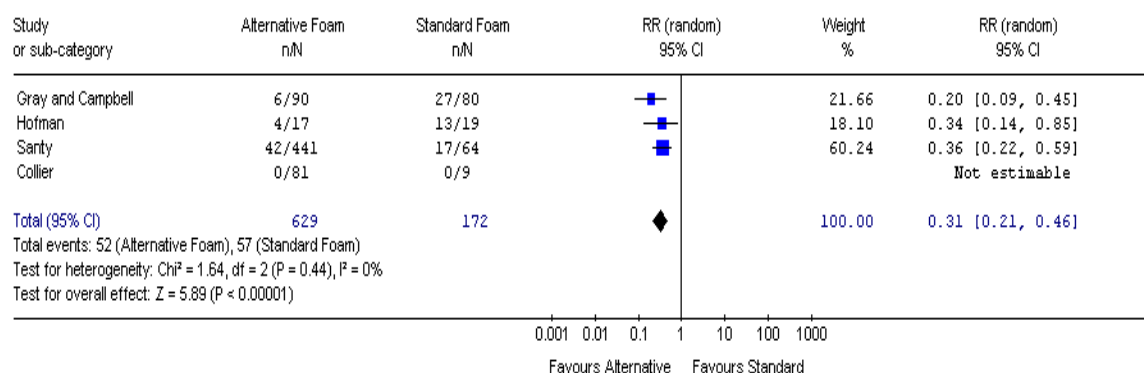


Figure 4.1. Relative risk of acquiring pressure ulcer under alternative foam mattress in comparison to standard mattress

Table 4.2. Principal characteristics of studies comparing the efficacy of turning schedules to standard care in preventing pressure ulcers

Study	Population	Treatment	Control	Follow up	Outcome Measures
Defloor, 2005 ⁵³ N=838	Geriatric nursing home patients Braden score < 17 Norton score < 12 Mean age: 84 yrs.	Turning every 4 hours Turning every 6 hours Both groups used a viscoelastic polyurethane foam mattress.	Turning every 2 hours Turning every 3 hours Both groups used a standard hospital mattress	4 weeks	PU grade 2 or greater AHCPR classification system
Vanderwee, 2007 ⁵⁴ N=235	Belgian elder care nursing home PU-free Median age: 84 yrs	4 hrs supine and 2 hrs side All patients used a vesicoelastic overlay	4 hrs supine & 4 hrs side All patients used a vesicoelastic overlay	15 days (mean)	PU grade 2-4. EPUAP classifications

AHCPR, Panel for the Prediction and Prevention of Pressure Ulcers in Adults, 1992; EPUAP, European Pressure Ulcer Advisory Panel.

Strategy 3: Nutritional supplementation

Five studies were found evaluating the effects of nutritional supplementation in comparison to standard care on the incidence of PUs.^{50,58-62} All studies were RCTs and included acute and LTC patients (65 or older) with immobility primarily due to hip fractures. Nutritional supplementation was administered from 2 to 26 weeks, which added 254 to 1500 calories per day to the standard hospital diet. The main characteristics of the included studies are reported in Table 4.3.

Figure 4.2 displays the RR of acquiring PU when using nutritional supplementation versus standard care in patients with no PU at baseline. Meta-analytic results of the five selected studies resulted in a significantly lower incidence of PU when an oral nutritional supplement was provided to patients compared to standard care (RR = 0.84; 95% CI, 0.73-0.96).

Strategy 4: Skin care protocols for urinary/fecal incontinence

Two studies were found providing data on the incidence of PUs in an incontinence skin care protocol group in comparison to a standard care group.^{28,29,63} Both studies had a pre- and post-intervention study design and evaluated the efficacy of skin cleansers and protectants versus unstructured skin care. Participants were LTC residents with an average age of 83 years. The selected studies are described in Table 4.4.

Combined data shows that an incontinence skin care protocol is effective in reducing the number of new PUs in targeted patients in comparison to standard care. The associated RR was 0.36 (95% CI, 0.17-0.75). However, the meta-analytic result is determined by the study by Hunter et al.,²⁸ since no new cases of PU were found by Bale et al.⁶³ during either standard care or the skin care protocol (Figure 4.3).

Strategy 5: Registered nurse time increase

The literature search strategy identified a total of 2,292 titles related to staff time. Two hundred and ninety two titles were duplicated in more than one database, leaving 2,000 records for review. After assessing titles and abstracts, 53 studies were selected for full text review. Fifty publications were excluded for not fulfilling the pre-defined inclusion/exclusion criteria.

A number of observational studies, which were excluded, provided some evidence of an association between higher total staffing levels and improved quality of care in LTC facilities, indicated by lower death rates, shorter length of stay, improved functional outcomes, fewer PUs, fewer urinary tract infections, less urinary catheter use, and less antibiotic use.⁶⁴⁻⁶⁶ Lower staffing levels, particularly in hospitals, were associated with adverse patient outcomes.⁶⁷⁻⁷⁰ In addition, some studies reported that greater numbers of licensed staff were associated with better quality of care and improved patient outcomes.⁷¹⁻⁷³

Three studies were identified which provided data that could be used to estimate the impact of increasing RN time on prevention of PU (Table 4.5).⁷⁴⁻⁷⁶ A meta-analysis could not be performed due to differences in outcome measures and study designs.

A large cross-sectional descriptive study by Bostick⁷⁴ among 413 facilities found that nursing facilities with more RN staff time had a lower prevalence of PUs after controlling for other facility characteristics (OR 0.97, P=0.03). The mean (SD) hours of RN, licensed practical nurse (LPN), and nursing assistant/aide (NA) hours PRPD in their study was 0.22 (0.20), 0.61 (0.30), and 1.50 (0.72), respectively.

A retrospective cohort study by Horn et al.⁷⁷ among 1524 residents in 95 LTC facilities

participating in the National PU Long-Term Care (NPULS) found that new resident (OR 0.28, $P<0.001$), nutritional intervention (OR 0.57, $P=0.016$), antidepressant use (OR 0.74, $P=0.024$), use of disposable briefs for more than 14 days (OR 0.67, $P=0.005$), RN hours of 0.25 hours PRPD or more (OR 0.62, $P<0.001$), NA hours of 2 hours per resident per day or more (OR 0.57, $P<0.001$), and LPN turnover rate of less than 25% (OR 0.62, $P<0.001$) were significantly associated with decreased likelihood of developing a Stage I to IV PU.

Horn et al.⁷⁶ performed a secondary analysis of a subset of the data from the NPULS analysis⁷⁷ (1376 residents in 82 facilities). After excluding 148 residents at 13 facilities with 40 or more minutes of RN direct care, they found that more RN direct care time PRPD (based on 10-minute increments, with an optimal 30 to 40 minutes PRPD) was associated with: development of fewer PUs (10-20 min: OR, 0.68, $P=0.02$; 20-30 min: OR, 0.53, $P<0.001$; 30-40 min: OR, 0.16, $P<0.001$); fewer hospitalizations ($P<0.001$); fewer urinary tract infections ($P=0.009$); less weight loss ($P=0.008$); decreased use of catheters ($P=0.01$); decreased deterioration in the ability to perform ADL ($P<0.001$); and greater use of oral nutritional supplements ($P<0.001$). Although increasing time of LPNs and certified nursing assistants did not reduce all of the outcomes, they were associated with the development of fewer PUs.

The Horn studies provided some indication of what extra staff time might prevent PU, for example, giving nutrition, changing briefs, getting patients moving etc.

Table 4.3. Principal characteristics of studies comparing the efficacy of nutritional supplementation to standard care in preventing pressure ulcers

Study	Population	Treatment	Control	Follow up	Outcome Measure
Bourdel 2000 ⁷⁸ N= 672	>65 years of age Critically ill, unable to move or eat independently. Free of PU Mean age: 83yrs.	Standard diet (1800kcal/day) plus 2 oral supplements per day (400kcal/day)	Standard diet (1800kcal/day)	15 days or discharge	All grades of PU
Ek 1991 ⁶⁰ N=495	Long-term medical care residents hospitalized for greater than 3 weeks. Average age: 80 yrs 29% of patients malnourished on admission.	Standard hospital diet (2200kcal/day) plus Standard supplement (400kcal/day)	Standard Hospital diet (2200kcal/day)	26 weeks	Incidence of PU (no grading system reported)
Delmi 1990 ⁵⁹ N=59	Hip Fractures Mean age: 82 yrs. Baseline nutritional status not reported 80% of study sample deficient in Vitamin D, A, carotene and retinol binding protein	Standard hospital diet (not described) with daily oral high protein supplement (254kcal/day)	Standard Hospital diet (not described)	6 months	All grades of PU at 6 months
Houwing 2003 ⁶² N=103	Hip Fractures PU Dutch consensus Meeting scoring system > 8 (at risk) Mean age: 81yrs.	Standard hospital diet (not described) and 1 high protein supplement (500kcal/day)	Standard hospital diet (not described) and non-caloric water- based placebo	28 days or at discharge	PU stage 1 or 2
Hartgrink 1998 ⁶¹ N=140	Hip Fractures High risk for PU Mean age: 84 yrs.	Standard hospital diet (not described) and nasogastric tube feeding of Nutrison Steriflo energy plus (1,500kcal/day)	Standard diet	2 weeks	PU grade 2 or higher

PU, pressure ulcer.

Review: Wound Prevention_Beds and Surfaces
 Comparison: 09 Standard Diet vs. Standard Diet plus supplementation
 Outcome: 01 Incidence of Pressure Ulcers

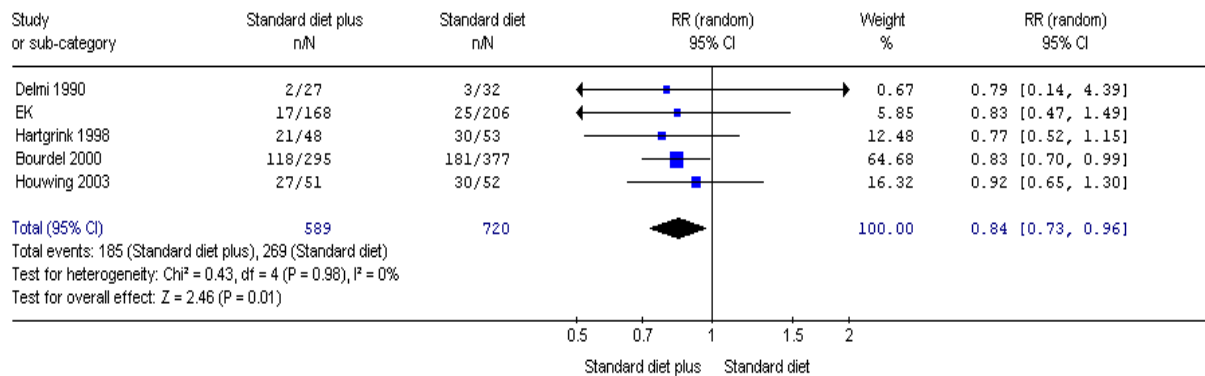


Figure 4.2. Relative risk of acquiring pressure ulcer with oral nutritional supplementation in comparison to standard care

Review: Pressure Ulcer Prevention
 Comparison: 21 Skin Care Protocol vs. No Skin Care Protocol
 Outcome: 03 Incidence of PU Grade I or II

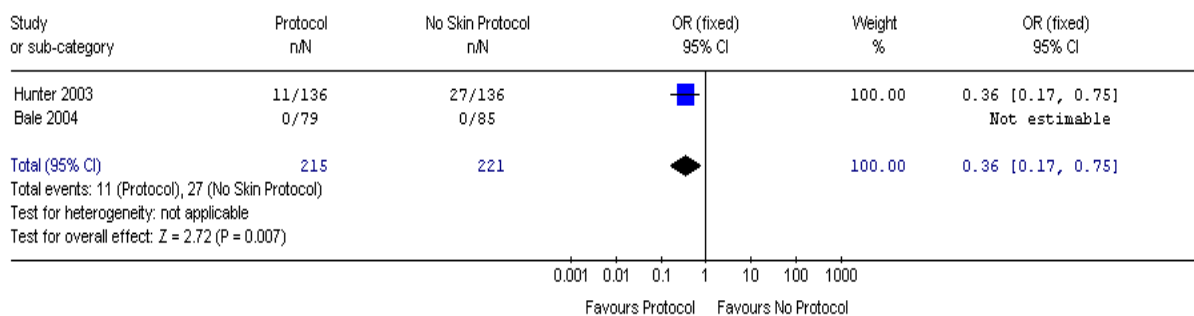


Figure 4.3. Relative risk of acquiring pressure ulcer under skin care protocols for urinary/fecal incontinence in comparison to standard care

Table 4.4. Principal characteristics of studies comparing the efficacy of incontinence skin care protocols to standard care in preventing pressure ulcers

Study	Population	Pre-Phase	Post-Phase	Follow up	Outcome Measure
Bale 2004 ⁶³ N=164 *Pre n=79 Post n=85 *Pre and Post were different cohorts.	Residents in nursing home setting with urinary or urofecal incontinence Mean age Pre: 83 (8.2) yrs. Mean age Post: 84 (8.3)	Unstructured delivery of standard skin care.	Education training session None /mild dermatitis: Spray cleanser and barrier cream Mod/Severe dermatitis: spray cleanser and barrier film	Not reported	Incidence of moderate to severe incontinence dermatitis Incidence of PU grade 1
Hunter 2003; ²⁸ Thompson 2005 ²⁹ N=272 Pre: 136 Post: 136 Majority of Pre and Post were same patients	Patients in rural long term care homes 81% of sample had urinary or fecal incontinence Mean Age: Pre=83 yr (10) Mean Post=8 yr (11.5)	Unstructured skin care with barrier cream, paper briefs, peri-wash and wipes	Check every 2 hours Cleanse with no-rinse body wash and apply skin protectant. Body wash used as a skin cleanser, hair wash and cleanser after soiling. Skin protectant used every 8 hours and after every cleansing when incontinent.	3 months pre-intervention and 3 months post-intervention	Incidence of Stage 1 and II PU by NPUAP definitions

Table 4.5. Principal characteristics of studies evaluating the relationship between registered nurse time and the development of pressure ulcer

Author/Study date	Study design	Data source	Nursing facilities	Residents	RN HPRD	OR (95% CI)	P-value	Notes
			N	N	Mean (SD)			
Bostick, 2004 ⁷⁴ USA	Cross-sectional descriptive survey	1999-2000 data from MDS and OSCAR System	413	39636	0.224 (0.195)	0.97	0.03	Controlling for facility characteristics
Horn et al, 2004 ⁷⁷ USA	Retrospective cohort study	LTCs in the National PU LTC Study. Feb/1996-Oct/1997	95	1524	≥0.25	0.62 (0.48-0.80)	<0.001	Controlling for resident, treatment, and facility characteristics
Horn et al, 2005 ⁷⁶ USA	Retrospective study Secondary analysis of a subset of NPULS	Residents' medical records during 12-week periods in 1996-7	82	1376	0.27* (0.01-0.62)			Controlling for resident, treatment, and facility characteristics
				310	<0.17*	Ref		118 developed PU
				531	0.17-0.33*	0.68	0.02	169 developed PU
				355	0.33-0.5*	0.53	<0.001	89 developed PU
			180	0.5-0.67*	0.16	<0.001	17 developed PU	

*Measures include only time spent on direct patient care.

RN, registered nurse; HPRD, hours per resident per day; OR, odds ratio; CI, confidence intervals; MDS, Minimum Data Set; OSCAR, Online, Survey, Certification, and Reporting System; NPULS, National Pressure Ulcer Long-Term Study; PU, pressure ulcer.

Chapter 5: Costing

Introduction

The objective of costing is to estimate the annual cost of care for residents with PUs in LTC homes in Ontario. The second objective is to provide a guide to resource usage through the use of activity-based costing methodology.

This costing analysis used data from several sources, including the MDS, Ontario LTC homes survey,⁴⁸ and literature among others as outlined in Chapters 2, 3 and 4 and as below, respectively.

Standard care

Standard care was defined as non-interventional (observational) care and was comparable with current practice. The cost of standard care to the MOHLTC was estimated from a variety of data sources, including the per diem rate of funding for LTC residents, administrative data on health care resource utilization (MDS), Ontario Health Insurance Plan (OHIP) billing database, CIHI - Discharge Abstract Database (DAD), and estimates from the literature. The categories of cost included nursing and personal care, physician visits, emergency department (ED) visits, prescription drugs, laboratory and diagnostic tests, and hospitalizations. Costs of care were stratified by presence of PU (Stage 0-I = no PU; Stage II-IV = PU), as well as by risk of developing PU (low vs. high) as defined by a clinical risk algorithm (see details in Chapter 2).

MDS cohort and risk stratification

The MDS was used to identify the relevant cohort of LTC residents (see details in Chapter 2). The MDS cohort was identified at the admission assessment (initial assessment) to LTC homes and followed for one year. Only those residents aged 70+ years at admission were included. Assessments were scheduled to occur every 90 days. This is based on the fact that in the Ontario MDS, residents were assessed upon admission and at 3-month intervals, or when significant changes in health status occurred. Follow-up assessments were incorporated in the analysis if they occurred within +/-15 days of the scheduled date (e.g., the 90-day assessment was considered valid if it occurred between 75 and 105 days). The clinical risk algorithm was calculated for each follow-up assessment. If risk was not calculable on a follow-up assessment (e.g., if they had a quarterly assessment which did not include all information needed to determine risk category), residents were assigned to the same risk group of the previous assessment. The cohort was stratified by PU risk (low/high) and PU stage (0-I, II, III-IV).

Nursing and personal care

The Ontario MOHLTC funds LTC homes at a rate of \$133.75 PRPD. This rate includes the following components: nursing and personal care (\$73.69), programming and support services (\$7.12), raw food (\$7.00) and other accommodation costs (\$45.94). The nursing and personal care component of the per diem cost was adjusted using the case mix index (CMI). The CMI value is an estimate of the relative resource use of an average resident within a

resource intensity group (RUG-III) relative to the average complex continuing care resident. More information can be found regarding the RUG-III group at <http://www.cihi.ca/casemix>. The mean CMI for residents with/without PU by risk status as obtained from the MDS was multiplied by the nursing and personal care component to estimate costs. The mean CMI was calculated from the second assessment of the MDS cohort and ranged from 0.52 to 0.94 depending on PU stage and risk status (Table 5.4).

Physician visits

The costs of physician office visits were estimated by linking the MDS cohort with the Ontario Health Insurance Plan (OHIP) database. The OHIP database contains information on claims for physician services provided to Ontario residents covered by OHIP. A location code in the database indicates if the services were provided in the emergency department, physician office or in the hospital setting. The data linkage and related data analyses were performed by a data analyst at the MAS, the Ontario MOHLTC. Physician fees paid were extracted from the linked database.

OHIP physician claims within +/-15 days of each assessment date were used to calculate the mean and SD of costs per month (Table 5.1). Physician costs were transformed into cost per resident per week. No physician office visits were recorded for residents in the low risk PU stage III-IV stratum. We therefore assumed the same costs as for the high risk PU stage III-IV stratum.

Emergency Department (ED) visits

ED physician charges were obtained as described above using the ED location code. To calculate non-physician costs related to ED

visits, \$200 was added to each visit (B Chen, personal communication). Costs were transformed into weekly costs per resident. No visits were recorded for residents in the low risk PU stage III to IV stratum (Table 5.2). The same costs as for the high risk PU stage III to IV stratum were assumed.

Drug, laboratory and diagnostics

Costs for prescription drugs and laboratory tests and resource use for diagnostics (x-rays) were based on data reported by Friedman & Kalant.⁷⁹ This study was a concurrent cross-sectional study of 101 patients at an acute care hospital and 102 patients at a LTC hospital in Quebec. Resource use measures, including the number of medical specialist consultations, drugs, biochemical tests and radiographic examinations were used to assess the quality of care. The two groups were closely matched in terms of age, sex, nursing care requirements and major diagnoses. Friedman & Kalant⁷⁹ reported the combined annual cost per bed for selected drug categories (antibiotics, anticoagulants, cardiac drugs, psychotherapeutic agents, anxiolytics, sedatives and hypnotics, diuretics). Drug costs were \$4.76 per resident per week. The reported weekly costs per bed for laboratory tests (biochemical tests) were \$1.25. Drug costs and laboratory costs were inflated to 2007 costs.⁸⁰

The costs for x-rays were estimated using the frequency of x-rays (46 x-rays per 1,000 patient-weeks in LTC) as reported by Friedman & Kalant⁷⁹ and Ontario unit costs.⁸¹ Unit costs were based on the cost for a single view chest x-ray (\$21.90) (OHIP), which is the same as for typical upper and lower extremities two-view x-rays. The assumption was that most x-rays performed in this population are for chest (respiratory infections, etc.) and fractures. The estimated cost for x-rays per resident per week was \$1.01.

Hospitalizations

To estimate hospitalization costs, the MDS cohort was linked to the CIHI-DAD. The DAD contains demographic, administrative, and clinical data on hospital discharges (inpatient acute, chronic, rehabilitation) and day surgeries across Canada.⁸² The resource intensity weights (RIW) for hospitalizations occurring within +/- 15 days of the assessments was multiplied by the average cost per hospital stay of \$4,732 (financial year 2006/07)⁸³ to obtain the cost of each hospitalization.

The cost of in-hospital physician visits was obtained from the OHIP data on physician fees charged in hospital. No visits were recorded for residents in the low risk PU stage III-IV stratum (Table 5.3). The same costs as for the high risk PU stage III-IV stratum were assumed.

The costs per month were transformed to costs per visit using the number of residents in the cohort and the number of hospitalizations within this cohort.

Summary

Table 5.4 and Figures 5.1 and 5.2 give an overview of all costs incurred by residents in LTC. The costs of the “other” funding components were fixed at \$420.42 per resident per week. Of all other cost items, the nursing and personal care component accounted for 71% to 87% of total costs. The table reports the average cost per resident whether or not the resident had physician visits or hospital stays.

Table 5.1. Physician visits/fees paid for office visits per month

PU Risk	PU stage	N Patients	N Patients with a visit	N visits	Mean \$ per month*	SD \$ per month
Low	0 to I	6,865	735	4,427	144.83	151.53
Low	II	52	10	87	183.00	195.16
Low	III to IV	18	0	0	--	--
High	0 to I	13,630	1,645	11,598	165.94	161.72
High	II	682	116	989	214.52	199.70
High	III to IV	380	66	460	176.91	126.78

Table 5.2. Emergency department visits/fees paid for office visits per month

Risk	PU stage	N Patients	N Patients with a visit	N visits	Mean \$ per month*	SD \$ per month
Low	0 to I	6,865	56	185	226.03	281.86
Low	II	52	1	4	126.44	.
Low	III to IV	18	0	0	--	--
High	0 to I	13,630	173	633	169.36	212.48
High	II	682	11	32	160.10	240.34
High	III to IV	380	9	24	150.29	108.90

Source (Tables 5.1 and 5.2): MDS and OHIP data, analyzed and provided by MAS, MOHLTC, May 09, 2008.

*Interpretation: physician costs per patient (who had at least 1 visit) within 30 days of their assessment.

PU, pressure ulcer; SD, standard deviation; MDS, Minimum Data Set; OHIP, Ontario Health Insurance Plan; MAS, Medical Advisory Secretariat; MOHLTC, Ministry of Health and Long-Term Care.

Table 5.3. Hospitalization cost per episode

Item	Risk of PU	PU Status	Cost (\$) *
Hospitalization	Low	0 to I	7,446.61
	Low	II	4,342.23
	Low	III to IV	--
	High	0 to I	6,929.97
	High	II	6,622.34
	High	III to IV	5,212.44
In-hospital physician charges	Low	0 to I	401.35
	Low	II	353.83
	Low	III to IV	--
	High	0 to I	318.24
	High	II	381.22
	High	III to IV	277.80

*Costs in Canadian dollars.

PU, pressure ulcer.

Table 5.4. Cost per resident per week in the Ontario Long-Term Care homes

Item	Risk of PU	PU Status	Value/ Cost (\$ per week)	
LTC cost				
Case Mix Index	Low	0 to I	0.52	
	Low	II	0.54	
	Low	III to IV	0.70	
	High	0 to I	0.71	
	High	II	0.90	
	High	III to IV	0.94	
MOHLTC Funding				
Nursing and personal care	All	All	515.83	
Other	All	All	420.42	
Physician visit cost				
	Low	0 to I	3.62	
	Low	II	8.21	
	Low	III to IV	Same as high risk cost (see text)	
	High	0 to I		4.67
	High	II		8.51
	High	III to IV	7.17	

Table 5.4. Cost per resident per week in the Ontario Long-Term Care homes (continued)

Item	Risk of PU	PU Status	Value/ Cost (\$ per week)
ED Visits			
Physician services	Low	0 to I	0.43
	Low	II	0.57
	Low	III to IV	0.83
	High	0 to I	0.50
	High	II	0.60
	High	III to IV	0.83
Non-physician cost	Low	0 to I	5.39
	Low	II	15.38
	Low	III to IV	12.63
	High	0 to I	9.29
	High	II	9.38
	High	III to IV	12.63
Drugs	All	All	6.14
Lab Tests	All	All	1.61
X-Rays	All	All	1.01
Hospitalization			
Hospitalization	Low	0 to I	15.95
	Low	II	58.45
	Low	III to IV	0.00
	High	0 to I	23.96
	High	II	43.05
	High	III to IV	38.41
In-hospital physician services	Low	0 to I	3.68
	Low	II	20.41
	Low	III to IV	??
	High	0 to I	4.72
	High	II	10.62
	High	III to IV	8.77

To calculate weekly Ministry funding, the “nursing and personal care” component was adjusted with the case mix index (CMI):

Total = (“CMI” * ”Nursing and personal care”) + “Other”

To calculate weekly ED visit costs, non-physician costs were added to physician charges:

Total = “ED visits physician charges” + “Non-physician costs”

PU, pressure ulcer; LTC, long-term care; ED, emergency department.

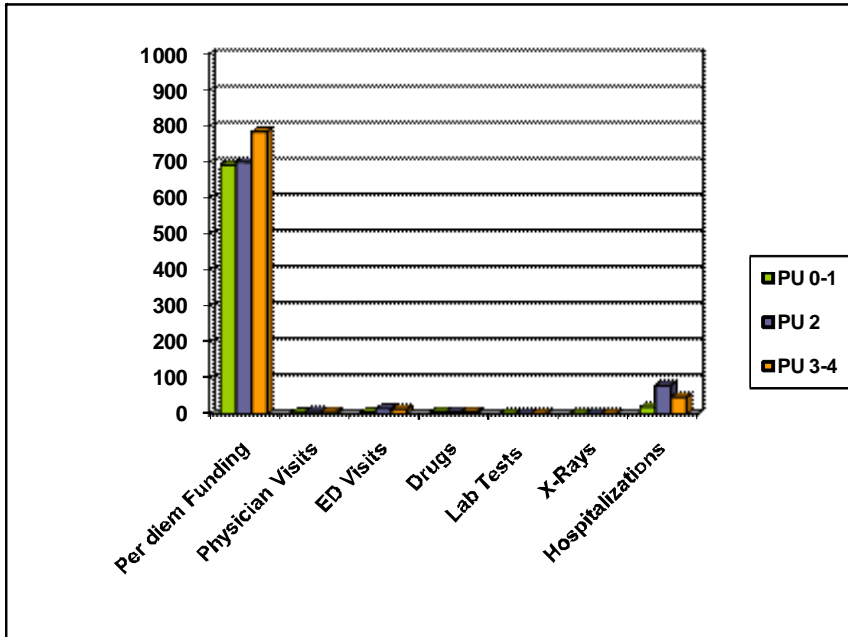


Figure 5.1. Mean cost per low risk resident per week

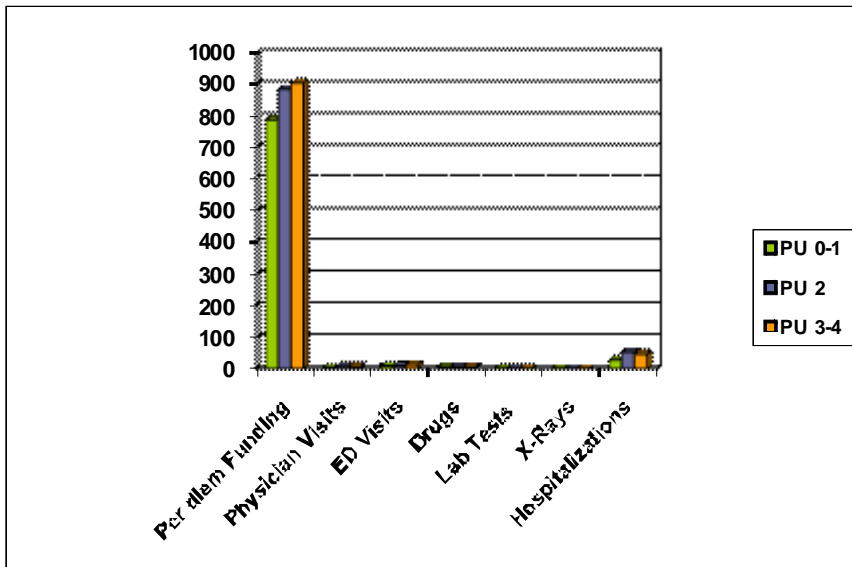


Figure 5.2. Mean cost per high risk resident per week

Strategy 1: Alternative foam mattress

Standard care

Various types of mattresses are in use in LTC homes. Currently, 54% of beds in LTC homes have standard mattresses, 46% have specialty mattresses, of which 85% are AF mattresses and 15% are high-end specialty mattresses (see details of the Ontario LTC homes survey in Chapter 3).⁴⁸ Evidence suggests that AF mattresses could reduce the incidence of new PUs by 69% (see details in Chapter 4). Specialty mattresses are much more expensive than AF mattresses and are therefore funded through the HINF.⁸⁴ There is no evidence that specialty mattresses have any benefit over AF mattresses for PU prevention.⁵⁰

Because of the lack of evidence and special funding mechanism, high end specialty mattresses have not been included in this analysis. Details as to which residents (risk/PU status) receive AF mattresses were not available. Standard care was therefore defined as 54% standard mattresses and 46% AF mattresses across risk and PU strata.

Intervention

The target was to replace all standard mattresses with AF mattresses only where such mattresses were not currently in use in order to reduce the incidence of PU.

Resource use and costs

The unit cost for the standard mattress was \$225. Most of the AF mattresses currently used (98%) cost \$450 per mattress; other foam mattresses were \$350. The cost of the most common AF mattress was used (\$450). Based on the Ontario

LTC homes survey,⁴⁸ both standard and AF mattresses have a average lifespan of 7 years. Refer to Chapter 3 for further details.

Strategy 2: Alternative foam mattress and 4-hourly turning/repositioning

Standard care

Presently, 54% of all mattresses in LTC homes are standard mattresses while 46% are AF mattresses. Approximately 3% of residents at low risk of PU were immobile as are 55% of high risk residents (Table 5.5). These residents would potentially benefit from repositioning. However, only 25% of immobile residents at high risk of developing PU were on a repositioning schedule (Table 5.6). Among immobile low risk residents, only 5% were on such a schedule. Residents on turning / repositioning programs were reported as being turned or repositioned every 2 hours or 12 times per day. Refer to Chapters 2 and 3 for further details.

Table 5.5. Standard care for immobile LTC residents at low risk for pressure ulcer

	Standard Mattress (54%)	AF Mattress (46%)
Repositioning program		
Yes (%)	5	2
No (%)	95	44

Table 5.6. Standard care for immobile LTC residents at high risk for pressure ulcer

	Standard Mattress (54%)	AF Mattress (46%)
Repositioning program		
Yes (%)	25	11
No (%)	75	35

Source: Minimum Data Set data; Ontario Long-Term Care homes survey.⁴⁸

Intervention

This intervention comprised two components: 1) AF mattresses and 2) turning/repositioning schedule. All residents were assumed to receive an AF mattress. All immobile high risk residents were turned/repositioned every 4 hours (i.e., 6 times per day). The proportion of immobile low risk residents on a turning/repositioning program remained unchanged, however, the frequency of repositioning changed from the current 2-hourly turning/repositioning schedule (on a standard mattress) to turning/repositioning every 4 hours (on an AF mattress).

Resource use and costs

Resources needed for this intervention were 5 min of PSW time per repositioning. The salary for a PSW ranged from \$14 to \$20.50 per hour, with a weighted mean of \$16.97 per hour (Ontario LTC homes survey).⁴⁸ The cost PRPD for repositioning every 2 hours was therefore \$16.97. Repositioning every 4 hours incurred a daily cost of \$8.49 per resident. It was assumed that there are no cost savings when switching from a 4-hourly turning schedule to a 2-hourly turning schedule. All standard mattresses (54% of all mattresses) were replaced with AF mattresses at a cost of \$450 per mattress. Refer to Chapter 3 for further details.

Strategy 3: Nutritional Supplementation

Background

The RNAO best practice guidelines on Risk Assessment and Prevention of Pressure Ulcers indicate that nutritional assessments should be undertaken for residents on admission to a LTC home, on entry to any new health care

environment or whenever the client's condition changes.²⁷ If a nutritional deficit is suspected, a registered dietician should be consulted and appropriate interventions implemented. The steps or levels of care include increasing protein intake, increasing calorie intake to spare proteins, supplementation with multi-vitamins, or supplementation with products that provide complete nutrition. If dietary intake remains inadequate, alternative nutritional interventions, such as enteral nutrition support and parenteral nutrition should be considered.

Standard care

The MDS data provide the following profile of the current rates of malnutrition and of the use of nutrition interventions in Ontario LTC homes.

Table 5.7. Prevalence of malnutrition and nutrition interventions in Ontario LTC homes

Proportion of residents in LTC homes that are malnourished (malnutrition is defined as weight loss of 5% or more in the preceding 30 days or 10% or more in the preceding 180 days)	6.1%
Proportion of residents in LTC homes on between-meal supplements	14.35%
Proportion of residents in LTC homes on enteral nutritional support	1.08%
Proportion of residents in LTC homes on parenteral nutritional support	0.04%

Source: Minimum Data Set data

The cost of three meals per day for each resident in LTC homes in Ontario is covered by the daily raw food per diem amount of \$7.00. . To the extent that the costs of nutritional support exceed the daily per diem, limited additional funding mechanisms are available. Residents may cover the cost of nutritional interventions out of pocket, or the LTC home may apply for funding via the HINF.

HINF covers treatment costs for residents with acute or intensive service needs, thus allowing these residents to remain in the LTC homes when they would otherwise require in hospital care. The nutritional interventions funded by the HINF include complete nutritional supplement support, enteral nutrition support and total parenteral nutrition. The HINF has very stringent criteria that must be met in order for residents to qualify for funding of oral nutritional supplementation (ONS).

Supplements currently in use

A survey⁴⁸ of Ontario LTC homes revealed that supplements manufactured by Nestle Canada and Abbott Laboratories are currently in use. The most popular supplement, Resource 2.0 from Nestle Canada, was used by six homes and Beneprotein powder used by 4 homes. Other products used in at least one facility included Boost Regular, Resource Regular, Boost 1.5 Plus, and Ensure Regular.

The survey of Ontario LTC homes also revealed that few homes provided doses of ONS large enough to deliver sufficient nutritive content. Most homes reported dosing of two to three times per day with 30 to 80 ml per dose.

The estimation of staff costs for delivering a nutritional intervention requires an understanding of the personnel involved as well as the total amount of time required.

Administering oral supplements involves preparing the supplement and ensuring that the resident consumes the supplement in its entirety. According to the survey of Ontario LTC homes,⁴⁸ PSWs typically administer oral supplements, RPNs occasionally administer supplements and RNs rarely administer supplements. The survey also revealed that it may take approximately one hour to administer supplements to eight residents, reflecting an average of 7.5 minutes per resident. Refer to Chapter 3 for further details of the Ontario LTC homes survey.⁴⁸

Intervention

The proposed nutritional intervention was an ONS delivering calories, proteins, vitamins and nutrients similar to supplements which were associated with a benefit for prevention and treatment of PUs in relevant clinical trials. ONS for the prevention of PUs was considered to be directed toward all LTC residents at high risk of developing PUs, who were malnourished, consistent with the clinical trial evidence.

The nutritional content of supplements currently used, in addition to other supplements available from these companies, was compared to the nutritional content of supplements in the relevant clinical studies. Each trial in the meta-analysis by Stratton et al.³⁰ used a supplement that included vitamins and minerals in addition to protein. Supplements providing 2 kilocalories per ml, such as Resource 2.0, were the most comprehensive. Protein powder supplements such as Beneprotein lacked additional nutrients such as vitamins and minerals. As a result, a 2.0 kilocalorie per ml oral supplement (Resource 2.0) was chosen as the optimal intervention. For example, delivered at 237 ml per day, Resource 2.0 provides 20 g of protein as well as vitamins and minerals. Other supplements which provided adequate nutrients included 1.5 calorie per ml

supplements such as Boost 1.5 Plus and Ensure Plus. One calorie per ml supplements were found to provide either insufficient calories or protein and were not considered.

The volume of ONS required to deliver the nutritional content similar to that of the relevant trials was approximately 235 mL per day. Thus a dose of 80 mL three times per day was considered the optimal intervention.

It is not possible to deliver ONS to residents of LTC homes who were unable to consume oral nutrition. The proportion of residents on parenteral/IV nutrition was taken as an indication of the proportion of residents unable to consume fluids orally. Since the MDS data revealed that less than 1% of residents were on parenteral/IV nutrition (Table 5.7), the assumption was made that the proposed intervention could be administered to 100% of the residents in need.

Resource use and costs

The base case cost of oral nutritional supplementation was estimated at \$8.50 per day, including staff costs for administration. The cost per day of the ONS may be as low as \$4.74, when incorporating assumptions that reflect the lowest prices and least amount of resource utilization. The cost per day may be as high as \$13.81, when incorporating assumptions that reflect the highest prices and greatest amount of resource utilization. Tables 5.8 and 5.9 shows the assumptions that were used to estimate the range of costs of the nutrition intervention.

Table 5.8. Resource utilization for nutritional supplementation

Item	Estimate	Source
No. of times ONS administered per day	3	Expert opinion
Mean time per administration	7.5 minutes	Survey of Ontario LTC homes ⁴⁸ (Chapter 3)
Staff mix in LTC	RN/RPN/PSW 10%/16%/74%	Survey of Ontario LTC homes ⁴⁸ (Chapter 3)
Staff mix for supplement administration (base case and sensitivity analysis of the lowest possible cost)	PSW 100%	Based on expert opinion that staff most likely to administer ONS are PSWs.
Staff mix for supplement administration (sensitivity analysis of the highest possible cost)	PSW 82%, RPN 18%	Based on reported staff mix in LTC homes and based on an assumption that RNs do not administer ONS
Proportion of residents at high risk of developing a pressure ulcer who are malnourished	9.7%	MDS
Proportion of malnourished residents at high risk of developing a pressure ulcer who are currently receiving ONS	40.5%	MDS
Proportion of residents with a PU currently receiving ONS	34.32%	MDS

ONS, oral nutritional supplement; LTC, long-term care; RN, registered nurse; RPN, registered practical nurse; PSW, personal support worker; PU, pressure ulcer; MDS, Minimum Data Set.

Table 5.9. Unit costs of nutritional supplements

Item	Estimate	Source
Supplement cost (base case)	\$ 0.0089 per mL	Nestle rep (Resource 2.0 Wholesale price)
Supplement cost (sensitivity analysis of the highest possible cost)	\$0.013 per ml	Resource 2.0 retail price
Supplement cost (sensitivity analysis of the lowest possible cost)	\$0.0056 per ml	Estimated wholesale price of Boost 1.5 Plus
Mean wage PSW	\$16.97	Survey of Ontario LTC homes ⁴⁸
Mean wage RPN	\$21.66	Survey of Ontario LTC homes ⁴⁸

LTC, long-term care; PSW, personal support worker; RPN, registered practical nurse.

Strategy 4: Skin care protocols for incontinence care

Standard care

Approximately 86% of the residents in LTC homes in Ontario have some degree of incontinence.²⁷ Specifically, more than 40% of the LTC residents need assistance with toileting, 41% use disposal briefs, 48% need barrier cream, 44% depend on bed pads, and about 44% of the residents use all four interventions.⁴⁸

These residents are incapable of maintaining continence independently and need special incontinence skin care management. However, the best practice guidelines do not explicitly address different types of interventions for treatment of PU. The LTC homes survey in Ontario⁴⁸ showed that currently 50% of the residents use only soap and water for cleansing.⁴⁸ The standard care of changing briefs of residents is 5 times per day, and all incontinence care is provided by PSWs.⁴⁸

Intervention

Evidence from the literature,^{28,29,63} was used to guide incontinence skin care practices. Therefore, the intervention consisted of the following, and to be done by a PSW:

- #1. Three minutes⁴⁸ for assessment of urinary/fecal incontinence every 2 hours,^{28,29,63} for a total of 36 minutes per 24 hours.
- #2. The application of no-rinse cleanser and barrier cream 6 times per 24 hrs.^{28,29}
- #3. Changing briefs 6 times/24 hrs.²⁹

Resource use and costs

The required data for costing incontinence care consisted of the following:

The mean average time of staff in assessment of skin care, time spent in cleansing with skin care products (e.g., triple care or soap), and unit cost of the products (price of the incontinent skin care products vs. the price of soap and water, cost of disposable briefs).

Data for staff time were obtained from the LTC homes survey in Ontario⁴⁸ and from the literature.^{29,63} The cost of the skin care products (e.g., triple care) and staff wages were obtained from the Ontario LTC homes survey.⁴⁸

Using the data for each task, the costs per daily assessment of residents for incontinence care was as follows:

(A) Mean time per assessment for incontinence = 3 minutes

(B) Number of assessments for incontinence = 12 times/24 hrs

(C) Staff (PSW) salary/hour = \$16.97/hour

Therefore, the cost of assessment of incontinence PRPD = \$10.18

Similarly, the costs of changing briefs and providing incontinent skin care were:

(A') Mean time per change of brief = 5.5 minutes

(B') Number of changes of briefs per day = 6 times

(C') Staff (PSW) salary/hour = \$16.97/hour

(D') Cost of skin care products (cost of cleansing and barrier creams) = \$0.40/change of brief

(E') Cost/brief = \$0.67

Therefore the cost of changing briefs and providing incontinent skin care PRPD = \$15.75/resident/day

Thus:

Total cost of incontinence skin care protocol (assessment, cleaning, and changing briefs) PRPD = \$25.93

In comparison to the standard care:

(A') Time per cleaning with soap and water = 9.5-15 minutes

(B') Number of cleanings per day = 5 times

(C') Staff (PSW) salary/hour = \$16.97/hour

(D') Cost/brief = \$0.67

Total cost of incontinence care in the standard care PRPD = \$16.78 - \$24.55

Thus the average (range) incremental costs of the incontinence care protocol was \$8.87 (\$1.38 - \$9.15).

Strategy 5: Registered nurse time increase

Background

LTC residents have complex needs, which require an appropriate level of care and mix of care providers. Staffing is not an intervention, but it is a critical factor in carrying out interventions to improve the quality of care in LTC homes. There is a general understanding that nurse staffing levels are important; however the optimal staffing to improve health outcomes of LTC residents is unclear.

Staffing

Types of direct care staff include RNs, registered qualified nursing assistants/licensed practical nurses (RPN/LPN), therapists, and others.⁴⁸

RNs are persons who have graduated from a recognised formal nursing educational program and have qualified to practise nursing as RNs according to appropriate provincial legislation. Depending on the size of the facility, this may include the Director of Nursing, the Assistant Director of Nursing, supervisors and general duty nursing staff who qualify as RNs (Statistics Canada: Residential Care Facilities Survey 2005/2006 “Instructions and Definitions”).⁸⁵

RPN/LPNs are persons authorized to function as nursing assistants according to appropriate provincial legislation.⁸⁶ Other direct care staff includes PSWs or nursing aides (NAs), health care aides, graduate nurses, etc.⁸⁶

Two main staffing measures have been used to assess the quality of care: the number of nursing hours per resident per day (HPRD) and staffing ratios.

Nursing hours per resident per day

The reported average total HPRD of nursing and personal care in Ontario, in 2007, was 2.86.⁸⁷ Based on the available evidence, and in the absence of a more rigorous evidence-based study to determine appropriate staffing levels, and the staffing standards in other jurisdictions, the RNAO suggested a minimum staffing standard of 3.5 nursing and personal care HPRD for facilities with an average case mix.

Standard care

Estimates of the standard care staffing level and time were obtained via a telephone survey of a random sample of 34 LTC homes in Ontario, stratified by LHIN between April and May, 2008. See further details in Chapter 3.⁴⁸

The average total nursing time in the LTC homes in Ontario were 2.64 HPRD, including: 0.27 HPRD of RN time; 0.42 HPRD of RPN time; and 1.94 HPRD of PSW time.⁴⁸ In addition, the survey found that RNs provide 10% of nursing and personal care, RPNs provide 16% of care, and PSWs provide 74% of care. The total staff for a 24-hour period, for the 34 homes surveyed, housing a total of 2,835 residents, was reported to be 935.⁴⁸

Intervention

The intervention assumed that RN time is increased from the standard care 0.27 HPRD to a target of 0.58 HPRD for all high risk LTC residents.

Resource use and costs

Staff salaries were obtained via the above-mentioned survey of LTC homes in Ontario.⁴⁸ Costs PRPD for standard care and for the targeted prevention strategy (i.e., increase in RN time for the prevention of a PU), and incremental costs PRPD were calculated as follows:

The standard care staffing HPRD for each staffing level (i.e., RN, RPN, and PSW) were calculated by dividing the reported staffing hours per day by the total number of residents in LTC. Then, the total staffing HPRD was calculated by adding the HPRD for all staffing levels.

The standard care cost PRPD for each staffing level was calculated by multiplying the average cost per hour with the standard care staffing HPRD (e.g. RN cost per hour times RN HPRD). The total cost PRPD was calculated by adding the cost PRPD for all staffing levels.

Cost estimates of staffing are shown in Table 5.10. The estimated standard care costs PRPD for a RN, RPN, and PSW were \$8.44, \$9.10, and \$32.92, respectively. The estimated cost PRPD of increasing RN time to 0.58 HPRD and maintaining other standard care staffing levels would be \$18.13. The incremental cost of increasing RN time for all high risk LTC residents for the prevention of PUs was estimated at \$9.69 per day.

Table 5.10. Cost estimates (per resident per day) of staffing

Staff	Cost (\$/hr)*	Standard care [§]	Standard care cost (\$) PRD (low/high)	Target	Target cost (\$) PRD		Incremental cost (\$) PRPD
		HPRD		HPRD	Low risk	High risk	
RN	31.26 (20-40)	0.27	8.44 (5.4-10.8)	0.58	8.44 (5.4-10.8)	18.13 (11.6-23.2)	9.69 (6.2-12.40)
RPN	21.66 (20-27)	0.42	9.10 (8.4-11.3)	0.42	9.10 (8.4-11.3)	9.10 (8.4-11.3)	0.00
PSW	16.97 (14-20.50)	1.94	32.92 (27.2-39.8)	1.94	32.92 (27.2-39.8)	32.92 (27.2-39.8)	0.00
Total		2.64	50.46 (41.0-61.9)	2.94	50.46 (41.0-61.9)	60.15 (47.2-74.3)	9.69 (6.2-12.40)

*Staff wages: Ontario Long-Term Care homes survey (N=17).⁴⁸

[§]Staffing ratios: Ontario Long-Term Care homes survey (N=24).⁴⁸

HPRD, hours per resident per day; PRPD, per resident per day; RN, registered nurse; RPN, registered practical nurse; PSW, personal support worker.

Chapter 6: Health-related quality of life

Introduction

PU are common in LTC residents which impose a significant financial as well as health burden on health care systems.⁸ For LTC residents, the development of a PU is associated with many concomitant conditions and a range of symptoms. Qualitative work has shown that the impact of both PU and related treatments is wide-ranging, with physical, emotional, social, and financial aspects affected, whilst pain, restricted activities, changes in body image and the loss of independence/control are profound.⁸⁸⁻

⁹¹ It is therefore important to measure their summative impact on an individual's health-related quality of life (HRQOL).⁹¹ Community-based preference (utility)-weighted HRQOL measures are a preferred summative measure of burden of illness,⁹² but the impact of PU on utility-based HRQOL in LTC residents has not been quantified previously. Utilities for LTC residents have been previously estimated using expert judgment only.

The MDS is the most widely used health assessment instrument for institutional settings,⁹³ and its applications include health care planning,⁹⁴ case-mix,⁹⁵ quality of care improvement,⁹⁶ and outcome measurement.^{93,97} MDS-based HRQOL measure (Minimum Data Set Health Status Index, MDS-HSI), developed and validated previously^{98,99} offers an opportunity to estimate utilities of LTC residents.

The objective was to use MDS health status assessment information to estimate health status utilities in LTC residents in Ontario, both with and without PUs.

Methods

Setting and population

All residents in 89 LTC homes in Ontario who had a full MDS assessment were included in this analysis. If a person had more than one full assessment, one was randomly selected. This sample was representative of the population in LTC homes during the study period between May 14, 2004 and November 7, 2007.

Data sources

Minimum Data Set

LTC population-based data from the MDS 2.0 Canadian version was used to estimate utilities of LTC residents in Ontario. The reliability and validity of the MDS for clinical practice and research purposes has been demonstrated in several studies.¹⁰⁰⁻¹⁰³

Minimum Data Set Health Status Index (MDS-HSI)

The MDS-HSI is based upon the Health Utilities Index Mark 2 (HUI2), encompassing seven attributes to define health states: sensation (vision, hearing, and speech), mobility, emotion, cognition, self-care, pain, and fertility.¹⁰⁴⁻¹⁰⁷ Each HUI2 attribute has four or five levels, ranging from severely impaired to no impairment/normal. All attributes of health except fertility were used in this study.

Details of the derivation of the MDS-HSI can be found in Wodchis *et al.*^{98,99} Similar to the HUI2

measure, the MDS-HSI was derived in two steps: first relevant items from the MDS assessment including sensation (i.e. vision, hearing, and speech), mobility, emotion, cognition, self-care, and pain symptoms from the MDS were mapped on to the HUI2 health status classification system. Second, subjects were assigned MDS-HSI scores using the Canadian HUI2 community preference weights.¹⁰⁵⁻¹⁰⁷

Risk of pressure ulcer

LTC residents were stratified into low, moderate and high risk (co-morbidity) for developing PU stage II to IV,³¹ based on the validated MDS derived risk-adjustment model described in Berlowitz *et al.* (2001).⁴¹ The risk coefficients from Berlowitz *et al.*⁴¹ were adopted to measure deciles of predicted log(odds). Residents falling into deciles 1 to 3 were classified as low risk, deciles 4 to 8 moderate risk, and deciles 9 to 10 high risk (based on <1% PU rate, 1-3% PU rate, >3% PU rate, respectively). PU risk classification was also explored using two levels: low risk (deciles 1 to 3) and high risk (deciles 4 to 10). See further details in Chapter 2.

Results

A total of 8,058 LTC residents: 7,319 (90.8%) without PU and 739 (9.2%) with PU completed a full MDS assessment. The average age of the LTC residents was 83.6 years. In the low risk group (n=2,419), 23 (1%) had PU. In the high risk group (n=5,639), 716 (13%) had PU.

The unadjusted mean MDS-HSI scores by stage, age, are reported in Tables 6.1. The MDS-HSI mean scores did not differ across age group.

The mean MDS-HSI scores for LTC residents with PU and those without PU were significantly different across risk strata: for low risk, 0.40 vs. 0.47, P=0.031; and for high risk, 0.27 vs. 0.33, P<0.0001 (Table 6.2).

Discussion

Utility scores for LTC residents are low. The mean MDS-HSI scores were significantly lower for LTC residents with PU than those without PU, with a moderate decrement of 0.10 in utility. LTC residents with PU had significantly lower HRQOL compared to those without PU, regardless of their risk status (co-morbidity).

The MDS-HSI enables use of population-based preference scores obtained for the HUI using a standard gamble method. These population reference scores are more representative than utilities estimated by small panels of experts.

There are a number of limitations to this analysis. First, the cross-sectional nature of this study limits assessment of changes in the HRQOL of LTC residents over time. Second, the MDS-HSI scores of LTC residents with PU may not be generalizable to all people with PU in the community and to other LTC settings. The sample includes only 89 of the over 600 LTC homes in Ontario which have MDS available. These 89 LTC homes were not randomly sampled, and may possibly be among the LTC homes with higher standards of care. Finally, the correlation between MDS-HSI and the HUI2 at an individual level is modest.⁹⁸

In the absence of self-reported data, community-weighted preference estimates for LTC residents with and without PU provide important summary outcome measures for the economic evaluation of PU prevention and care among residents in LTC homes in Ontario.

Table 6.1. Mean MDS-HSI by highest pressure ulcer stage (at admission) and age group

Age (yr)	Pressure Ulcer Stage														
	0			I			II			III			IV		
	N	mean	SD	N	mean	SD	N	mean	SD	N	mean	SD	N	mean	SD
<75	908	0.40	0.18	39	0.29	0.15	56	0.37	0.19	19	0.30	0.13	26	0.25	0.14
75-84	2975	0.38	0.18	115	0.31	0.17	176	0.29	0.13	40	0.26	0.16	40	0.27	0.13
85+	3330	0.37	0.17	141	0.28	0.16	222	0.27	0.13	59	0.28	0.14	54	0.24	0.14

MDS-HSI, Minimum Data Set-Health Status Index; SD, standard deviation.

Table 6.2. Mean MDS-HSI by risk distribution on admission

Risk Distribution at Admission	PU Status						P-value
	Without PU			With PU			
	N	Mean	SD	N	Mean	SD	
Low	2396	0.474751	0.178587	23	0.400553	0.153226	0.031
Moderate	3793	0.345056	0.152645	237	0.328428	0.154221	0.108
High	1130	0.258566	0.115136	479	0.239454	0.11903	0.003

MDS-HSI, Minimum Data Set-Health Status Index; SD, standard deviation.

Chapter 7: Cost-effectiveness and cost-utility analysis

Introduction

The objective of this CEA was to compare the costs and consequences associated with standard care and five strategies for preventing PUs in LTC homes in Ontario. The analysis employed a decision analytic model to simulate the lifetime of a cohort of LTC residents and estimate the costs, disease burden, life years and QALYs associated with standard care and each of the prevention strategies.

Methods

Perspective

The analytic perspective was that of the Ontario MOHLTC. As a result, only direct medical costs incurred by the ministry were included in the analysis.

Time horizon

The model time horizon was the lifetime of the cohort. Residents were followed from 83.6 years (average resident age) to death.

Comparators

The comparators included the current standard care and five strategies to prevent PUs in LTC homes in Ontario. The five strategies are:

1. AF mattress: replacing standard mattresses with an AF mattress only where such mattresses are not currently in use;
2. AF mattress and 4-hourly turning/repositioning: replacing standard mattresses with an AF mattress and introducing a turning/repositioning program among LTC residents with mobility deficits who are at high risk of developing PUs not currently on a turning/repositioning schedule;
3. Nutritional supplementation: daily multivitamin supplementation among LTC residents with nutritional deficits who are not currently receiving nutritional supplements and at high risk of developing PUs;
4. Skin care protocol for incontinence: daily skin assessment and use of skin cleansers and barrier creams for residents with urinary or fecal incontinence who are at high risk of developing PUs and not receiving skin care for incontinence; and
5. RN time increase: an additional 20 minutes (from 0.27 hours to 0.58 hours) per resident per day (PRPD) of RN time for residents who are at high risk of developing PUs.

Target population

The target population was residents of LTC homes in Ontario.

Outcome measures

Outcomes considered in the analysis include: (1) the lifetime risk of developing a PU; (2) the lifetime risk of developing a chronic PU; (3) the lifetime risk of local infection; (4) the lifetime

risk of systemic infection; (5) life expectancy (6) quality-adjusted life expectancy (QALYs); (7) direct lifetime costs; and (8) the incremental cost-effectiveness ratio (ICER). The ICER is a ratio of the incremental cost associated with a strategy compared to standard care divided by the incremental benefit, characterized in this analysis as QALYs gained.

$$\text{ICER} = \Delta\text{Cost} / \Delta\text{QALY} =$$

$$\frac{\text{Cost (strategy)} - \text{Cost (standard care)}}{\text{QALYs (strategy)} - \text{QALYs (standard care)}}$$

QALYs (strategy) – QALYs (standard care)

where ICER = incremental cost-effectiveness ratio, Δ (delta) = incremental, and QALYs = quality-adjusted life years.

Model parameters

Table 7.1 summarizes values used in the base case analysis (expected value calculation): effectiveness of each of the five strategies in preventing PU, compared to standard care; intervention cost PRPD; target population; and the proportion of target population already receiving the proposed strategy. Effectiveness is expressed as the relative risk (RR) of PU incidence in the strategy under consideration relative to standard care. Model parameters pertaining to the natural history model of PU are reported in Chapter 2 (Table 2.2) and Chapter 3.

Among the five prevention strategies, AF mattress and 4-hourly turning/repositioning was the most effective strategy for the prevention of PU incidence (RR 0.21 [95% CI, 0.08, 0.59]), followed by RN time increase (RR 0.25 [0.15, 0.40]), AF mattress (RR 0.31 [0.21, 0.46]), skin care protocol for incontinence (RR 0.36 [0.17, 0.75]), and nutritional supplementation (RR 0.85 [0.73, 0.99]) (Table 7.1).

The cost of the intervention PRPD ranged from \$0.09 for the AF mattress (cost amortized over 7 years, the average lifespan of an AF mattress) to \$9.69 for the RN time increase (Table 7.1).

The target populations of these strategies vary (Table 7.1). While replacement of standard mattresses with AF mattresses (AF mattress strategy) is an attractive strategy, it should take into account the fact that approximately 46% of the LTC residents in Ontario are already using AF mattresses. Thus, AF mattresses are targeted to 54% of LTC residents using standard mattresses in Ontario. The AF and 4-hourly turning/repositioning strategy would be best targeted to high risk residents with mobility restrictions (approximately 55% of high risk residents). This means that turning/repositioning protocols are relevant only to residents with impaired mobility. Among this group of residents, approximately 25% are already under turning/repositioning protocols.

A targeted prevention approach was also deemed to be suitable for other strategies, including nutritional supplementation (i.e., for high risk residents with nutritional deficits), and skin care protocol (i.e., for high risk residents with urinary or fecal incontinence). The RN time increase strategy seemed to be most applicable to residents at high risk for PUs (Table 7.1).

Utility

Community-weighted preference estimates for LTC residents with and without PU were derived using a validated instrument, the MDS-HSI. A total of 8,058 residents with full MDS assessment were included in the MDS-HSI analysis: 7,319 (90.8%) without PU and 739 (9.2%) with PU. There were significant differences in the unadjusted mean MDS-HSI scores between LTC residents with PU and those without PU: for low risk, 0.40 vs. 0.47, P=0.031;

and for high risk, 0.27 vs. 0.33 (P<0.0001). Further details regarding the MDS-HSI can be found in Chapter 6.

Modeling

A comprehensive PU policy model was constructed using population-based cost and practice data from 91 LTC homes including 18,891 residents (21% of Ontario LTC homes residents) for the CEA. Refer to Chapter 2 for details regarding the Markov model used to represent the natural history of PU incidence and prognosis among residents in LTC homes in Ontario.

Analysis

The model was analyzed using an expected value calculation, one-way sensitivity analyses and probabilistic sensitivity analysis.

Expected value calculation

The base case expected value calculation employed the best estimates for each of the model inputs: probabilities, costs and utilities. In this way, the expected value of costs, life years, QALYs, and health outcomes (lifetime risk of PU, chronic PU, PU-related local infection, PU-related systemic infection, and PU-related death) were evaluated for standard care, and for each of the five strategies. The ICER was calculated for each of the five strategies compared to standard care.

One-way sensitivity analysis

To assess the effect of uncertainty in key model parameters, a series of one-way sensitivity

analyses was performed. In these analyses, expected value calculations are performed across the range of plausible values for an input parameter, while keeping all other parameters constant. Plausible ranges were defined as 95% confidence intervals (CI) where available, or as ranges of data, where 95% CI were not available. Plausible values for RR estimates of interventions under evaluation were derived from a series of systematic reviews as part of the project for the prevention and treatment of PUs (Chapter 4), utility estimates from the MDS-HSI data (Chapter 6), cost estimates from various costing sources documented in Chapter 5, CMI values from the MDS data (Chapter 5), and estimates of death in LTC from the MDS data, and hospital-related death from the linked MDS and CIHI-DAD data.

In order to simplify interpretation of the one-way sensitivity analyses, results for each strategy are presented in units of Net Monetary Benefit (NMB). Using a willingness-to-pay (WTP) threshold of \$50,000 per QALY,¹⁰⁸ which is commonly used in CEA as a threshold to indicate good value for money, the ICER can be converted to NMB using the following formula:

$$\text{NMB} = \text{WTP threshold} * \Delta\text{QALY} - \Delta\text{Cost};$$
where

NMB = Net Monetary benefit, WTP = willingness-to-pay, QALY = Quality-adjusted life years, and Δ (delta) = incremental.

Strategies with a higher NMB were considered more desirable.¹⁰⁸ A NMB >0 suggests that the strategy is economically attractive at the willingness-to-pay threshold used in its calculation. A NMB <0 suggests that the strategy is not economically attractive.

The one-way sensitivity analysis results were summarized in the following way: if the NMB became <0 for any plausible range of the input

variable in pairwise comparisons with the baseline strategy, the strategy was considered to be sensitive to that variable.

Table 7.1. Effectiveness* of prevention strategies, intervention cost,** and target population

Strategy	RR (95% CI)*	Intervention cost (\$) (95% CI) PRPD**	Target population	Target population already receiving the strategy (%)
Standard care	Reference	Base cost	LTC residents	N/A
AF mattress vs. Standard mattress	0.31 (0.21, 0.46)	0.09	LTC residents	46
AF mattress and 4-hourly turning/repositioning vs. Standard mattress and 2-hourly turn	0.21 (0.08, 0.59)	8.84	55% of high risk residents with mobility problems	25
Nutritional supplementation vs. none	0.85 (0.73, 0.99)	8.50 (4.74, 13.81)	9.7% of high risk residents with nutritional deficiency	40
Skin care protocol for incontinence vs. none	0.36 (0.17, 0.75)	8.82 (1.36, 9.15)	72% of high risk residents with incontinence	50
RN time increase vs. none	0.25 (0.15, 0.40)	9.69 (6.2, 12.40)	100% high risk residents	0

*Effectiveness is expressed as the relative risk of pressure ulcer incidence in the strategy under consideration relative to standard care.

**Incremental cost = strategy cost minus standard care cost.

RR, relative risk; PRPD, per resident per day; LTC, long-term care; N/A, not applicable; AF, alternate foam; RN, registered nurse.

Probabilistic sensitivity analysis

Probabilistic sensitivity analyses were performed to assess the joint effects of uncertainty in the model parameters on the model outcomes. In this analysis, each parameter is defined by a distribution that reflects the plausible range or known distribution of the parameter. Beta distributions were used for probabilities, log-normal distributions for RRs, normal distributions for case mix indices, and gamma distributions for health utilities (Table 7.2). Probabilistic sensitivity analyses are performed in two steps. First, values for specified parameters (probabilities, RRs, costs and utilities) were sampled from their probability distributions representing uncertainty in these parameters (5,000 samples). For each set of sampled values, the outcomes (health outcomes, cost, life years, QALYs and ICER) were calculated. The output of probabilistic sensitivity analysis is a distribution for each of the outcomes.

Cost-effectiveness acceptability curve

A cost-effectiveness acceptability curve graphs the proportion of the samples in which a strategy is cost-effective (y-axis) for a range of WTP thresholds (λ , x-axis). The curve is interpreted as the probability that a strategy is cost-effective when compared to standard care at a given WTP threshold. Details on parameter inputs and their distributions for the 35 input variables are provided in Table 7.2.

Results

Summary of long-term clinical effectiveness and cost-effectiveness are outlined in Table 7.3.

Health outcomes

Under standard care, the lifetime risk of PU was projected to be 50%; the lifetime risk of chronic PU was 32%; the lifetime risk of PU-related local infection was 13%; and the lifetime risk of PU-related systemic infection was 9%. The average life expectancy of an 83.6-year old cohort of residents was estimated to be 3.43 years, and the quality adjusted life expectancy was 1.35 QALYs (both discounted at 5%) (Table 7.3).

All prevention strategies reduced the burden of disease associated with PU (Table 7.3). Compared to standard care, the absolute reduction in lifetime risk of PU ranged from 0.06% to 15%. The greatest reductions were observed with the RN time increase strategy and the AF mattress and 4-hourly turning / repositioning strategy. With these strategies, the lifetime risk of PU was reduced by approximately 25-30% in relative terms and 14% in absolute terms, from approximately 50% to approximately 36%. Smaller reductions were observed with the nutritional supplementation and skin care protocol strategies. Smaller reductions in the burden of disease relative to standard care were observed with other projected outcomes, including the lifetime risk of chronic PU (0.04% to 11% absolute risk reduction), PU-related local infection (0% to 5% reduction), and PU-related systemic infection (0.01% to 4% reduction). Again, the most favorable outcomes were observed in both the RN time increase strategy and the AF mattress and 4-hourly turning / repositioning strategy.

All strategies produced QALY gains. Relative to standard care, the improvement was 0.0127 QALYs for AF mattress, 0.0142 for AF mattress and 4-hourly turning/repositioning, 0.0002 for nutritional supplementation, 0.0046 for skin care protocol for incontinence, and 0.0165 for RN time increase (Table 7.3). Expressed in quality-adjusted days gained, gains ranged from less

than one day to approximately six days. The strategies also had a positive, and qualitatively similar impact on life expectancy (LYs gained ranged from <1 to 8 days). There were small differences between life expectancy and quality-adjusted life expectancy estimates, suggesting that most of the health gained is associated with the reduction in PU-related death.

Table 7.2. Parameters modified in the probabilistic sensitivity analysis

Category	Description	Distribution type	Expected value	Variation
Probability				
Infection	Local infection given PU	Beta	0.115	alpha = 4.5902, beta = 35.4098
	Systemic infection given PU	Beta	0.143	alpha = 9.3984, beta = 56.3902
Death	Sepsis given PU	Beta	0.200	alpha = 447.2, beta = 1788.8
Transitions	low risk to high risk of PU	Beta	0.004	alpha = 2.6771, beta = 712.3229
	high risk to low risk of PU	Beta	0.004	alpha = 6.4591, beta = 1512.541
Scaling factors				
PU progression	PU 0-I	Triangular	0.139	Min = 0.1122, Max = 0.1530
	PU I-II	Triangular	1.070	Min = 0.8915, Max = 1.3159
	PU II-III	Triangular	0.378	Min = 0.3466, Max = 0.3967
	PU III-IV	Triangular	0.449	Min = 0.2900, Max = 0.7666
PU healing	PU I	Triangular	1.339	Min = 1.0233, Max = 1.4974
	PU II	Triangular	0.457	Min = 0.1198, Max = 0.7019
	PU III	Triangular	1.033	Min = 0.8147, Max = 1.1637
	PU IV	Triangular	0.975	Min = 0.8044, Max = 1.1841
Case Mix Index (for cost estimate)	Low risk no PU	Normal	0.520	SD = 0.1336
	High risk no PU	Normal	0.710	SD = 0.1067
	Low risk PU II	Normal	0.540	SD = 0.1325
	High risk PU II	Normal	0.900	SD = 0.1121
	Low risk PU III-IV	Normal	0.700	SD = 0.1324
Disutility (1-utility)	High risk PU III-IV	Normal	0.940	SD = 0.0625
	No PU			
PU	Low risk	Gamma	0.525	alpha = 8.6503, lambda = 16.4690
	High risk	Gamma	0.675	alpha = 21.9487, lambda = 32.5263
PU	Low risk	Gamma	0.600	alpha = 15.3051, lambda = 25.5320
	High risk	Gamma	0.731	alpha = 6.0488, lambda = 8.2737
Relative risk				
Interventions	AF mattress	Log-normal	0.316	sigma (SD of logs) = 0.20003
	AF mattress and 4-hourly turning/repositioning	Log-normal	0.239	sigma (SD of logs) = 0.509718
	Nutritional supplementation	Log-normal	0.812	sigma (SD of logs) = 0.06987
	Skin care protocol	Log-normal	0.387	sigma (SD of logs) = 0.378642
	RN time increase	Log-normal	0.258	sigma (SD of logs) = 0.250212
PU progression	PU 0-I	Log-normal	2.132	sigma (SD of logs) = 0.0873
	PU I-IV	Log-normal	2.485	sigma (SD of logs) = 0.0872
PU healing	PU I	Log-normal	0.612	sigma (SD of logs) = 0.1761
	PU II	Log-normal	0.558	sigma (SD of logs) = 0.1355
	PU III	Log-normal	0.480	sigma (SD of logs) = 0.4183
	PU IV	Log-normal	0.576	sigma (SD of logs) = 0.3860

RR estimates for interventions under evaluation, PU progression by stage, and healing rate by stage. Effectiveness is expressed as the relative risk of pressure ulcer incidence in the strategy under consideration relative to standard care. PU, Pressure ulcer; CMI, case mix index ; RR, relative risk ; SD, standard deviation.

Costs and Cost-Effectiveness

The average lifetime direct medical cost of a resident under standard care was estimated to be \$153,148 over an average lifespan of 3.43 years (Table 7.3). All five strategies increased costs overall, with cost increases ranging from \$80 (AF mattress) to \$4,448 (RN time increase) per resident. In pairwise comparisons with standard care, both the AF mattress strategy and the AF mattress and 4-hourly turning/repositioning strategy were economically attractive although not cost saving. Both these strategies were associated with highly attractive ICERs (\$5,234 per LY and \$6,328 per QALY for the AF mattress strategy; \$4,287 per LY and \$5,234 per QALY for the AF mattress plus 4-hourly turning / repositioning strategy). In contrast, the remaining three strategies were highly unattractive with ICERs ranging between \$269,000 / QALY and \$1.2 million/QALY.

Scenario-based sensitivity analysis

The baseline analysis assumed that no cost savings would occur due to lower labor costs for the AF plus 4-hourly turning/repositioning strategy. This conservative assumption was employed because of uncertainty regarding current turning practice. Outcomes under the assumption that turning was currently occurring on a 2-hourly schedule and cost avoidance could be achieved with less turning using a 4-hourly schedule was also evaluated. This scenario resulted in much more attractive outcomes for the AF plus 4-hourly turning strategy (reported in “Scenario analysis, Table 7.3). Under this scenario, the AF mattress and 4-hourly turning/repositioning resulted in net cost saving of \$651 per resident (assuming a cost saving due to decreased PSW time of \$8.49 (range: \$7.00 - \$20.50)). The AF mattress and 4-hourly

turning/repositioning therefore also became a dominant strategy relative to standard care in Ontario (lower cost, improved health) (Table 7.3).

Univariate sensitivity analysis

In a series of sensitivity analyses (Table 7.4), the reported base-case findings of costs and consequences associated with the five prevention strategies were evaluated across plausible ranges of input data in the following categories of model parameters: (1) natural history parameters including probabilities of death and local or systemic infections; (2) costs of hospitalizations, case mix index (CMI), and interventions; (3) utility estimates of residents with and without PU; and (4) effectiveness of the prevention strategies (i.e., RR estimates of reducing the incidence of PU). Model outputs were expressed as NMB as described above, in which costs and QALYs were collapsed into a single value.

The AF mattress strategy and the AF+4 hourly turning strategy remained economically attractive (i.e., NMB values >0) across changes in all individual variables, with the exception of utility values (Table 7.4). As values for utilities of patients with and without PU changed across their plausible ranges, AF strategies were no longer economically attractive (i.e., NMB values <0). The RN time increase strategy was robust to changes in all input parameters, as was the nutritional supplementation strategy. The skin care protocol was also sensitive to changes in utility values, becoming economically attractive at some utility values.

Probabilistic sensitivity analysis

Results from the probabilistic sensitivity analysis are depicted in Table 7.5 and Figures 7.1 and 7.2. The quality-adjusted life expectancy was 1.37 years, with a SD of 0.37 in

the standard care strategy. The expected cost was \$153,500 for standard care, with a SD of \$7,200. The 95% credible intervals for all strategies with the exception of nutritional supplementation, reported in NMB, crossed zero. In other words, it was 95% certain that the nutritional supplementation strategy was economically unattractive, at a conventional threshold of \$50,000 per QALY gained (WTP threshold). But for other four strategies, the attractiveness was uncertain at this level (95% credible interval).

The AF mattresses (with and without 4-hourly turning/repositioning) strategies were most often economically attractive at a WTP threshold of \$50,000: 64% of the simulations were economically attractive (Table 7.5). This can be interpreted as a 64% probability that these strategies are cost-effective, at the chosen threshold. The skin care protocol and RN time increase strategies were economically attractive in only 8% of the simulations. The nutritional supplementation strategy was not economically attractive (0%).

The cost-effectiveness acceptability curve (Figure 7.2) shows qualitatively similar results. It also demonstrates that these results are not affected by the cost-effectiveness threshold (WTP threshold) that is adopted. At a WTP threshold of \$100,000/QALY, the skin care protocol and RN time increase strategies became more attractive, but were economically attractive in fewer than 30% of the simulations. The attractiveness of AF mattress and AF mattress plus 4-hourly turning/repositioning strategies changed only very slightly. In contrast, the economic attractiveness of nutritional supplementation remained unchanged at this WTP threshold (<1%).

Summary

The CEA results suggest that all prevention strategies with the exception of nutritional supplementation are likely to have some effect on the burden of disease associated with PU in LTC homes in Ontario. The largest expected gain was associated with increasing the amount of care time provided by RNs and implementation of AF mattresses (with or without turning/repositioning protocols). These strategies reduced the lifetime risk of PU by 11-15%, and the lifetime risk of chronic PU by 8-11%. Gains in health per individual were small, 2-8 days of quality adjusted survival gained.

All strategies were associated with increased costs. AF mattresses (with or without turning/repositioning) strategies were economically attractive in deterministic analyses. All other strategies were not economically attractive in deterministic analyses. They were costly and only marginally effective.

Probabilistic sensitivity analyses suggested that the certainty that AF mattress (with or without turning/repositioning) strategies were economically attractive was moderate (approximately 65%). It was quite certain that none of the other three strategies considered were economically attractive.

Table 7.3. Summary of long-term clinical effectiveness and cost-effectiveness

Description	Standard care	AF mattress	AF mattress and 4-hourly turning	Nutritional supplementation	Skin care protocol	RN time increase
Quality of evidence		4 RCT's	1 RCT	4 RCT's	1 controlled study	
Health outcomes						
Lifetime probability of PU	50.00%	-11.23%	-12.52%	-0.06%	-3.84%	-15.36%
Lifetime prob. of chronic PU	31.46%	-7.68%	-8.70%	-0.04%	-3.01%	-11.10%
Lifetime prob. of PU-related local infection	12.67%	-2.82%	-3.20%	0.00%	-1.32%	-4.66%
Lifetime prob. of PU-related systemic infection	9.37%	-2.15%	-2.47%	-0.01%	-1.00%	-3.60%
Cost-effectiveness						
Life years	3.4263	0.0154	0.0174	0.0002	0.0059	0.0213
QALYs	1.3540	0.0127	0.0142	0.0002	0.0046	0.0165
Cost	\$153,148	\$80	\$74 [1]	\$194	\$1,329	\$4,448
ICER (life years)	-	\$5,215	\$4,287 [1]	\$924,887	\$223,498	\$208,841
ICER (QALY)	-	\$6,328	\$5,234 [1]	\$1,186,022	\$287,133	\$269,202
Scenario analysis: Labor savings for AF + 4 hourly turning / repositioning						
Cost	\$153,148		-651 [2]			
ICER (life years)	-		Dominant [2]			
ICER (QALY)	-		Dominant [2]			

Notes: [1] Assuming no cost saving due to a reduction in turning schedule from 2-hour to 4-hour schedule. [2] Assuming a cost saving due to reduction in personal support worker's time of \$8.49 (range \$7.00, \$20.50). AF, alternate foam; RN, registered nurse; RCT, randomized controlled trial; PU, pressure ulcer; QALY(s), quality-adjusted life year(s).

Table 7.4. Results from univariate sensitivity analysis

Parameter	Parameter Values			Net monetary benefit by strategy relative to standard care*									
				AF mattress		AF mattress +4-hourly turning/repositioning		Nutritional supplementation		Skin care protocol		RN time increase	
	Base	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Probabilities: Infection													
Local infection	0.115	0.062	0.168	\$593	\$766	\$682	\$879	-\$185	-\$182	-\$1076	-\$998	-\$3,528	-\$3,264
Systemic infection	0.143	0.098	0.266	\$631	\$814	\$725	\$933	-\$185	-\$182	-\$1,058	-\$979	-\$3,476	-\$3,194
Probabilities: Death													
LTC-low risk (weekly)	0.0007	0.0005	0.0019	\$728	\$623	\$834	\$720	-\$186	-\$177	-\$1,040	-\$1,000	-\$3,412	-\$3,277
LTC-high risk (weekly)	0.0025	0.0016	0.0036	\$872	\$604	\$1,006	\$691	-\$198	-\$172	-\$1,069	-\$981	-\$3,543	-\$3,196
Hospital-low risk	0.1349	0.0385	0.1746	\$842	\$687	\$954	\$790	-\$196	-\$182	-\$1,096	-\$1,020	-\$3,602	-\$3,344
Hospital-high risk	0.1663	0.0385	0.2316	\$1,214	\$637	\$1,409	\$730	-\$225	-\$177	-\$1,128	-\$1,004	-\$3,786	-\$3,281
Cost: Hospitalizations													
Both with and without PU	\$6,924	\$3,462	\$10,386	\$737	\$645	\$846	\$741	-\$183	-\$184	-\$1,012	-\$1,052	-\$3,313	-\$3,452
Cost: CMI													
Low risk no PU	0.52	0.26	0.78	\$1,239	\$143	\$1,399	\$188	-\$177	-\$190	-\$854	-\$1,210	-\$2,754	-\$4,012
High risk no PU	0.71	0.5	0.92	\$1,219	\$163	\$1,406	\$181	-\$174	-\$193	-\$767	-\$1,297	-\$2,440	-\$4,325
Low risk PU II	0.54	0.28	0.8	\$183	\$199	\$226	\$1,361	-\$190	-\$177	-\$1,218	-\$845	-\$4,040	-\$2,726
High risk PU II	0.9	0.68	1.12	\$473	\$909	\$540	\$1,047	-\$188	-\$180	-\$1,144	-\$919	-\$3,784	-\$2,981
Low risk PU III-IV	0.7	0.44	0.96	\$508	\$874	\$587	\$1,000	-\$186	-\$181	-\$1,107	-\$957	-\$3,646	-\$3,120
High risk PU III-IV	0.94	0.82	1.06	\$623	\$759	\$715	\$872	-\$185	-\$182	-\$1,065	-\$999	-\$3,500	-\$3,265

Table 7.4. Results from univariate sensitivity analysis (continued)

Parameter	Parameter Values			Net monetary benefit by strategy relative to standard care*									
				AF mattress		AF mattress +4-hourly turning/repositioning		Nutritional supplementation		Skin care protocol		RN time increase	
	Base	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Cost of interventions													
AF mattress	\$0.09	\$0.05	\$0.14	\$714	\$660	\$816	\$763	-\$184	-\$184	-\$1,032	-\$1,032	-\$3,383	-\$3,383
AF mattress + turning	\$0.09	\$0.05	\$0.14	\$714	\$660	\$816	\$763	-\$184	-\$184	-\$1,032	-\$1,032	-\$3,383	-\$3,383
Nutrition. supplement	\$8.50	\$4.74	\$13.81	\$691	\$691	\$793	\$793	-\$97	-\$305	-\$1,032	-\$1,032	-\$3,383	-\$3,383
Skin care protocol	\$8.87	\$1.38	\$9.15	\$691	\$691	\$793	\$793	-\$184	-\$184	\$108	-\$1,074	-\$3,383	-\$3,383
RN time increase	\$9.69	\$6.20	\$12.40	\$691	\$691	\$793	\$793	-\$184	-\$184	-\$1,032	-\$1,032	-\$1,756	-\$4,646
Health utilities													
Low risk no PU	0.475	0.296	0.653	-\$159	\$1,269	-\$153	\$1,425	-\$194	-\$178	-\$1,329	-\$866	-\$4,438	-\$2,805
High risk no PU	0.325	0.181	0.469	-\$134	\$1,245	-\$164	\$1,437	-\$198	-\$174	-\$1,445	-\$751	-\$4,855	-\$2,388
Low risk PU	0.401	0.247	0.554	\$1,328	-\$218	\$1,503	-\$230	-\$176	-\$196	-\$806	-\$1,390	-\$2,594	-\$4,649
High risk PU	0.269	0.138	0.4	\$944	\$167	\$1,088	\$185	-\$199	\$193	-\$901	-\$1,294	-\$2,921	-\$4,322

Parameter	Parameter Values			Net monetary benefit by strategy relative to standard care*									
	Base	Min	Max	AF mattress		AF mattress +4-hourly turning/repositioning		Nutritional supplementation		Skin care protocol		RN time increase	
				Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Relative Risks													
AF mattress	0.31	0.21	0.46	\$821	\$516	\$825	\$746	-\$184	-\$184	-\$1,032	-\$1,032	-\$3,383	-\$3,383
AF mattress + turning	0.21	0.08	0.59	\$691	\$691	\$916	\$462	-\$184	-\$184	-\$1,032	-\$1,032	-\$3,383	-\$3,383
Nutritional supplement	0.85	0.73	0.96	\$691	\$691	\$793	\$793	-\$175	-\$192	-\$1,032	-\$1,032	-\$3,383	-\$3,383
Skin care protocol	0.36	0.17	0.75	\$691	\$691	\$793	\$793	-\$184	-\$184	-\$957	-\$1,178	-\$3,383	-\$3,383
RN time increase	0.25	0.15	0.4	\$691	\$691	\$793	\$793	-\$184	-\$184	-\$1,032	-\$1,032	-\$3,338	-\$3,445

*Net monetary benefit by strategy relative to standard care calculated using \$50,000 per QALY gained.

AF, alternate foam; RN, registered nurse; min, minimum; LTC, long-term care; PU, pressure ulcer; CMI, case mix index.

Table 7.5. Results from probabilistic sensitivity analysis

Comparators	Outcome	Mean	SD	95% CI		CE (%)*
				LB	UB	
Standard care	Cost	\$153,533	\$7,236	\$141,070	\$169,188	
	QALYs	1.3693	0.3692	0.6250	2.0449	
AF mattress	Cost	\$153,605	\$7,459	\$140,843	\$169,990	
	QALYs	1.3823	0.3814	0.6027	2.0778	
	NMB**	\$578	\$1,618	-\$2,508	\$3,905	63.60
AF mattress + 4-hourly turning/repositioning	Cost	\$153,598	\$7,477	\$140,823	\$170,000	
	QALYs	1.3835	0.3825	0.5995	2.0789	
	NMB**	\$641	\$1,814	-\$2,810	\$4,395	63.46
Nutritional supplementation	Cost	\$153,724	\$7,223	\$141,274	\$169,363	
	QALYs	1.3695	0.3693	0.6242	2.0459	
	NMB**	-\$182	\$39	-\$260	-\$108	0.00
Skin care protocol	Cost	\$154,824	\$7,182	\$142,441	\$170,428	
	QALYs	1.3738	0.3728	0.6180	2.0529	
	NMB**	-\$1,066	\$719	-\$2,483	\$429	6.74
RN time increase	Cost	\$157,879	\$7,076	\$145,707	\$173,289	
	QALYs	1.3855	0.3843	0.5998	2.0810	
	NMB**	-\$3,500	\$2,600	-\$8,600	\$1,500	7.72

*% of simulations which are cost-effective relative to standard care at a willingness-to-pay threshold of \$50,000 per QALY gained.

**NMB relative to standard care calculated using \$50,000 per QALY gained.

AF, alternate foam; SD, standard deviation; CI, credibility interval; CE, cost-effective; QALY, quality-adjusted life years; NMB, net monetary benefit; RN, registered nurse.

LB, lower bound; UB, upper bound.



Figure 7.1. Cost-effectiveness plane showing the scatter plot of 5000 Monte Carlo simulations of the probabilistic model for the prevention strategies for pressure ulcer

AF, alternate foam; RN, registered nurse.

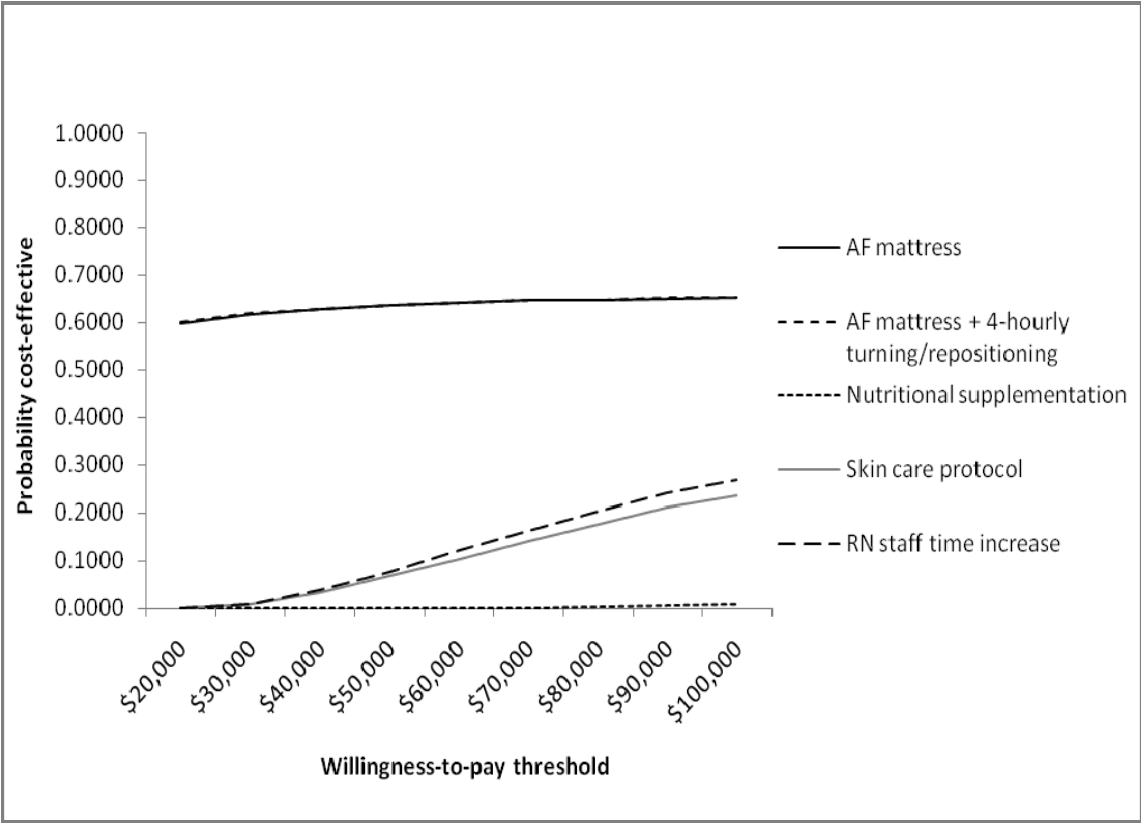


Figure 7.2. Cost-effectiveness acceptability curves for the five prevention strategies for pressure ulcer

AF, alternate foam; RN, registered nurse.

Chapter 8: Budget and health impact analysis

Introduction

A large Canadian study revealed that the overall prevalence of PUs in all types of health care institutions was 26%.⁵ For LTC homes, this prevalence reached almost 30%.⁵ Thus, the epidemiological impact of PUs in Canada is significant. The economic burden associated with PUs is also substantial. In the Canadian health care system, PUs cost approximately \$2.1 billion annually.⁴

The CEA in Chapter 7 found that all prevention strategies with the exception of nutritional supplementation are likely to have some effect on the burden of disease associated with PU in LTC homes in Ontario, but with increased costs. Whilst economic evidence is undoubtedly useful to consumers, it does not address the issue of affordability. Healthcare purchasers are concerned not just with maximising efficiency but also with the goal of remaining within their annual budgets. This analysis examined the issue of affordability from the Ontario MOHLTC perspective over a 5-year time horizon (***budget impact***). We also estimated the aggregate effects on health among LTC residents of each strategy (***health impact***).

The objective of this analysis was to determine the health and budget impact of standard care and each of the five strategies for preventing PUs in LTC homes in Ontario, Canada.

The identified five strategies that have the potential to reduce the incidence of PUs in LTC homes include:

STRATEGY 1 - AF mattress: replacing standard mattresses with an AF mattress only where such mattresses are not currently in use.

STRATEGY 2 - AF mattress and 4-hourly turning / repositioning: replacing standard mattresses with an AF mattress for residents where such mattresses are not currently in use and introducing a 4-hourly turning / repositioning program among LTC residents with mobility deficits who are at high risk of developing PUs.

STRATEGY 3 - Nutritional supplementation: daily multinutrient supplementation among LTC residents with nutritional deficits who are at high risk of developing PUs and not currently receiving nutritional supplements.

STRATEGY 4 - Skin care protocol for incontinence: daily skin assessment and use of skin cleansers and barrier creams for residents with urinary or fecal incontinence who are at high risk of developing PUs and not receiving a skin care protocol for incontinence.

STRATEGY 5 - RN time increase: an additional 20 minutes (from 0.27 hours to 0.58 hours) PRPD of RN time for residents who are at high risk of developing PUs.

Methods

An economic and health impact model was developed in order to estimate the 5-year budget and health impact of standard care and each of the five strategies for preventing PUs. The target population for the analysis was residents aged 65 years and older of all LTC homes in Ontario. Overall patient demographic characteristics are described in Table 8.1. The analysis estimated the annual budget required by the Ontario MOHLTC to implement each prevention strategy (PU-strategy implementation budget) as well as the health care budget for the MOHLTC associated with treating PUs (PU-related health care budget).

Table 8.1. Characteristics of long-term care residents in Ontario, Canada

Characteristics	Description	Value	Source
Average age (year)	All residents	83.6	MDS
Gender	Female	69%	MDS
	Male	31%	MDS
PU risk at admission	Low risk	38%	MDS
	High risk	62%	MDS
Residents with AF mattress	Residents currently on AF mattresses	46%	Ontario LTC homes survey ⁴⁸
Residents on a turning/repositioning schedule	High risk of PU with mobility deficits	55%	MDS
Residents with urinary/fecal incontinence	High risk of PU with urinary/fecal incontinence	72%	MDS
Malnourished residents	High risk of PU with malnutrition	9.7%	MDS

AF, Alternate foam; MDS, Minimum Data Set; PU, pressure ulcer; LTC, long-term care.

The health and budget impact analysis proceeded through a series of steps:

STEP 1: Estimate the number of residents in long-term care homes in Ontario

The number of residents of LTC homes was estimated using data on the number of beds in operation in Ontario LTC homes and the occupancy rate for the years 1996 to 2005 (Statistics Canada).¹⁰⁹ Using a linear regression analysis, the relationship between the year and the number of beds was estimated. The resulting equation was $y = 2076.87 * x - 4080196.58$, $R^2 = 0.92$; where x represents the year and y represents the number of residents. The equation was used to estimate the number of residents of LTC homes from 2008 to 2012.

The use of Statistics Canada data on the number of residents over time simultaneously accounts for several factors affecting changes in the number of residents over time, including death rates and growth rates in the LTC sector due to the aging of the population.

STEP 2: Estimate the proportion of LTC residents targeted by each strategy

The MDS data (chapters 2 and 5) and the LTC survey (chapter 3)⁴⁸ were used to estimate the proportion of LTC residents currently receiving each strategy intervention. The proportion of residents that would be targeted by each strategy was then calculated.

STRATEGY 1: AF mattress: Currently, 46% of the LTC residents in Ontario are already using AF mattresses. Thus, AF mattresses are targeted

to 54% of LTC residents using standard mattresses in Ontario.

STRATEGY 2: AF mattress and 4-hourly turning / repositioning: As noted for strategy 1, 46% of beds in LTC homes in Ontario are already equipped with AF mattresses, and as a result, the proportion of residents targeted for AF mattresses is 54%. In the CEA (chapter 7), the base case analysis assumes no cost avoidance with the proposed 4 hourly turning / repositioning on AF mattresses compared to 2 hourly turning / repositioning on standard mattresses. As such, the budget and health impact analysis assumes the same targeted population for the current strategy as that for strategy 1 (i.e., AF mattress). Of note, the proportion of residents who are at high risk for PU and with mobility problems is approximately 55%. Of these residents, 25% are currently on a turning schedule. The proportion of immobile residents targeted to receive turning/repositioning is approximately 75%.

STRATEGY 3: Nutritional supplementation: The proportion of malnourished residents at high risk for developing PUs is 9.7%, and currently 40% of these residents are receiving nutritional supplementation (MDS). The proportion of malnourished residents at high risk of PU targeted by this strategy is 60%.

STRATEGY 4: Skin care protocol for incontinence: The proportion of residents with urinary or fecal incontinence is 72%, and currently 50% are treated with a skin care protocol. The proportion of residents with urinary or fecal incontinence targeted by this strategy is 50%.

STRATEGY 5: RN time increase: The proportion of residents in LTC homes that are at high risk for developing PUs is 62%, and currently none of these residents receives increased staffing levels of an additional 20-minutes of RN time per day. The proportion of

residents at high risk for developing PUs targeted by this strategy is 100%.

STEP 3: Estimate the implementation budget for each of the prevention strategies

To estimate the PU-related strategy implementation budget, the unit cost for each strategy was multiplied by the number of residents that would be targeted by the strategy.

Unit costs

The unit cost for strategy 1 was the cost of the AF mattress (\$450). The unit cost for strategy 2 was assumed to be equivalent to the unit cost for strategy 1 as any cost savings resulting from a four-hourly turning/repositioning strategy was not estimated (as noted in Chapter 3, it is not possible to accurately estimate the frequency of turning in standard care). As a result, the four hourly turning / repositioning regimen was assumed to have no impact in terms of staff-time and thus no impact in terms of cost). For strategy 1 and 2, the implementation costs were assumed to occur in only the first year of residency in LTC homes, due to the average 7 year life-span of AF mattresses. The budget impact analysis accounts for the fact that there will be new mattresses each year due to the growth in the LTC population.

The unit cost for strategy 3 (nutritional supplementation) was estimated at \$8.50 per patient per day, based on the cost of nutritional supplements and the staff time required to administer them (see Chapter 5 for further details). The implementation costs of nutritional supplementation were applied to the targeted population each year.

The unit costs for strategy 4 (skin care protocol) was estimated at \$8.81 per patient per day, based on the cost of skin care products, briefs and staff time (see Chapter 5 for further details). The

implementation costs of the skin care protocol were applied to the targeted population each year.

The unit cost for strategy 5 (RN time increase) was estimated at \$9.69 per resident per day, based on the hourly wage for RNs (see Chapter 5 for further details). The implementation costs of the RN time increased strategy were applied to the targeted population each year.

STEP 4: Estimate the total cost for each strategy

The average per-resident lifetime total care cost for LTC residents was derived from the base-case CEA for each strategy (see Chapter 7 for details). This total cost was divided by the estimated average life expectancy to derive the annual per-resident total costs.

STEP 5: Estimate the total cost in the absence of pressure ulcer for each strategy

Average per-resident lifetime total costs in the absence of PU (e.g., housing and medical care cost in the absence of PU, Figure 8.1) were calculated by setting incidence of PU to zero in all strategies of the decision analytic model (chapters 2 and 7). Annual total costs in the absence of PU were estimated similarly to those in step 4 (i.e., lifetime total cost divided by estimated average life expectancy).

STEP 6: Estimate the pressure ulcer - related cost for each strategy

For each strategy, the average per-resident PU-related cost was estimated by subtracting the total cost in step 4 by the corresponding total cost in the absence of PU from step 5.

STEP 7: Estimate the pressure ulcer - related health impact for each strategy

The health impact was estimated as the number of PU cases (stage I to IV), PU-free residents (stage 0), and total number of QALYs for each strategy. These health impact outcomes were derived from the CEA model (Table 8.2).

Population-based outcomes related to the health system impact were derived by multiplying the total number of residents in each given year by the rate of residents with any stage of PU, PU-free residents, and annual QALYs (Table 8.3).

Results

Health impact analysis

In 2008, the total estimated number of LTC residents in Ontario was 90,158. Table 8.3 presents the health system impact over a 5-year time horizon for each strategy.

In the standard care, it was estimated that 11,739 residents had a PU in 2008. Prevention strategy with the highest impact in reducing PUs was RN time increase (4,517 PUs prevented), followed by AF mattress plus turning/repositioning (3,381 PUs prevented), AF mattress alone (2,984 PUs prevented), skin care protocol (1,379 PUs prevented), and nutritional supplementation (54 PUs prevented). Similar patterns were found for the number of PU-free residents in 2008.

The total incremental QALYs gained in 2008 by each PU-prevention strategy in comparison to standard care was: 211 for RN time increase, 192 for AF mattress plus 4-hourly turning/repositioning schedule, 173 for AF mattress alone, 60 for a skin care protocol, and 3 for nutrition supplementation.

Budget impact analysis

The costs for implementing strategies for preventing PUs are reported in Table 8.4. The AF mattress with or without 4 hourly turning / repositioning was with an implementation cost of \$21.9 million in the first year and approximately 0.5 million each in the subsequent four years (given an average lifetime of up to 7 years for AF mattresses). The strategies with the lowest implementation costs was nutritional supplementation (\$9.4 million), but this was in part due to the low targeted number of residents potentially affected by the prevention. The implementation cost for skin care protocol was \$64.8 million, and RN time increase \$197.8 million. The 5-year strategy implementation budget impact for all strategies was as follows: AF mattress with or without 4 hourly turning/repositioning schedule (\$23.9 million), nutrition supplementation (\$49.0 million), skin care protocol (\$338.7 million), and RN time increase (\$1,034.8 million).

Figure 8.1 depicts the economic impact produced by each targeted strategy in 2008 in different types of budgets studied. Compared to standard care, PU-related expenditures were all reduced albeit by different amount in each of the four prevention strategies. The increasing RN time strategy reduced PU-related expenditures by \$26.7 million, AF mattress plus turning/repositioning schedules \$19.7 million, AF mattress \$17.3 million, skin care protocol \$7.5 million and nutritional supplementation \$267,061.

Although RN time substantially reduced PU-related costs compared to standard care, this strategy required high annual implementation cost. Overall, strategies involving AF mattress with or without 4-hourly turning/repositioning reduced PU-related costs with relatively smaller implementation expenditures. Consequently, they were with smaller (incremental) total budget impact.

Table 8.2. Parameters for estimating budget and health impact of pressure ulcer prevention strategies in LTC residents in Ontario

Input data	Description	Standard Care	AF mattress	AF mattress+4-hourly turning/repositioning	Nutrition Supplement	Skin care protocol	RN time increase
Health outcomes							
Annual PU rate of occurrence	Stage I	6.95%	4.68%	4.39%	6.91%	5.97%	3.72%
	Stage II	4.79%	3.82%	3.68%	4.77%	4.27%	3.13%
	Stage III	0.61%	0.55%	0.54%	0.61%	0.58%	0.51%
	Stage IV	0.67%	0.66%	0.66%	0.67%	0.67%	0.65%
Annual rate of PU-free residents	Stage 0 (no PU)	86.98%	90.29%	90.73%	87.04%	88.51%	91.99%
Annual QALYs	All residents	0.395	0.397	0.397	0.395	0.396	0.398
Annual cost estimate							
Total cost	Per resident	\$44,698	\$44,748	\$44,722	\$44,799	\$45,332	\$46,596
PU-related costs	Per resident	\$861	\$668	\$642	\$858	\$777	\$564
Implementation costs	Per resident		\$450	\$450	\$3,105	\$3,218	\$3,539

AF, Alternate foam; PU, Pressure ulcer; QALY, quality-adjusted life years; RN, registered nurse.

Table 8.3. Total health impact produced by pressure ulcer prevention strategies in Ontario, Canada

Strategies	Health outcomes	Years					TOTAL
		2008	2009	2010	2011	2012	
Standard care	PU cases	11,739	12,009	12,279	12,550	12,820	61,397
	PU-free patients	78,420	80,226	82,033	83,839	85,646	410,163
	QALYs	35,629	36,449	37,270	38,091	38,912	186,351
AF mattress	PU cases	8,754	8,956	9,158	9,359	9,561	45,789
	PU-free patients	81,404	83,279	85,154	87,030	88,905	425,772
	QALYs	35,802	36,627	37,451	38,276	39,101	187,257
AF mattress + 4-hourly turning/repositioning	PU cases	8,358	8,550	8,743	8,935	9,128	43,714
	PU-free patients	81,801	83,685	85,569	87,454	89,338	427,847
	QALYs	35,820	36,646	37,471	38,296	39,121	187,353
Nutrition Supplement	PU cases	11,685	11,954	12,223	12,492	12,761	61,114
	PU-free patients	78,474	80,282	82,089	83,897	85,705	410,446
	QALYs	35,632	36,453	37,273	38,094	38,915	186,367
Skin care protocol	PU cases	10,359	10,598	10,836	11,075	11,314	54,182
	PU-free patients	79,799	81,637	83,476	85,314	87,152	417,378
	QALYs	35,688	36,510	37,332	38,155	38,977	186,662
RN time increase	PU cases	7,222	7,388	7,554	7,721	7,887	37,772
	PU-free patients	82,937	84,847	86,758	88,668	90,579	433,789
	QALYs	35,840	36,666	37,491	38,317	39,142	187,456

AF, Alternate foam; PU, Pressure ulcer; QALY, quality-adjusted life years; RN, registered nurse.

Table 8.4. Strategy implementation budget impact analysis for all targeted strategies for preventing pressure ulcers in Ontario

PU Strategies	Unit cost	Residents receiving intervention in 2008	Per targeted resident cost in 2008	Strategy cost (year)				
				2008	2009	2010	2011	2012
AF mattress ¹	\$450.00	48,686	\$450	\$21,908,486	\$504,679	\$504,679	\$504,679	\$504,679
AF mattress+ 4-hourly turning ¹	\$450.00	48,686	\$450	\$21,908,486	\$504,679	\$504,679	\$504,679	\$504,679
Nutritional Supplementation ²	\$8.50	3,019	\$3,105	\$9,371,319	\$9,587,194	\$9,803,070	\$10,018,946	\$10,234,822
Skin care protocol ²	\$8.81	55,898	\$3,539	\$197,838,946	\$202,396,324	\$206,953,701	\$211,511,079	\$216,068,457
RN time increase ²	\$9.69	20,123	\$3,218	\$64,753,973	\$66,245,633	\$67,737,292	\$69,228,951	\$70,720,611

¹ The strategy has a one-time implementation cost. To estimate first year cost, the unit cost was multiplied by the number of patients receiving intervention. Subsequent year costs represent incremental number of residents for each year requiring the strategy.

²The strategy has daily costs. The estimated yearly costs, the unit cost was multiplied by the number of residents receiving strategy and by the number of days in one year (365.25).

AF, Alternate foam; PU, pressure ulcer; RN, registered nurse.

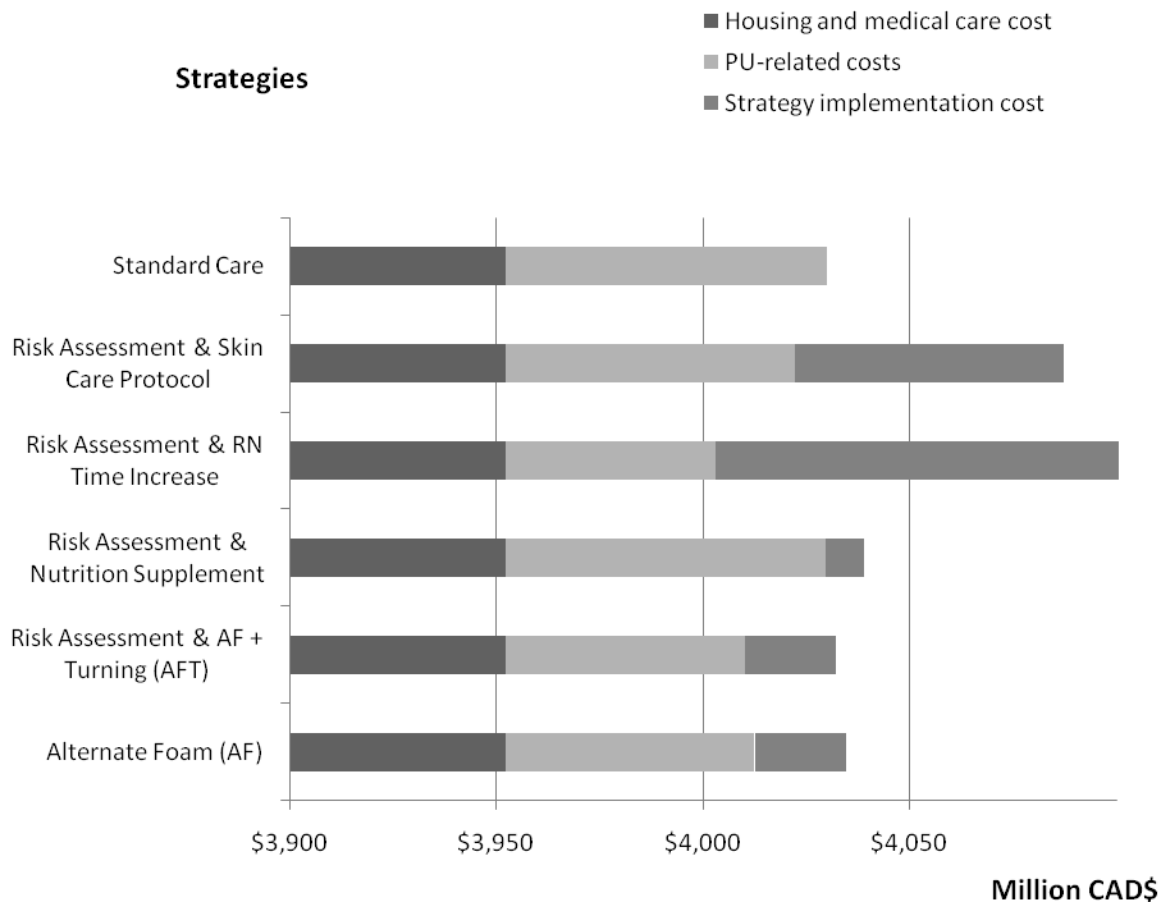


Figure 8.1 Budget impact results for the year 2008 (base case) across all pressure ulcer prevention strategies.

AF, Alternate foam; CAD, Canadian dollars; RN, registered nurse.

Chapter 9: Discussion

This health technology assessment represents our current understanding of the potential health benefits and costs associated with strategies designed to prevent the occurrence of PUs in Ontario LTC homes.

With respect to clinical outcomes, the Ontario Pressure Ulcer Model (OPUM) suggests that ALL strategies are associated with small to moderate sized gains in health relative to standard care. Expected gains per resident range from 0.0002 to 0.0165 QALYs (1-6 quality-adjusted life days per person). Gains are produced by prevention of PUs (1-15% reduction in lifetime incidence), and the associated reductions in morbidity and mortality. Because the quality of life of patients with PUs does not appear to be very much lower than comparable patients without PUs, preventing PUs produces only modest reductions in morbidity. Most QALY gains were generated by the reduction in PU-related systemic infection and death. Over a 5-year period, 508 PU-related deaths are projected to occur among Ontario's 90,158 current LTC residents. The most effective strategies considered (i.e., AF plus 4-hourly turning/repositioning and RN time increase) would decrease PU-related deaths to 270 and 339, respectively, over the same 5-year period.

With regards to economics, no strategies were cost saving; all incurred incremental costs. AF mattresses with or without 4-hourly turning / repositioning were attractive alternatives in comparison to standard care under conventional thresholds (\$50,000/QALY gained). Other alternatives were not considered cost-effective, with ICER estimates much higher than the conventional threshold for willingness to pay. Specific conclusions for each strategy relative to standard care are as follows:

1. Prevention of PUs with AF mattresses is an attractive strategy. It is supported by high quality evidence, and has a relatively modest initial one-time implementation cost (\$22M). Although not cost saving overall, it is associated with estimated PU-related savings of 17.3 million per year, averting approximately 3,000 cases of new PUs, and 173 QALY gains each year.
2. The 4-hourly turning strategy on an AF mattress was supported by one reasonable-quality, moderate-sized randomized trial, and has a relatively modest initial one-time implementation cost (\$22M) similar to the AF mattress alone strategy. This strategy reduces PU incidence by 79%. It is also an attractive strategy relative to standard care, and is associated with PU-related cost savings of \$19.7 million per year, preventing approximately 3,300 new cases of PU and increasing 192 QALYs each year. It became a dominant strategy relative to standard care on one-way sensitivity analysis (i.e., health gains and cost saving). However, what "standard care" means with respect to turning frequency is uncertain. The base-case analysis assumed that turning was occurring at 2-hourly intervals, as per current guideline recommendations and thus assumes no incremental cost/savings for changing the turning schedule. The realization of large expected cost savings by moving from a 2-hourly to 4-hourly turning schedule, as explored in our scenario analysis, is contingent on the validity of this assumption.
3. Nutritional supplementation targeting residents with nutritional deficits and at risk for PU was the least attractive strategy. Although the efficacy of this intervention is supported by 5 randomized controlled trials

conducted in a variety of clinical settings, the pooled estimate of 16% reduction of PU was considered modest. Consequently, this strategy was not considered cost-effective in preventing PUs at an ICER of \$1,186,022 per QALY gained. Furthermore, this alternative increased the budget by approximately \$16 million per year, and was associated with an implementation cost of \$9.4 million.

4. Skin care protocols for incontinence care was also not considered an attractive strategy. Two small studies (non-randomized before-after studies) demonstrated a PU risk reduction of 64%. Because of the size and design of these studies, these efficacy estimates are considered of low quality. This strategy produced an ICER per QALY gained of \$287,133, and was associated with an implementation cost of \$64.8 million per year and an incremental cost of \$57.2 million per year.
5. The effectiveness of increasing RN time to care for high PU risk LTC patients was supported by three non-randomized studies that showed a consistent effect; one study demonstrated a clear dose-response relationship between increased RN time and the prevention of PUs. This strategy was projected to be the most effective, but also the most costly of all the strategies considered, with an implementation cost of approximately \$198 million per year. Although this alternative reduced PU-related costs substantially because of its high estimated efficacy, it is not considered cost-effective at an ICER of \$269,202.

Particular strengths of this analysis include:

- i. Grounding of prognostic estimates in Ontario data. The natural history of PU was derived from data collected in Ontario long-term care homes. We believe that this represents a sound basis for projections of potential health

and economic consequences of PUs in Ontario.

- ii. Calibration of the prognostic model. The prognostic model was not only developed from, but calibrated to, Ontario LTC PU incidence and prevalence data.
- iii. Content validation of the prognostic model. An expert panel, in addition to external PU experts, provided insight into the current biological understanding of PUs. The current model reflects these insights in its categorization of health states related to PU (e.g. stages I-IV, no use of stage classification to represent PU healing, and distinction between healable and non-healable PUs).
- iv. Use of content experts to select the strategies to be considered.
- v. Derivation of efficacy estimates from comprehensive systematic reviews. Estimates of the efficacy of PU preventive interventions were derived from a process of systematic reviews, in most cases performed by the MAS staff. For several strategies, these efforts were supplemented with systematic reviews performed by THETA staff.
- vi. Grounding of costing estimates in Ontario-derived data. Most frequency estimates (e.g. physician use, hospitalization rates) were derived from the MDS. Unit costs were derived from large Ontario administrative data sources.
- vii. Grounding of health utility estimates in Ontario using MDS data with a large sample size, validated utility instrument, which includes stratification by risk and PU status.
- viii. Use of a survey of long-term care homes to characterize current practice. The validity of estimates of the marginal effects of new

interventions depends on our understanding of standard care.

Limitations of this analysis include:

- i. Potentially limited generalizability of the MDS to all LTC homes in Ontario. The MDS is a relatively new instrument, includes data from only 91 of 613 LTC facilities in the province, and has a mean follow-up of 12 months per patient. The extent to which these 91 facilities are representative of all LTC facilities is uncertain. The duration of follow-up is also relatively short. Because the mean survival of LTC residents in Ontario is approximately 3 years, a longer follow-up period is desirable.
- ii. Linking intermediate to long-term outcomes. Most of the randomized trial data characterizing preventive strategies had short durations (weeks to months) and looked at intermediate outcomes, typically incidence of PU. While this is undoubtedly a clinically important outcome, the design of the analysis requires projection of the number of QALYs associated with PU for each preventive strategy. The accuracy of these projections are related to the validity of the projections of the natural history of PU. While the natural history model has been carefully developed and validated, there is still a greater degree of uncertainty associated with the projections than if the long-term consequences of PU had been directly observed and reported in the trials where effectiveness data were reported.
- iii. Uncertainty regarding current practice patterns in Ontario LTC homes. The accuracy of the projections of potential health gains relative to standard depends on the accuracy with which the standard care is described. The Ontario LTC homes survey does include a survey of care directors of a randomly

selected sample of LTC facilities. The survey provided a large amount of useful data and offered important insights, but uncertainties remain. For example, the rate of repositioning among LTC residents is not clear. Current guidelines call for 2-hourly repositioning among LTC residents with impaired mobility. The MDS suggests that fewer than half of high-risk LTC residents with impaired mobility are on a repositioning program, but the accuracy of this data is unknown; interviews with care directors suggest that repositioning cannot always be carried out according to guidelines. This particular example highlights the importance of obtaining accurate estimates of current practice in developing sound policies with respect to PU prevention.

- iv. It is worth noting, however, that the potential savings associated with changing turning frequency may be very large. If turning need only be carried out on a 4-hourly basis, staffing requirements may be reduced, or care reallocated to other needed areas, potentially improving the quality of care. Uncertainty with respect to the optimal frequency of turning, therefore, deserved further exploration in clinical studies.

In summary, the OPUM model suggests that AF mattresses with or without turning/repositioning strategies considered appear to be economically attractive and improve health among long-term care residents. Policy recommendations should incorporate and integrate the evidence of economic attractiveness (i.e. value for money) generated by this report, in addition to quality of the effectiveness evidence, the magnitude of the treatment effects, potential PU-related budget impact, impact on the health system, and social values with respect to long-term care provision.

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Appendix A:

National Pressure Ulcer Advisory Panel (NPUAP) revised classification of pressure ulcer stage

Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. This may also present as an intact or open/ruptured serum-filled blister.

Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

Appendix B:

Search strategy identifying articles relevant to staffing ratios/time

Concepts – ‘PUs’, ‘Long Term Care’ and ‘Staffing Ratios/Staff time’

#	Searches
1	PU/
2	skin ulcer/
3	leg ulcer/
4	foot ulcer/
5	Bed sore?.mp.
6	Bedsore?.mp.
7	Chronic skin ulcer:.mp.
8	(Decubitus adj2
9	(Decubitus adj2
10	Foot ulcer:.mp.
11	Heel ulcer:.mp.
12	Pressure damag:.mp.
13	Pressure injur:.mp.
14	Pressure related
15	Pressure sore?.mp.
16	PU:.mp.
17	Trophic ulcer:.mp.
18	decubitus.mp.
19	((plantar or heel* or
20	((bed or pressure or
21	((pressure or bed or skin
22	(chronic adj2
23	or/1-22
24	exp Homes for the
25	Frail Elderly/
26	exp Geriatrics/
27	exp Long-Term Care/
28	exp homes for the aged/ or exp
29	exp Geriatric Nursing/
30	exp geriatric assessment/
31	exp Veterans/
32	exp hospitals, veterans/
33	elder?.mp.
34	elderly.mp.
35	senior citizen?.mp.
36	geriatri:.mp.
37	extended care.mp.
38	or/24-37
39	exp Patient Care Team/
40	exp "personnel staffing and
41	exp personnel turnover/
42	exp nursing staff/
43	nursing care/
44	ma.fs.
45	manpower.mp.
46	(wound: adj2 team?).mp.
47	(staff: adj2 ratio?).mp.
48	(staff: adj2 level:).mp.
49	staff: time.mp.
50	(staff: adj2 mix???.mp.
51	(staff: adj2 turnover?).mp.
52	exp nursing evaluation research/
53	exp nursing administration research/
54	exp nursing methodology research/
55	exp nursing audit/
56	exp nursing assessment/
57	exp interprofessional relations/
58	exp clinical nursing research/
59	exp nurse's role/
60	exp models, nursing/
61	exp nurse-patient relations/
62	exp nurses/
63	exp nursing/
64	exp economics, nursing/
65	exp nursing, practical/
66	exp interdisciplinary communication/
67	interdisciplinary.mp.
68	inter-disciplinary.mp.
69	multidisciplinary.mp.
70	multi-disciplinary.mp.
71	interprofessional:.mp.
72	inter-professional:.mp.
73	or/39-72
74	23 and 38 and 73
75	limit 74 to yr="1980 - 2008"
76	limit 75 to (comment or editorial or
77	75 not 76
78	remove duplicates from 77

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