

Pressure Ulcer Multidisciplinary Teams via Telemedicine (PUMTT): A Pragmatic Randomized Controlled Trial in Long-Term Care

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ABSTRACT

Background

Pressure ulcers (PrUs) increase the risk of death among elderly patients by as much as 400%, increase the frequency and duration of hospitalization, and decrease quality of life. The cost of treating PrUs is substantial, about \$9,000 CAD per patient per month in the community setting. There is limited evidence that expert multidisciplinary teams (EMDTs) are effective in the management of chronic wounds. A field evaluation was conducted to address the effectiveness of EMDTs in the treatment of PrUs in long-term care (LTC) settings.

Objective

The objective of this study was to evaluate the clinical effectiveness and cost-effectiveness of EMDTs versus “usual” care teams for the treatment of PrUs in LTC homes.

Methods

A multi-method study was conducted that consisted of a pragmatic cluster stepped wedge randomized controlled trial, qualitative methods to increase the understanding of trial results, and an economic evaluation. The intervention consisted of 4 to 14 months of mentorship per home from an advanced practice nurse who communicated with an EMDT.

Results

One hundred thirty-seven residents with 259 PrUs were recruited into the study. The primary outcome, rate of healing, was judged based on wound surface area. No difference was detected in healing rates before and after exposure to the intervention. Secondary outcomes showed a trend toward shortened healing times, an increased probability of healing, and decreased prevalence rates. The economic evaluation estimated that the use of EMDTs would reduce direct care costs by \$651 per resident.

Limitations

- The study was powered to detect a 40% difference in rate of healing between control and intervention periods.
- Healing rate calculations used in the study were based on stage II PrUs (less than 50% of all PrUs recruited).
- The dose of intervention may have been too low to allow for detection of an overall effect.
- Data were abstracted from residents' charts upon study completion in order to evaluate resource use.

Conclusions

The use of EMDTs did not improve the rate of healing of PrUs in LTC homes.

PLAIN LANGUAGE SUMMARY

Pressure ulcers (PrUs) represent a considerable health issue among older patients. These ulcers increase the risk of their mortality by as much as 400%, increase the frequency and duration of hospitalization, and decrease the quality of life. The cost of treating pressure ulcers is quite substantial. Although many studies have commented on the value of an approach that uses an expert multidisciplinary team (EMDT), there is limited evidence to demonstrate their effectiveness in the management of chronic wounds.

The objective of this study was to evaluate the effectiveness and cost-effectiveness of using EMDTs in the treatment of PrUs in long-term care (LTC) homes. The study was conducted in 12 LTC homes and consisted of a randomized controlled trial, methods to help us understand trial results, and a cost-effectiveness study. Each home received 4 to 14 months of mentorship from an advanced practice nurse with expertise in skin wound care who communicated with an EMDT situated in an outpatient wound clinic. Information was collected from digital photos, wound pain and quality of life surveys, case summary and referral tools, and notes in residents' charts. Information was also collected from field notes kept by the study nurses. In addition, 5 homes were selected for in-depth observation and interviews.

One hundred and thirty-seven residents with 259 PrUs were recruited into the study over the 17-month period. No difference was detected in healing rates before and after exposure to the intervention. There was a trend toward shorter healing times, increased probability of healing, and increased incidence rates when exposed to the intervention; none of these differences were statistically significant. The economic evaluation estimated that adopting EMDTs would reduce direct care costs by \$651 per resident. The qualitative study identified barriers to provision of optimal wound care that included high levels of turnover and poor organization of wound care delivery in some settings.

The use of an EMDT did not improve the rate of PrU healing in LTC homes.

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LIST OF ABBREVIATIONS

ADOC	Assistant director of care
APN	Advanced practice nurse
BMI	Body mass index
CCAC	Community care access centre
CI	Confidence interval
CIHI	Canadian Institute for Health Integration
COE	Centre of excellence
DOC	Director of care
ED	Emergency department
EMDT	Expert multidisciplinary team
ET	Enterostomal therapist
GP	General practitioner
HRQOL	Health-related quality of life
ICD-10	<i>International Classification of Diseases</i> , 10th Revision
IRR	Incidence rate ratio
LHIN	Local health integration network
LOS	Length of stay
LTC	Long-term care
MAS	Medical Advisory Secretariat
MOHLTC	Ministry of Health and Long-Term Care
MRD	Most responsible diagnosis
NP	Nurse practitioner
NPWT	Negative pressure wound therapy
OCCI	Ontario Case Costing Initiative
OHTAC	Ontario Health Technology Advisory Committee
OT	Occupational therapist
PrU	Pressure ulcer
PSW	Personal support worker
PUMTT	Pressure ulcer multidisciplinary teams via telemedicine
Q4	Fourth quarter
QALD	Quality-adjusted life-day
QALY	Quality-adjusted life-year

RCT	Randomized controlled trial
RN	Registered nurse
RNAO	Registered Nurses' Association of Ontario
RPN	Registered practical nurse
RR	Relative risk
SD	Standard deviation
UCT	“Usual” care team
VAC	Vacuum-assisted closure
VAS	Visual Analog Scale
WTP	Willingness-to-pay

BACKGROUND

Description of Condition

A pressure ulcer (PrU), also known as a pressure sore, decubitus ulcer, or bedsore, is defined as localized injury to the skin and/or underlying tissue occurring most often over a bony prominence, caused by pressure, or pressure in combination with shear. (1) According to the National Pressure Ulcer Advisory Panel's updated pressure ulcer staging system from 2007, PrUs are classified into 6 categories: stage I, nonblanchable erythema; stage II, partial thickness skin loss; stage III, full thickness skin loss; stage IV, full thickness tissue loss; unstageable, with depth obscured by slough and/or eschar; and deep tissue injury with unknown depth. (2)

Prevalence and Incidence

A survey of PrU prevalence in Canada estimated rates across settings as follows: 25.1% (95% confidence interval [CI], 23.8%–26.3%) in acute care settings; 29.9% (95% CI, 28.3–31.4%) in non-acute care settings; 22.1% (95% CI, 20.9%–23.4%) in mixed health settings; and 15.1% (95% CI, 13.4%–16.8%) in community care. The overall estimate of PrU prevalence in all health care institutions across Canada was 26.0% (95% CI, 25.2%–26.8%). (3) The Canadian prevalence estimates were higher than those reported in the other countries such as the United States and the Netherlands, suggesting that PrUs are a significant concern in all Canadian health care settings. (3)

Definitions of *Team* and *Multidisciplinary Team*

There are many definitions of the word *team*. Some define it as “a group of people with a full set of complementary skills required to complete a task, job, or project. Team members: (1) operate with a high degree of interdependence, (2) share authority and responsibility for self-management, (3) are accountable for the collective performance, and (4) work toward a common goal and shared reward(s). A team becomes more than just a collection of people when a strong sense of mutual commitment creates synergy, thus generating performance greater than the sum of the performance of its individual members” (see www.businessdictionary.com). (4) Whereas Harvard Business School describes *team* as “a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they are mutually accountable,” (5) MIT Information Services and Technology identifies it as “people working together in a committed way to achieve a common goal or mission. The work is interdependent and team members share responsibility and hold themselves accountable for attaining the results.” (6)

In health care, many studies have shown that teams promote care co-ordination and are potentially effective in improving quality of care, particularly in settings serving the chronically ill. (7, 8) Although some studies in long-term care (LTC) homes have reported that team processes of care are associated with better outcomes, (9, 10) the extent to which staff actually work in teams has been largely unknown. A recent study by Temkin-Greener et al (11) showed that in an average facility, about 16% of direct care staff reported working in daily care teams responsible for the day-to-day provision of care to the residents.

In a 2009 report, the Ontario Health Technology Advisory Committee (OHTAC) discussed multidisciplinary wound care teams with special attention to the management of chronic wounds as follows: “The term ‘multidisciplinary’ refers to multiple disciplines on a team and ‘interdisciplinary’ to such a team functioning in a co-ordinated and collaborative manner. There

is general consensus that a group of multidisciplinary professionals is necessary for optimum specialist management of chronic wounds stemming from all aetiologies. However, there is little evidence to guide the decision of which professionals might be needed form an optimal wound care team.” (12)

Multidisciplinary Teams and Centres of Excellence for Chronic Disease Management

Although evidence supporting the use of expert multidisciplinary teams (EMDTs) in the treatment of chronic wounds is limited, there is evidence supporting the effectiveness of these teams in the management of other chronic conditions such as heart disease and diabetes. (13, 14) In addition, there is evidence from a controlled clinical trial (15) and randomized controlled trials (RCTs) (16, 17) that demonstrates the effectiveness of EMDTs in managing delirium in older patients, (15) decreasing acute care service use by low-income community-based older patients, (16) and reducing rates of rehospitalization of older patients after discharge from the emergency department (ED). (17)

Expert multidisciplinary teams are often aligned with centres of excellence (COEs). The COE concept brings together dedicated specialists from different disciplines with an interest in specific patient populations. COEs treat these patients in high volume and apply the knowledge gained to improve the quality of care. (18) The COE approach may be effective for the management of numerous costly and complex conditions and procedures, including headache, (19) falls, (20) cardiac surgery, (21) asthma, (22, 23) and penile prostheses. (24)

Centres of excellence in wound care exist in some countries for the treatment of problematic, non-healing wounds. Denmark has the most established COE for wound care, with descriptive reports suggesting it is highly effective in the treatment of chronic wounds. (25) There is wide variation among existing COEs for wound care, but most tend to be based in acute care homes, have outpatient and inpatient units, serve broad geographical areas, and provide service to large volumes of patients. Despite the existence of these COEs and their perceived value, there are very few data on their clinical effectiveness and cost-effectiveness.

Service delivery by EMDTs traditionally necessitates the transport of patients with chronic conditions to the EMDTs, or vice versa. The use of telemedicine may offer a means to deliver chronic wound care services remotely, decreasing the need for travel. Digital photography also provides the potential for more comprehensive and accurate documentation of wound healing. (26)

Wound Care Supported by Telemedicine

There is no widely accepted definition of *telemedicine*. However, it can be conceptualized as the delivery of health services, and of consumer and provider education, via information and communication technology. (27) Various forms of telemedicine have been shown to be effective for numerous chronic conditions, including heart failure, (28-30) diabetes, (31, 32) arthritis, (33) cancer, (34) chronic obstructive pulmonary disease, (35) and osteoporosis. (36)

The use of telemedicine to deliver chronic wound care services has grown exponentially over the past 5 years due to advances in technology and its increasing acceptance among health care professionals. Synchronous (e.g., videoconferencing) and asynchronous (e.g., digital photos) applications have been used successfully with various chronic wound populations, with studies demonstrating a high degree of concordance between face-to-face and remote wound

assessment and treatment plans. (37, 38) Dobke et al (39) demonstrated the effectiveness of telemedicine (digital photos plus comprehensive electronic patient summary) in the management of 120 patients with chronic wounds in LTC homes or receiving home care, with only 2 of 120 cases differing in their approach between face-to-face and remote specialist consultation.

Telemedicine to support wound care has also been suggested to be cost-effective, although few studies have examined this. Rees et al (40) conducted a cohort study using digital photos and comprehensive electronic patient summary transmission between visiting nurses and plastic surgeons for a small sample of housebound patients ($n = 19$) who had chronic PrUs. Results of this study suggest these patients had fewer ED visits, fewer hospitalizations, and shorter lengths of stay (LOSs) compared with a retrospective review of records from a matched sample.

An interesting study by Dobke et al (41) compared the effectiveness of field nurses plus specialist wound care nurses versus comprehensive EMDTs (a field nurse, a specialist wound care nurse, an internal medicine specialist, a vascular surgeon, a podiatrist, a physical therapist, a nutritionist, and a social worker) in the management of 124 non-healing chronic wounds in residents in LTC homes in California. Both groups were supported with telemedicine (i.e., digital photos plus a comprehensive electronic patient summary). In all but 3 cases, assessment and management plans were identical between groups, bringing into question the need for an EMDT for the management of all chronic wounds.

Ontario Context: The Role of Expert Multidisciplinary Teams in Wound Care

In 2008, OHTAC requested that the Ontario Medical Advisory Secretariat (MAS) undertake a systematic review of the literature to determine the effectiveness of interventions to prevent and treat PrUs. This review suggested there was moderate quality evidence to support the use of hydrocolloid dressings versus saline gauze in the treatment of stage II and III PrUs. (42) There was low- or very-low-quality evidence to support the effectiveness of any other intervention in the treatment categories included in this review. The paucity of evidence is echoed by Reddy et al (43) in their systematic review of treatment of PrUs. Furthermore, contextualization of the evidence by an Ontario expert panel confirmed that PrU healing is a complex process influenced by dynamic interplays between wound-specific (e.g., ulcer stage and location, exudate, infection), patient-specific (e.g., mobility, nutrition, incontinence, comorbidities), and environmental (e.g., support surfaces, repositioning schedules, staffing patterns) factors, leading the authors to suggest that an EMDT was needed to assess these variables to determine the optimal treatment for each individual.

There is limited evidence that EMDTs are effective in the management of chronic wounds (39, 44, 45); most of the evidence supporting the effectiveness of EMDTs involves the management of other chronic conditions such as heart disease and diabetes. In the systematic review of the literature by MAS to determine the effectiveness of interventions to prevent and treat PrUs, the role of EMDTs was found to be inconclusive. (42) Numerous studies have suggested that an EMDT approach might improve wound healing, but most are descriptive studies. Only 2 clinical trials identified in the systematic review evaluated the effectiveness and cost-effectiveness of EMDTs in the treatment of chronic wounds. One study was a pseudorandomized pragmatic cluster trial reported by Vu et al. (44) This study evaluated the impact of a nurse-pharmacist in-house EMDT team trained in wound care using a standardized treatment protocol, on the healing rates of uncomplicated leg and PrUs in 176 residents of LTC homes in Australia. There was a nonsignificant difference between the proportion of wounds healed in 6 months (61.7% vs 52.5%, treatment vs control, $P = 0.074$, relative risk [RR] = 1.19) and a nonsignificant difference

in mean time to healing (82 vs 101 days, treatment vs control, $P = 0.095$). Interestingly, more residents in the intervention group had better pain control at 6 months (38.6% vs 24.4%, treatment vs control, $P = 0.017$, RR = 1.58). The study also reported a mean cost savings per wound of \$277.9 AUD (95% CI, \$21.6–\$534.1 AUD).

The other clinical controlled trial with a before-and-after study design evaluated a new model of service delivery for 167 community-based patients with chronic leg ulcers. (45) Service was delivered by nurses trained in wound care, with enhanced linkages to medical specialists. The study demonstrated that more ulcers had healed in the postintervention phase at 3 months after study enrolment (56% vs 23%, postintervention vs preintervention phase, $P < 0.001$, OR = 4.17). Furthermore, patients were treated daily or more often in the preintervention phase (27% vs 6%, preintervention vs postintervention phase, $P < 0.001$), equivalent to a 34% RR reduction in frequency of daily treatments.

Although the expert panel felt strongly that EMDTs should play a significant role in the treatment of PrUs, the composition of these teams, specific roles and responsibilities of team members, and intensity of involvement were far less certain. Due to the complexity of PrUs, recommendations made by an expert panel, low-quality evidence supporting the effectiveness of EMDTs, and high PrU prevalence rates in LTC homes, a field evaluation was conducted to address the uncertainty surrounding the effectiveness of EMDTs for the treatment of PrUs in LTC homes.

OBJECTIVE OF THE STUDY

The purpose of this study was to evaluate the clinical effectiveness and cost-effectiveness of EMDTs versus “usual” care teams (UCTs) for the treatment of PrUs in LTC homes in Ontario.

The primary research question was this: does the use of EMDTs increase the rate of PrU healing relative to usual care, as measured by a change in wound surface area (in square centimetres) over time (in days)? Secondary research questions were the following:

- Is the use of EMDTs to increase the rate of PrU healing cost-effective?
- Are EMDTs in LTC homes in Ontario more effective than usual care, as judged by the proportion of PrUs healed?
- Are EMDTs in LTC homes in Ontario more effective than usual care in reducing the incidence rates of PrUs?
- Are EMDTs in LTC homes in Ontario more effective than usual care in reducing PrU-related pain?
- What are LTC home staff perceptions and experiences associated with EMDTs for PrU management?

In order to address these questions, we conducted a multi-method study: a pragmatic RCT, ethnographic observations and in-depth interviews to increase our understanding of trial results, and an economic evaluation.

PRAGMATIC RANDOMIZED CONTROLLED TRIAL IN LONG-TERM CARE

Population

The study population involved residents with reported stage II or greater PrUs, residing in LTC homes situated within the Toronto Central Local Health Integration Network (LHIN) or Central LHIN in Southern Ontario, Canada.

Home inclusion criteria were location within the Toronto Central LHIN or Central LHIN boundaries, location within 100 km of the hospital housing the EMDT, a minimum of 100 beds, home administrator consent, and a PrU prevalence greater than the provincial average (5.5% as documented in the fourth quarter [Q4] 2009 Minimum Data Set housed at the Canadian Institute for Health Information [CIHI]).

Residents were eligible if they had a reported PrU (stage II or greater) and provided informed consent. The legal representative was approached for consent if a resident was deemed incapable by the most responsible clinician.

(Stage I or deep tissue injury PrUs were ineligible as the skin typically remains intact; these ulcers are therefore not equally amenable to the objective measurement of wound healing using digital photography.)

Design

The study design was a pragmatic stepped wedge cluster RCT, with LTC homes being the unit of allocation (Table 1).

Table 1: Study Design

Fac No.	Time (mo)																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
12	—	—	—	—	—	—	—	C	C	C	C	C	C	P1	P1	P1	P2
11	—	—	—	—	—	—	C	C	C	C	C	P1	P1	P1	P2	P2	P2
10	C	C	C	C	C	C	C	C	C	C	C	C	P1	P1	P1	P2	P2
9	C	C	C	C	C	C	C	C	C	C	C	P1	P1	P1	P2	P2	P2
8	C	C	C	C	C	C	C	C	C	C	P1	P1	P1	P2	P2	P2	P2
7	C	C	C	C	C	C	C	C	C	C	P1	P1	P1	P2	P2	P2	P2
6	C	C	C	C	C	C	C	C	P1	P1	P1	P2	P2	P2	P2	P2	P2
5	C	C	C	C	C	C	C	P1	P1	P1	P2						
4	C	C	C	C	C	C	P1	P1	P1	P2							
3	C	C	C	C	C	P1	P1	P1	P2								
2	C	C	C	C	P1	P1	P1	P2									
1	C	C	C	P1	P1	P1	P2										

C, control; fac, facility; P1, intervention phase 1 (onsite 1 d/wk); P2, intervention phase 2 (primarily remote biweekly).

LTC homes were randomized to an intervention start date following a computer-generated number sequence, with length of control and intervention periods dependent on randomization. Phase 1 of the intervention was 3 months long for every home, whereas phase 2 ranged from 1 month (home 12) to 11 months (home 1). A stepped wedge design was selected in order to

retain the power of randomization while offering all homes exposure to a desirable intervention, and to enable staggered delivery of the intervention across homes by a small study team.

Participant Recruitment and Data Collection

LTC home staff obtained verbal permission from residents (or their legal representative if residents were not competent) to release their names to research assistants who then sought informed written consent. Research assistants visited homes on a biweekly basis throughout the study period to take digital photos of PrUs and to administer surveys: EQ-5D (EuroQoL, Rotterdam, the Netherlands) and Visual Analog Scale for pain (VAS-Pain). The EQ-5D and VAS-Pain surveys were administered to mentally competent residents. The EQ-5D was also administered to the clinician most familiar with each resident. Research assistants considered a PrU healed when no visible opening was apparent on the digital photo. Participant recruitment occurred from October 2010 to February 2012, with data collection closing in March 2012. PrUs were followed until healed, or until the end of the study period, whichever came first.

Usual Care Team

Teams within LTC homes typically included registered nurses (RNs), registered practical nurses (RPNs), personal support workers (PSWs), nutritionists, and physiotherapists, who may or may not have had expertise in wound care. Every home appointed a wound care lead for the study at the study start. During the control period, the wound care internal team in the LTC homes was managed and led by a designated wound care nurse in 8 of the homes and by the RN of each unit in 4 of the homes. All of the 12 homes had an ongoing enterostomal therapy service for wound care. Six of the homes had contracted enterostomal therapy services that visited the homes biweekly as needed. The other 6 homes used the enterostomal therapy service provided by a local community care access centre (CCAC). The ET nurses made a referral if indicated to the EMDT through the residents' attending physicians. The enterostomal therapy service was interrupted for PrU cases only during the intervention period when the study APN took over. These teams accessed other disciplines (e.g., enterostomal therapists [ETs] and occupational therapists [OTs]) via CCACs or contracted service provider agencies as they deemed necessary. If needed, patients were referred to an appropriate specialist (vascular surgeon, plastic surgeon) for consultation.

Expert Multidisciplinary Team

Each LTC home had a wound care team that took care of residents with chronic wounds. An EMDT was based in an acute care centre (a hospital in downtown Toronto) and worked collaboratively with LTC home wound care teams via an advanced practice nurse (APN) who had expertise in skin and wound care. This collaborative work was supported by telemedicine. The in-hospital based study EMDT was led by a nurse practitioner (NP) and included a chiroprapist, an OT, and a plastic surgeon, all of whom had expertise in wound healing. The EMDT had access to a wide variety of other specialists if additional consultations were required (e.g., specialists in infectious diseases or vascular surgery, etc.).

The intervention occurred in 2 phases: phase 1 (3 months long for every home) involved in-person support by the APN; phase 2 (1–11 months long, dependent on home randomization) involved primarily remote support by the APN via email and telephone.

Phase 1: In-Person Support

APNs visited homes on a weekly basis for 3 months to build relationships, establish multidisciplinary wound care teams within the homes, conduct case-based teaching at the bedside (including the use of digital photography), and provide educational sessions related to PrUs. They referred eligible patients according to a referral algorithm (Appendix 1). APNs assessed residents with reported PrUs, captured digital photos of the PrUs, and completed standardized comprehensive assessment and treatment forms (Appendix 2) with the LTC home staff. Residents were seen by the EMDT in the outpatient clinic at the hospital or via video link if indicated by the referral algorithm. All PrU education and treatment was based on Registered Nurses' Association of Ontario (RNAO) 2007 evidence-based guidelines, contextualized to the LTC setting. (46)

Phase 2: Remote Support

Phase 2 involved remote support, which was provided for 1 to 11 months per home. Home staff were asked to complete the assessment and treatment forms, take digital photos, and transmit the de-identified data via email to APNs every 2 weeks. APNs reviewed all data received and approved treatment plans or suggested changes if indicated. Furthermore, for patients who were eligible for referral based on the referral algorithm, APNs reviewed received data in consultation with the EMDT. This process was repeated biweekly for all PrUs until they healed or until the end of the study period, whichever came first, with treatment plans being reassessed and modified accordingly. Face-to-face (or video link) visits between residents, home staff, and the APNs, or between residents and the EMDT in the outpatient clinic, occurred after the team review of individual cases.

Sample Size

Overview

We simulated trial outcomes for a stepped wedge design that included 5 to 10 homes, with 170 patients per home, and a 20% dropout rate. Additional parameters of the simulation model included the measurement error of normalized wound surface areas (0.1 standard deviation [SD] units), the percentage of ulcers that were not likely to respond to the intervention (20%), the estimated prevalence of stage II to IV ulcers (4%), and the estimated annual incidence of stage II to IV PrUs (2.5%). The minimum clinically important difference was a 40% improvement in the normal rate of healing (8.65% per week), which corresponded to an absolute healing rate of 12.11% per week. A treatment effect was estimated for each simulated data set based on a linear mixed model that included random slopes for ulcers, a time-varying covariate for the treatment, and an interaction between the treatment and time. Each estimated treatment effect was evaluated for significance at the 5% level. The power was estimated as the proportion of significant treatment effects across the 1,000 simulated data sets; 80% power was considered adequate. Under these scenarios, the power for 10 homes was adequate to detect treatment effects that were 40% or larger than the normal rate of healing.

Detailed Sample Size Calculation Methods

The outcome measure is wound surface area and its healing trajectory over time. We were interested in detecting changes in the rate of wound healing between the intervention period (with EMDTs) and the usual care period (with UCTs). To do this, we analyzed the normalized wound surface area at time t : wound area (time t)/wound area (baseline). Estimation of the rate of wound healing is based on a linear mixed model for the normalized wound sizes.

To estimate power, we simulated data under a stepped wedge design over a 17-month study duration where normalized wound sizes were simulated from a hierarchical linear model with between-ulcer variation in healing rates.⁽⁴⁷⁾ We used an ulcer-specific weekly rate of wound healing to reflect wide heterogeneity in trajectories of wound healing over time; the ulcer-specific rates were drawn from a normal distribution with a mean of -0.0865 (per week) and an SD of 0.038 . The mean was chosen to reflect the 12-week mean healing time of stage II PrUs, while the SD reflected a wide range of ulcer healing trajectories that included the possibility of ulcers that were increasing up to a maximum of 200% over the study duration. The intervention was a time-varying covariate in the hierarchical model, whose values changed according to the stepped wedge design. Therefore, the effect of the intervention in the model was to increase the rate of healing. Furthermore, to reflect some heterogeneity in the application of the intervention between homes, we used a between-home SD of 0.02 in the distribution of the treatment effects. We investigated the stepped wedge design with between 5 and 10 homes, 170 patients per home, and a 20% dropout rate applied at baseline. Additional parameters of the simulation model included the measurement error of normalized wound surface areas (0.1 SD units), the percentage of ulcers that were not responsive to intervention (20%), the prevalence of stage II to IV ulcers (4%), and the annual incidence of stage II to IV PrUs (2.5%).

After discussion with study investigators, including wound care clinical experts, we estimated the minimal clinically important difference to be a 40% improvement in the normal rate of healing (8.65% per week), which corresponds to an absolute healing rate of 12.11% per week.

Using the R statistical software (version 2.9.1, the R Project for Statistical Computing, Vienna, Austria), we simulated 1,000 data sets under the stepped wedge design for each combination of the number of homes and the treatment effect, which we expressed as a percentage of the normal rate of wound healing. To examine the ability of the study design to detect both small and large treatment effects, we chose a range of treatment effects from 20% to 60%.

A treatment effect was estimated for each simulated data set based on a linear mixed model that included random slopes for ulcers, a time-varying covariate for the treatment, and an interaction between the treatment and time. The treatment effect in the model was the parameter corresponding to the interaction between time and treatment, as it reflected a change in the mean rate of healing due to the treatment. Each estimated treatment effect was evaluated for significance at the 5% level.

The power was estimated as the proportion of significant treatment effects, across the 1,000 simulated data sets; 80% power was considered adequate. Table 2 illustrates the power estimates for the simulation study. Under these scenarios, the power for 10 homes was adequate for treatment effects that were larger than 40% of the normal rate of healing, while the power was not adequate for any number of homes fewer than 8.

Table 2: Power Estimates

No. of Homes	Treatment Effect (% of Normal Healing Rate)								
	20	25	30	35	40	45	50	55	60
10	63	69	74.3	78.4	80.5	81.9	85	85.3	85.2
9	63	67.6	71.5	75.3	76.7	79.7	82.4	82.4	83.1
8	60.9	62.8	69.8	74	74.6	77.2	78.8	80.6	80.5
7	60.7	61.9	66.6	71.3	71	74.8	75.7	78.7	78.7
6	55.8	58	62.1	66.8	66.5	70.1	71.9	76	74.8
5	49.7	55.8	57.2	61.1	64	67.6	69	70.7	70.9

Statistical Methods

Demographic and clinical characteristics of the residents participating in the study, as well as the characteristics of the PrUs observed during the study, were described with means and SDs for continuous variables and frequencies and percentages for categorical variables. Exploratory descriptive analysis was performed for the outcomes of interest, including the number of PrUs that healed, decreased to 50% of their initial size, and recurred. Subsequently, appropriate models were fitted for the analysis of the outcomes, as described below.

Wound Healing Rate

There were 3 important methodological issues that we needed to consider when examining wound healing rate:

1. clustering
2. how to relate associate size to wound age
3. how to compare the healing rates in the preintervention and postintervention phases

Clustering

Some subjects had more than 1 PrU (there were 257 PrUs in 137 patients in 12 homes), and it was likely that 2 PrUs on the same subject would behave similarly over time. Likewise, subjects within the same home experienced the same staff and level of care, so 2 subjects in the same home might have had healing rates that were more comparable than the healing rates of 2 subjects in different homes. Where it was possible and necessary, clustering was accounted for in the analysis. Ignoring the clustering effect would have led to overly precise estimates of treatment effects and very small *P* values.

How to Associate Wound Size With Wound Age

To apply a statistical model to these data, first we needed to quantify a “healing rate” affected by the intervention. Then a statistical model with a healing rate variable would test whether this healing rate was faster in the intervention period. There are many possible mathematical models that relate wound size to time, but it is a good practice to use the simplest one.

An inspection of the plots of the logarithm of the wound areas versus time for each of the PrUs containing at least 2 measurements suggested that a simple exponential growth model, while not perfect, was a reasonable approximation for the majority of individual PrUs. The exponential growth model allows only the following areas: continuously increasing, continuously decreasing, or stable areas. There was no inclusion of PrUs that grew and then shrunk, or vice versa. Visual

inspection identified 7 PrUs that had clear departures from this 1-directional change model. The analyses described below were run with and without these 7 PrUs.

For a single PrU (indexed by i) measured at times $t = 0, 1, 2, \dots$, the exponential model relates wound area at time t (A_{it}) to time by the equation

$$A_{it} = A_{0i} \exp(\beta_i t) \times \exp(e_{it}) \quad (1)$$

where A_{0i} represents the area of PrU i at time 0; B_i is the growth rate for PrU i ; and $\exp(e_{it})$ represents the random variation of the actual measurements on PrU i around the trajectory described by the rest of the equation at time t .

The expected area at times $t = T$ and $t = T + 1$ are

$$E[A_{it} | t = T+1] = A_{0i} \exp(\beta_i(T+1)) \times E[\exp(e_{it})]$$

$$E[A_{it} | t = T] = A_{0i} \exp(\beta_i T) \times E[\exp(e_{it})]$$

The ratio of the later time to the earlier time is

$$\frac{A_{0i} \exp(\beta_i(T+1)) \times E[\exp(e_{it})]}{A_{0i} \exp(\beta_i T) \times E[\exp(e_{it})]} = \frac{\exp(\beta_i T + \beta_i)}{\exp(\beta_i T)} = \exp(\beta_i)$$

This shows that in the exponential model, the area of the PrU changes by a factor of $\exp(\beta_i)$ in each time interval. If $\beta_i > 0$, the PrU is not healing—it is growing; if $\beta_i < 0$, the PrU is healing. If $\beta_i < 0$, the greater the negative value, the faster the PrU is healing. In panel A of Figure 1, the solid line shows an underlying exponential healing curve corresponding to $\beta_i = -0.20$ (a weekly decrease in area by a factor of $\exp(-0.20) = 0.82$). The points represent 8 observed areas.

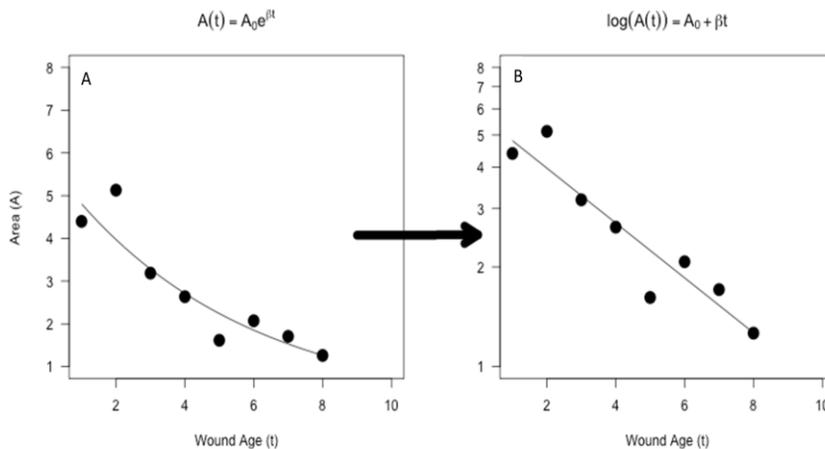


Figure 1: Exponential Model of Healing

Panel B shows that by taking the logarithm of each side of equation (1), we get a simple linear equation:

$$\log(A_{it}) = \log(A_{0i}) + \beta_i t + e_{it} = a_i + \beta_i t + e_{it}$$

If we use the logarithm of the observed areas as the outcome and time as the predictor, we can fit a linear regression to estimate the healing rate β_i .

Comparison of the Healing Rates in the Preintervention and Postintervention Phases

To test the hypothesis that the intervention has an effect on healing rates, we can assess whether the healing rates at times before and after the intervention are different. Figure 2 illustrates the type of simulation model we employed. We used a set of hypothetical subjects; here, they are all from a home where the intervention was introduced in week 12, so we have a maximum of 12 weeks of follow-up in the preintervention period and up to 23 weeks in the postintervention period.

The initial areas and the healing rates are allowed to vary across subjects. Panel A shows in grey 20 subjects with an average healing rate of 7% per week; healing rates t are in some cases higher than the average and in some cases lower than the average. The darker line in panel A is the average preintervention healing rate. Panel B below shows in grey 20 subjects with an average healing rate of 12% per week, again allowing for variation in healing rates between wounds. The darker line in panel B is the average postintervention healing rate.

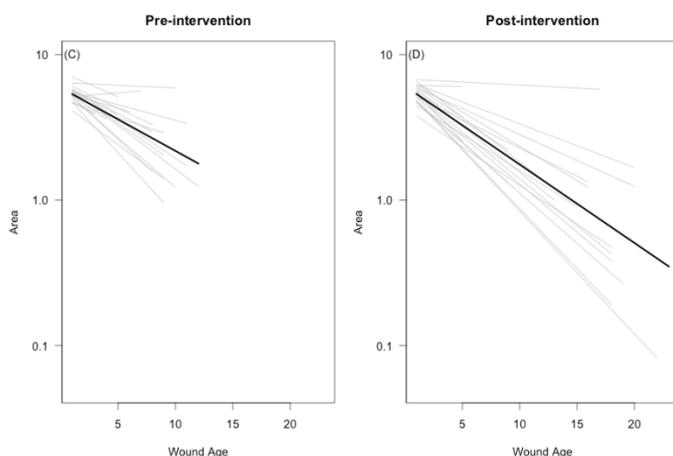


Figure 2. Simulation Model

Based on the observed areas of each wound in each week, we fitted a statistical model that corresponded to Figure 2 and estimated each wound's healing rate (grey lines) and the overall average healing rate (dark lines) both in the preintervention and postintervention periods. Our primary interest was the difference in the average healing rates—the difference in the slopes of the dark lines in Figure 2. We tested whether this slope was more negative (steeper downwards) for wounds measured in the postintervention phase than in the preintervention phase.

For any given PrU i , there is a time T_i at which the intervention took place. We can introduce a parameter Δ_i to represent the (possibly ulcer-specific) change in the slope after the intervention. Our general model for the regression of wound area over the time is now

$$\begin{aligned}\log(A_{it}) &= a_i + \beta_i t + I(t > T_i) \theta_i + I(t > T_i) \Delta_i t + e_{it} \\ &= [a_i + I(t > T_i) \theta_i] + [\beta_i + I(t > T_i) \Delta_i] t + e_{it}\end{aligned}$$

where $I(t > T_i) = 0$ when $t \leq T_i$, and 1 when $t > T_i$. The same model can also be expressed as 2 different equations, one for the preintervention period and one for the postintervention period:

$$\log(A_{it}) = a_i + \beta_i t + e_{it}$$

if $t < T_i$, and

$$\log(A_{it}) = (a_i + \theta_i) + (\beta_i + \Delta_i)t + e_{it}$$

if $t > T_i$.

Before time T_i , the slope and intercept are a_i and β_i ; but after time T_i , the slope and intercept are $(a_i + \theta_i)$ and $(\beta_i + \Delta_i)$. If Δ_i is negative, then the healing rate after the intervention is faster than the healing rate before the intervention. The treatment effect is represented by an interaction between time and treatment.

We can also introduce other predictors such as PrU stage into the same model to account for potential confounding.

The ulcer-specific intercepts, slopes, and treatment effects are assumed to come from a random effects distribution with an overall average intercept α_0 and average slope β_0 and respective variances:

$$a_i \sim N(\alpha_0, \sigma^2(a))$$

$$\beta_i \sim N(\beta_0, \sigma^2(\beta))$$

In some models, the treatment effects are assumed to vary from subject to subject around a common average Δ_0 :

$$\Delta_i \sim N(\Delta_0, \sigma^2(\Delta))$$

In other models, all the Δ_i are assumed to be equal to a common value Δ_0 .

When there were no random effects, we focused our attention on this common value Δ_0 . When random effects were introduced, we focused on the mean of the random effects distribution, Δ_0 . In both cases, we tested whether the average or common treatment effect Δ_0 was different from 0.

In the results, we fitted a number of different linear random effects models not described here. These models accounted differently for the clustering of the a_i , θ_i , β_i , and Δ_i parameters and consequently allowed us to test whether there was a statistical evidence of clustering at the different levels. All analyses were carried out using the lme4 package for linear mixed-effects

models in the statistical software package R, version 2.15 (the R Project for Statistical Computing).

Time to Healing

The effect of the intervention to “time to complete healing” was investigated using Cox proportional hazards model. Treatment was coded as a time-dependent covariate. Additional potential confounding covariates added to the model were wound area at the first visit (log-transformed), paraplegia or hemiplegia, diabetes, mental status, sex, congestive heart failure, continence, cerebrovascular accident (stroke), body mass index (BMI), and Charlson Comorbidity Index. The models were stratified by wound stage and wound location (grouped into buttock/coccyx/sacrum/hip/ischium, foot/heel/ankle bone, and other). Proportional hazards assumptions were tested and mitigated appropriately when violated. In order for the proportional hazards assumptions to hold, we added into the model an interaction between the logged wound area at the first visit and the time of event or censoring.

The hierarchical cluster structure of the data (multiple wounds in the same resident, many residents in the same home) was accounted for with the use of a robust *sandwich* variance estimator and with the use of *frailty* models employing random effects. (48, 49) The former approach is a “marginal” model that estimated the population-level averaged intervention effect, whereas the latter estimated the effect *within the homes*. Since we were also interested in the home-specific effect of the intervention, we focused our analysis on the application of frailty models for the home level. Estimates of the random effects across the different homes provided some information on how each home’s results compared with the average time to healing value during the baseline (corresponded to the intercept of the model) and during the intervention (effect of the intervention, which corresponded to the slope coefficient of the model).

We performed the following analyses: (a) an analysis where the model was adjusted for the wound stage and the initial size; (b) a series of separate analyses, 1 per wound stage; and (c) an analysis where the wound size and stage were not adjusted.

Time to Fifty Percent Area Reduction

Many of the wounds observed in the study did not heal during the study duration, which resulted in censored observations. Survival analysis statistical methods (such as those described in the previous section) are designed to accommodate this shortcoming and produce accurate estimates. Nevertheless, if the amount of censoring is large, this leads to problems. For this reason, we decided to analyze a different time to event outcome, measuring the time from when a wound entered the study to when its size (area) reached 50% of its initial size. This end point was chosen as clinically important using consensus from clinical experts. Time to 50% reduction was compared between the baseline and the intervention using the models described previously.

Incidence Rates

Incidence rates for PrUs were estimated and compared between the two phases. *Incidents* referred to resident-level incidents, not wound-level incidents; that is, an incident occurred when a resident without wounds developed a wound. The appearance of an additional wound on a resident who already had a wound did not correspond to an incident. Residents “at risk” were the residents who did not have wounds. For the estimation of the incidence rates for every home, the total number of incidents (new residents with wounds) and the total number of resident time at risk were used, for both baseline and intervention phases. The ratios of those 2

quantities were calculated, giving crude estimates of the incidence rates for each home for the 2 phases.

In order to estimate the effect of the intervention, we estimated the incidence rate ratio (IRR) between the 2 phases. The estimation method needed to account for a potential heterogeneity among the different homes. A random effects model, often used in meta-analyses, was employed.

EQ-5D Utility Scores

EQ-5D utility scores were compared between the baseline and intervention phases, with the use of mixed-effects linear models. Despite the fact that utility scores do not follow a normal distribution, linear models are frequently used in the analysis of these data and have been proven useful.

We used random effects for the home to account for the clustering, and for the patient level since we have longitudinal observations. The model was adjusted for variables that affected the utility scores (age, sex, BMI, and diabetes [please see Table A2 in Appendix 3]). Also, the visit number representing the time history of the patient was added into the model covariates to adjust for any potential effect of time and progress of the condition of the residents. BMI missing values were imputed using predictions from linear regression models fitted from each patient separately.

Separate models were fitted for proxy-reported and resident-reported scores. Nevertheless, the very small size of the latter made a model fitting effort questionable.

Pain Scores

Pain scores taken from the EQ-5D questionnaire administered by proxies were compared between the intervention and control arms. The pain score is an ordinal variable, taking values from 1 to 4, with higher values indicating greater pain. For the comparison, a mixed-effects proportional odds model was used, where we adjusted for clinical and demographic characteristics (similarly with the model for the utility score), as well as the number of visits, capturing the effect of time to the pain score.

Resident-reported VAS pain scores were also analyzed using linear mixed models similar to those used for the utility scores, although the small sample size of these data made any model fitting and results dubious.

Probability of Wound Healing Within Six Months

The probability of wound healing within 6 months from entering the study was estimated for both the baseline and the intervention phase using the Kaplan-Meier nonparametric method. For this estimation, no adjustment for wound stage was made. This probability estimate is an objective measure of how likely it is and how easily a pressure will ulcer heal under the conditions of the baseline and intervention phases. It can be therefore used as a means of comparing the 2 phases regarding the effectiveness of the provided care for wound healing; as such, the larger probability of healing in the intervention phase would indicate an effect of the intervention.

An alternative simple method for comparing the likelihood that a PrU will heal during the baseline and intervention phases is the proportion of the wounds healed in each of the phases. This type of measure suffers from many problems.

First, wounds did not participate in equal amounts of time in the phases. Depending on when wounds were diagnosed and entered the study, some participated for short or long times in the specific phases. Therefore, wounds had different time horizons in which they could be healed; that is, no common denominator existed. Such a proportion has a dubious meaning, and it cannot be used as a measure of how well the wounds are healed.

Second, there were differences in the lengths of time wounds were exposed to the baseline and intervention phases. Since wounds participated in random time lengths in both phases, the proportion of healed wounds calculated for each phase could not be compared. The randomization scheme used in the study aimed to minimize the overall time exposure to the 2 phases for all of the homes. However, this was not achieved exactly as we had uneven times of exposure of the homes between the 2 phases and, more importantly, even times of home exposure did not guarantee similar exposure times for the PrUs participating in the study.

Third, wounds that were observed in the baseline phase but continued in the intervention phase could not be properly included in any calculation of proportion of wounds healed in either phase as they belonged partially to both. Also, the elimination of those wounds from the analysis introduced bias as those wounds were more likely to be ones that were difficult to heal.

For those reasons, no statistical inference was made regarding the intervention effect based on proportions of wounds healed during the study phases.

TRIAL RESULTS

Home Recruitment

Eighty-one LTC homes were situated within the Toronto Central and Central LHINs and within 100 km of the EMDT. Of these, 63 had at least 100 beds (Figure 3).

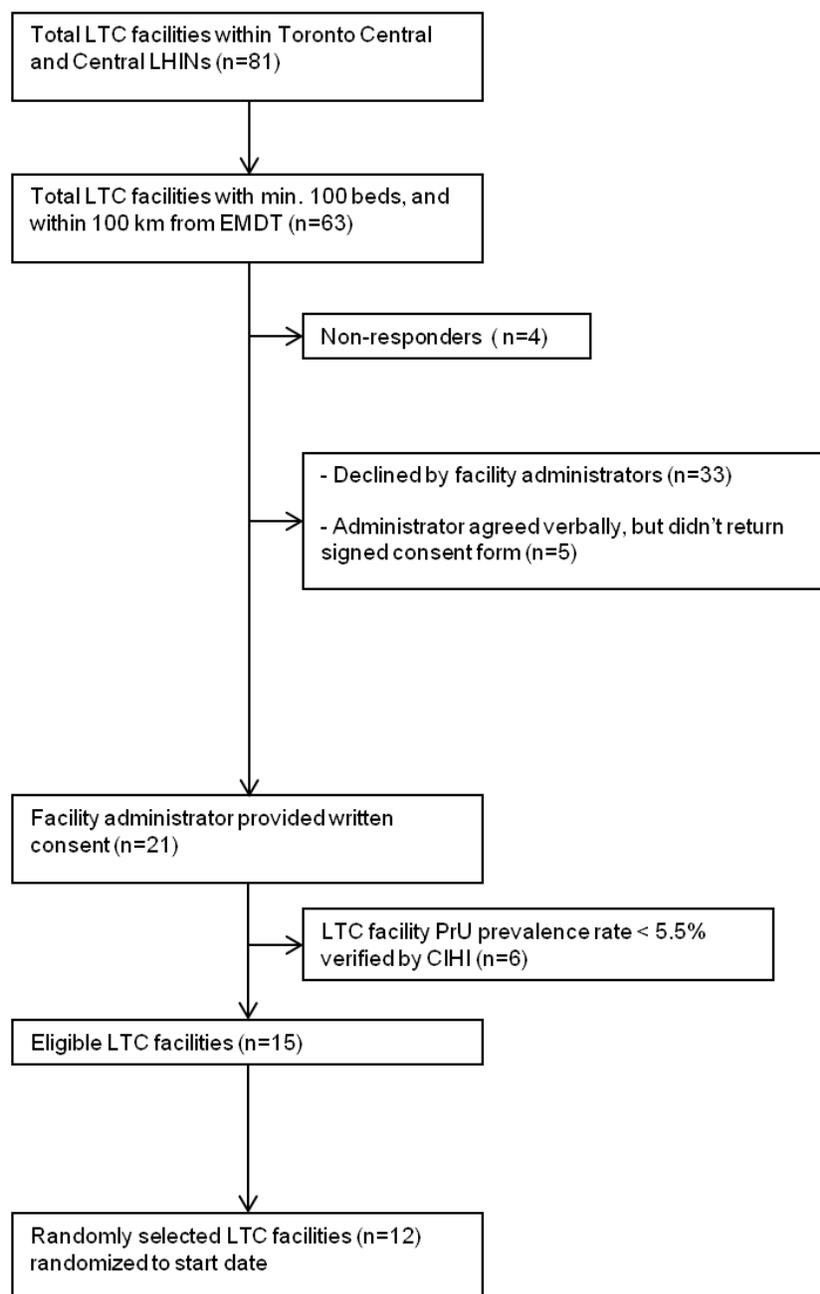


Figure 3: Consort Diagram—Home Level

Abbreviations: CIHI, Canadian Institute for Health Information; EMDT, expert multidisciplinary team; LHIN, local health integration network; LTC, long-term care; min, minimum; PrU, pressure ulcer.

Twenty-one of the 63 eligible homes (33%) agreed to participate. Prevalence data for PrUs were obtained from CIHI for these homes; 15 met the eligibility criteria of exceeding the provincial PrU prevalence rate of 5.5% in Q4 2009. Ten of these 15 homes were then randomly selected using a computer-generated number sequence, entering the study in October 2010, and were randomly assigned to a start date of intervention exposure. Despite homes having documented PrU prevalence rates greater than 5.5% in Q4 2009, PrU prevalence rates appeared lower than anticipated in many homes, leading to the decision to add 2 homes in the spring of 2011. Two additional homes from the original 15 were then randomly selected, and both agreed to participate. These homes were randomized to a start date, after consultation with a statistician to ensure this late introduction would not compromise the study design. In summary, homes 1 to 10 started in October 2010, while homes 11 and 12 started in April 2011 and May 2011, respectively. All homes remained in the study until March 2012. The average participating home size was 166 beds (SD = 37.1), representative of the average size of homes (170 beds) in the 2 study LHINs.

Participant Recruitment

Two hundred twenty-four residents with 277 PrUs from 12 homes were reported to the research assistants over the 17-month study period (Figures 4 and 5).

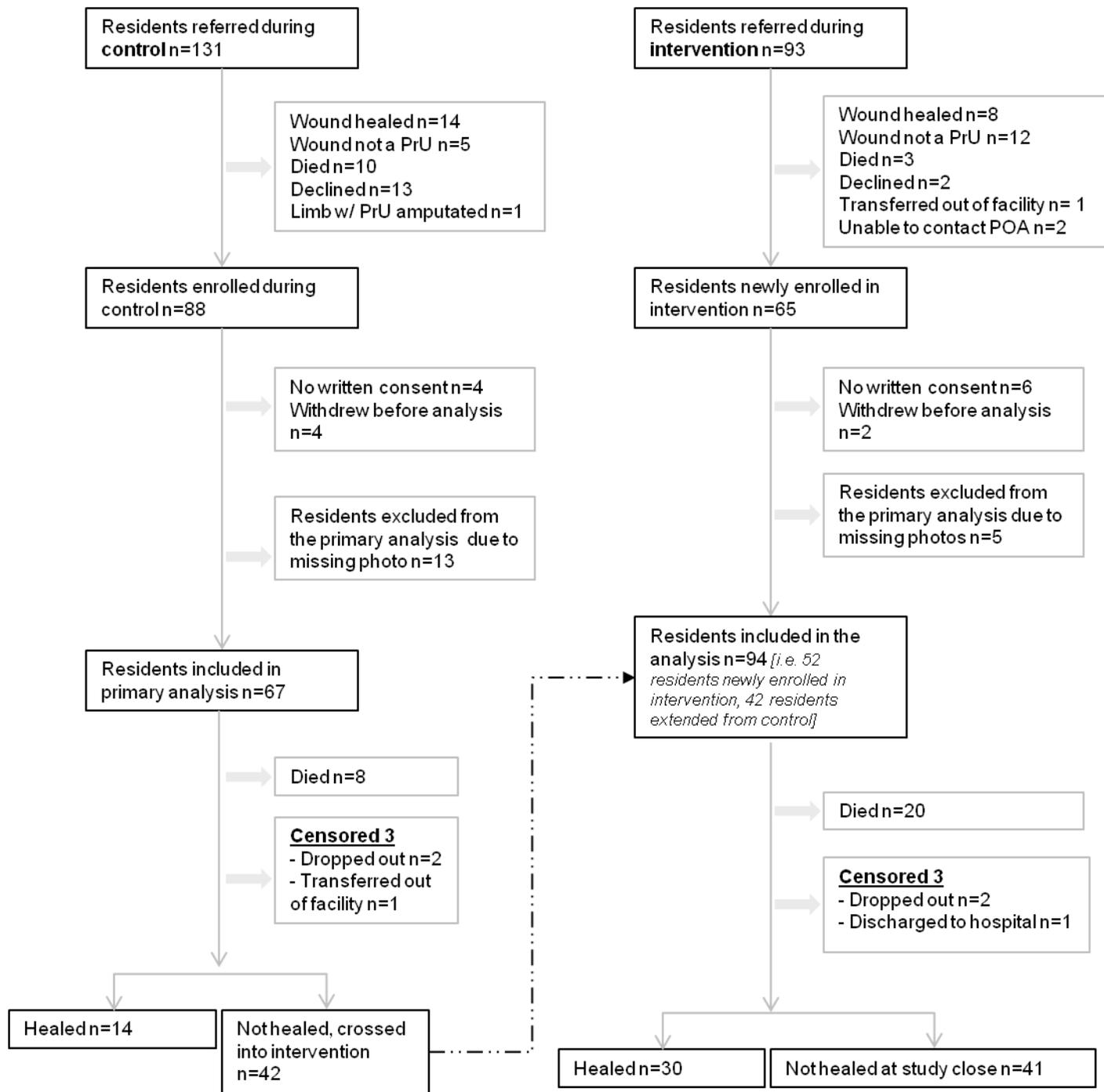


Figure 4: Resident Recruitment Diagram

Abbreviations: POA, power of attorney; PrU, pressure ulcer.

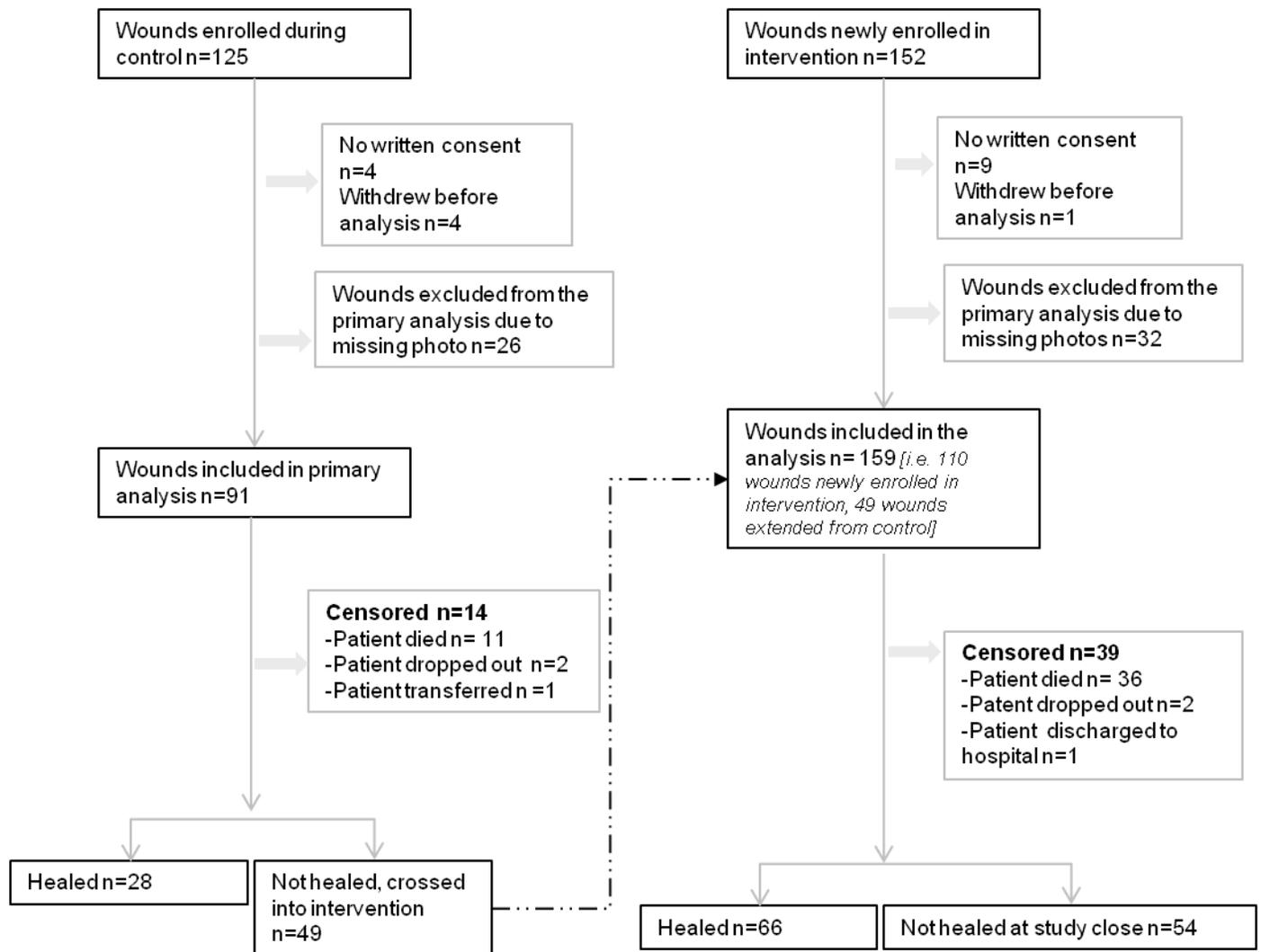


Figure 5: Pressure Ulcer Recruitment Diagram

One hundred and thirty-seven residents with a total of 259 PrUs from 12 LTC homes were recruited into the study over the 17-month study period. Fifty-eight of the total 259 PrUs were excluded because they had only 1 measurement or were “unmeasurable”; therefore, measurements from 201 PrUs (from 119 residents) were used in the analysis of the primary outcome (Table 3).

Table 3a: Participant Characteristics by Mean (SD) or Frequency (%)

Variable	Control (n = 67*)	Intervention (n = 94*)
Age in years	81 (12)	83 (12)
Sex (female)	43 (64.2%)	65 (69.1%)
Charlson comorbidities		
Alzheimer's disease/dementia	38 (56.7%)	62 (66.0%)
Diabetes	22 (32.8%)	36 (38.3%)
Stroke/TIA	20 (29.9%)	29 (30.9%)
Diabetes with end-organ damage	10 (14.9%)	22 (23.4%)
Paraplegia/hemiplegia	11 (16.4%)	15 (16.0%)
Any solid tumour	6 (9.0%)	16 (17.0%)
COPD	10 (14.9%)	7 (7.4%)
Congestive heart failure	4 (6.0%)	11 (11.7%)
Peripheral vascular disease	5 (7.5%)	6 (6.4%)
Myocardial infarction	3 (4.5%)	6 (6.4%)
Moderate or severe renal disease	1 (1.5%)	4 (4.3%)
Charlson Comorbidity Index	3 (2)	3 (2)
Other comorbidities		
Hypertension	37 (55.2%)	55 (58.5%)
Osteoarthritis	36 (53.7%)	42 (44.7%)
Osteoporosis	23 (34.3%)	33 (35.1%)
Coronary artery disease	15 (22.4%)	18 (19.1%)
Parkinson's disease	7 (10.4%)	9 (9.6%)
Contractures	5 (7.5%)	6 (6.4%)
Spasticity	4 (6.0%)	5 (5.3%)
Medical history		
UTI	9 (13.4%)	12 (12.8%)
MRSA	6 (9.0%)	10 (10.6%)
URTI/pneumonia	5 (7.5%)	5 (5.3%)
PrU risk factors		
Incontinence (urine)	66 (98.5%)	91 (96.8%)
Incontinence (stool)	58 (86.6%)	79 (84.0%)
Bedbound	49 (81.7%)	71 (87.7%)
Mental status (not alert/not oriented)	52 (77.6%)	78 (83.0%)
Nutritional supplement	55 (82.1%)	80 (85.1%)
Tube fed	5 (7.5%)	7 (7.4%)
Body mass index	25 (8)	24 (6)

Abbreviations: COPD, chronic obstructive pulmonary disease; MRSA, methicillin-resistant *Staphylococcus aureus*; PrU, pressure ulcer; TIA, transient ischemic attack; UTI, urinary tract infection; URTI, upper respiratory tract infection.

*42 participants crossed study phases, extending from control to intervention (i.e., were double counted).

Table 3b: Wound Characteristics and Outcomes

	Control	Intervention
Patient Outcomes		
Total time (d)	9,860	13,805
Died	8	20
PrU Outcomes		
Overall		
Initial wound area (cm ²)	5.7 (8.1)	4.6 (6.7)
Total time with PrU (d)	11,442	17,967
Total number of PrUs	91	159
Healed (healed/time [d])	28 (0.0024)	66 (0.0037)
Reduced by 50% (50% reduced/time [d])	66 (0.0058)	88 (0.0049)
Stage II		
Total time with PrU (d)	1,792	3,080
Total number PrUs	16 (18%)	35 (22%)
Healed (healed/time [d])	8 (0.0045)	17 (0.0055)
Reduced by 50% (50% reduced/time [d])	15 (0.0084)	34 (0.0110)
Stage III		
Total time with PrU (d)	4,016	4,187
Total number PrUs	30 (33%)	44 (28%)
Healed (healed/time [d])	11 (0.0027)	25 (0.0060)
Reduced by 50% (50% reduced/time [d])	24 (0.0060)	25 (0.0060)
Stage IV		
Total time with PrU (d)	3,504	5,639
Total number PrUs	25 (27%)	31 (19%)
Healed (healed/time [d])	4 (0.0011)	7 (0.0012)
Reduced by 50% (50% reduced/time [d])	14 (0.0040)	16 (0.0028)
Unstageable		
Total time with PrU (d)	2,130	5,061
Total number PrUs	20 (22%)	49 (31%)
Healed (healed/time [d])	5 (0.0023)	17 (0.0034)
Reduced by 50% (50% reduced/time [d])	13 (0.0061)	27 (0.0053)

Abbreviations: PrU, pressure ulcer.

*49 PrUs crossed study phases, extending from control to intervention (i.e., were double counted).

Residents included in the intervention period were comparable to those in the control period with respect to age, sex, PrU risk factors, and most comorbid conditions, with the exception of solid tumours (17.0% vs 9.0%), congestive heart failure (11.7% vs 6.0%), diabetes (38.3% vs 32.8%), and chronic obstructive pulmonary disease (7.4% vs 14.9%). There was a greater proportion of lower-stage and unstageable ulcers in the intervention period versus the control period (see Table 3b).

Prevalence of Pressure Ulcers

The mean PrU prevalence for LTC homes included in the study reported by CIHI for Q4 2009 was 8.1% (SD = 1.9). This value was substantially higher than the prevalence reported by home staff to the research assistants at study start (mean 3.7%, SD = 1.7) (Table 4). At intervention start, a bedside audit of every resident in each home was conducted to estimate the accuracy of reported rates in the control period. Mean bedside audit rates were slightly higher than mean rates reported 2 weeks prior to the audit (4.7% vs 3.5%) but well below the 2009 rates submitted to CIHI. Prevalence rates also appeared to drop in 11 of 12 homes between the intervention start and study close (an overall mean prevalence drop from 4.7% to 3.0%).

Table 4: PrU Prevalence

LTC Home	PrU Prevalence (%)				
	At Q4 2009 ^a	At Study Start ^b	Preintervention ^c	At Intervention Start ^d	At Study End ^e
1	9.9	4.4	6.2	6.8 (Feb. 2011)	4.4
2	10.2	5.9	2.5	3.5 (March 2011)	2.0
3	5.9	3.3	9.2	9.2 (April 2011)	8.3
4	7.0	4.4	1.0	3.9 (May 2011)	0 ^f
5	8.4	5.6	2.5	2.5 (June 2011)	0
6	6.3	3.8	2.9	3.8 (July 2011)	0.8
7	7.9	2.4	2.4	5.7 (Aug. 2011)	3.3
8	6.8	0.6	0.6	5.7 (Sept. 2011)	4.4
9	12.3	2.5	6.0	6.0 (Oct. 2011)	4.3
10	6.7	1.9	3.8	3.8 (Nov. 2011)	4.4
11	9.5	6.3	3.1	4.4 (Sept. 2011)	3.1
12	6.8	3.7	2.1	2.1 ^g (Nov. 2011)	1.6
Mean (SD)	8.1 (1.9)	3.7 (1.7)	3.5 (2.5)	4.7 (2.0)	3.0 (2.4)

Abbreviations: PrU, pressure ulcer; Q4, fourth quarter; SD, standard deviation.

^aBased on Minimum Data Set from Canadian Institute for Health Information.

^bBased on PrUs reported at study start: October 2010 for homes 1–10; April 2011 for home 11; May 2012 for home 12.

^cBased on PrUs reported 2 wk prior to the intervention start.

^dBased on identification by advanced practice nurses at the intervention start (i.e., the bedside audit).

^eBased on PrUs reported at the study's end.

^fThe director of care stopped referring residents with PrUs to the study advanced practice nurse in phase 2 of the intervention.

^gSeven residents were excluded from the bedside audit as requested by the director of care.

Note: Parts of this material are based on data and information provided by the Canadian Institute for Health Information. However, the analyses, conclusions, opinions, and statements expressed herein are those of the author, and not necessarily those of the Canadian Institute for Health Information.

Expert Multidisciplinary Team Intervention

Thirty-seven of the 137 residents (27%) met criteria for referral to the EMDT. Twenty-five of the 37 residents (68%) were referred, with a total of 28 consultations occurring for 24 of the 25 referred (1 resident died between the referral and consultation dates). Twelve of the 37 residents (32%) were not referred to the EMDT despite meeting referral criteria: 2 were seen by specialists situated in hospitals adjacent to the LTC homes; for 4 residents, an APN felt that the home's lack of adherence to treatment recommendations made referrals futile; and for 6 residents, no reason was cited for the nonreferral. The NP leading the EMDT attended all consultations and determined team membership for each consultation. The OT left the EMDT with 3 months of the study remaining and was not replaced. The chiroprapist attended 16 consultations (57%), the OT attended 13 (46%), the plastic surgeon attended 3 (11%), and an

orthopedic surgeon attended 1 consultation. A recommendation for a change in treatment resulted from 7 of the 28 consultations (25%). The average time from initial APN assessment to EMDT consultation was as follows: phone consultation, 6.8 weeks (SD = 5.3); video link consultation, 8 weeks; and clinic consultation, 10.5 weeks (SD = 3.5). Reasons for referral-to-consultation times exceeding 2 months were related to EMDT availability (n = 3) and to delays in APNs referring residents (n = 3). APNs e-mailed de-identified digital photos and clinical summaries to the EMDT 1 week prior to phone consultations for all referred residents. Most consultations occurred virtually (n = 25, 89%). Two residents were seen in person by the EMDT at the outpatient wound clinic, following initial e-mail and phone consultations. One resident's consultation occurred via video link. All staff involved in the video link visit (APN, wound care nurse at the home, EMDT) were very satisfied with the mode of consultation (personal communication with study staff, April 2012). A second resident in another home was scheduled for a consultation via video link, but the PrU healed before the visit occurred. Ten of the 12 homes did not have video links in place. The assessment and treatment of PrUs remained absolutely unchanged as a result of EMDT consultations for most residents (n = 19; 79%).

Primary Outcome

The primary outcome was the rate at which PrU surface area was decreasing over time (square centimetres per day). An assessor blinded to group allocation measured wound surface area from digital photos using a computer software program (Adobe Photoshop, Adobe Systems Incorporated, San Jose, California). Fifty-six of the total 259 PrUs were excluded because they had only 1 measurement. Two additional photos were deemed "unmeasurable"; therefore, measurements from 201 PrUs were used in the analysis of the primary outcome.

The primary analysis revealed that there was no overall change in healing rates (Table 5). There was no difference in the rate of healing before and after the intervention, with the average rate of healing being 0.0058 larger postintervention ($p = 0.57$). Preplanned subgroup analyses suggested a statistically but not clinically significant decrease in healing rates for the most severe PrUs.

Table 5: Primary Analysis—Healing Rate

Description of Model	Preintervention Slope (β) ^a	Change in Slope (Δ_0) ^b	Effect of Intervention		
			Relative Effect on Healing ^c Estimate	95% CI	P Value
Random effect for intercept and slope, common treatment effect, wound stage, CCI, recurrence, bedbound, any incontinence	-0.116	0.0055	1.006	0.985 to 1.027	0.6053
Random effect for intercept and slope, common treatment effect ^d	-0.114	0.0062	1.006	0.985 to 1.027	0.5392
Random effect for intercept slope, and treatment effect ^d	-0.122	0.0171	1.020	0.993 to 1.042	0.1610
Random effect for intercept and slope, common treatment effect, control for stage at diagnosis	-0.115	0.0053	1.006	0.985 to 1.026	0.6148
Models run by stage^d					
Stage II: random effect for intercept and slope, common treatment effect	-0.116	-0.040	0.968	0.882 to 1.062	0.0786
Stage III: random effect for intercept and slope, common treatment effect	-0.126	0.005	1.005	0.958 to 1.055	0.8277
Stage IV: random effect for intercept and slope, common treatment effect	-0.125	0.050	1.050	1.014 to 1.088	0.0063
Unstageable: random effect for intercept and slope, common treatment effect	-0.158	0.013	1.013	0.972 to 1.056	0.5328

Abbreviation: CCI, Charlson Comorbidity Index; CI, confidence interval.

^aNegative values indicate healing.

^bValues < 0 indicate benefit.

^cValues < 1 indicate benefit.

^dIndicates unadjusted analysis.

We checked for clustering of healing rates by home by comparing models with and without random effects for each home and found no evidence that there was a different rate of healing across homes ($P = 0.58$).

We also performed prespecified subgroup analyses based on ulcer stage. For stage II PrUs, there was a nonsignificant ($P = 0.079$) increase in healing rates after the intervention. For stage IV PrUs, there was a statistically significant trend toward harm: the wound growth rate after the intervention was 1.05 times the rate before the intervention ($P = 0.0063$).

As a check on the models above, which include all data, we ran an alternative adjusted analysis of 3 groups of ulcers (Table 6):

- group A—those ulcers that were seen only before the intervention
- group B—those ulcers that were seen only after the intervention
- group C—those ulcers that were identified before the intervention but that were also observed into the postintervention period

Group A let us estimate the healing rate in “pure” preintervention ulcers, and group B let us estimate the healing rate in an independent group of postintervention ulcers. The difference between the healing rates of the 2 groups gave us 1 estimate of the intervention effect. Group C let us estimate the “within-ulcer” effect of the intervention, by comparing the preintervention and postintervention healing rates of each ulcer.

Table 6: Results of Alternative Sensitivity Analysis of Healing Rates

Group	Healing Rate (SE)	Difference in Healing Rates (SE) ^a	Relative Effect on Healing (95% CI)	P Value
A: preintervention	-0.156 (0.087)	0.050 (0.094)	1.051 (0.874–1.263)	0.5916
B: postintervention	-0.106 (0.030)			
C: preintervention and postintervention	N/A	-0.070 (0.047)	0.932 (0.850–1.022)	0.1363

Abbreviations: CI, confidence interval; SE, standard error; N/A, not available.
^aNegative values indicate benefit.

The conclusions from this analysis are much the same as the conclusion from our main analysis: there is no significant increase in healing rates when comparing the postintervention period to the preintervention period. When we compare 2 separate groups of ulcers (groups A and B), we find that the healing rates for ulcers detected in the intervention period are slightly slower than those detected in the control period. The rate is 5% slower in the intervention period. When the same ulcer is tracked from the control period through the intervention period, the healing rate is 7% faster in the intervention period.

Secondary Outcomes

Proportion of Pressure Ulcers Healed

The proportion of wounds healed was an intended secondary outcome. However, we were not able to evaluate this outcome because wounds did not spend equal amounts of time in control and intervention periods. Therefore, wounds had different time horizons within which they could be healed; that is, there was no common denominator. Since wounds participated for various lengths of time in both periods, the proportions of healed wounds calculated for each period could not be meaningfully compared. To address this limitation, we evaluated the probability of healing at 6 months and time to healing as proxies for the proportion of PrUs healed over the study period.

Probability of Healing

The analysis of probability of healing was limited to the number of PrUs that were included in the analysis of the primary outcome (n = 201). The probability of healing was estimated using nonparametric Kaplan-Meier estimators, allocating healing events (numerator) and exposure time (denominator) to the appropriate arms of the study. The estimation was done separately for the control and intervention periods, without adjustment for PrU stage. The probability of healing for the control period was estimated to be 35.0% (95% CI 22.4–45.6), and for the intervention period to be 53.4% (95% CI 41.4–62.9). This difference is not statistically significant as the 2 CIs overlap.

Time to Healing

Of the 91 PrUs identified during the control period, 28 (30.8%) healed and 14 (15.4%) were censored during the control period. There were 49 (53.9%) wounds whose care continued to the intervention period, of which 24 healed (49.0%) while 25 were censored (51.0%) at the end of the study. From the 110 PrUs newly identified during the intervention period, 42 (38.2%) healed during the intervention period and 68 (61.8%) did not heal and were censored.

First, we observed the large proportion of censored observations ($n = 107$, 53.2%), which reduced the effective sample size of the analysis, potentially introducing bias for the estimate of the time to healing, resulting in potentially inaccurate approximations of the variances used in the analysis. Additionally, any occurrence of uneven censoring due to uneven lengths of observation times between the 2 periods might potentially have introduced bias in the estimation of the difference of the healing time between the 2 periods. We explored the time to healing with the use of a restricted mean (with the upper limit equal to 365 days) for the 2 periods. The restricted mean of healing time was 268 days (standard error = 20.8 days) for the control period and 220 days (standard error = 16.9) for the intervention period. Due to the large standard errors, this could not be assumed to be statistically significant.

Figure 6 shows the Kaplan-Meier “healing curves” for the 2 phases. The y-axis shows the “survival” for a particular time point t . Survival in this context means the probability of a wound not healing by time t ; $1 - S_t$ represents the probability of the wound healing by time t . A lower probability of “survival” therefore indicates faster healing.

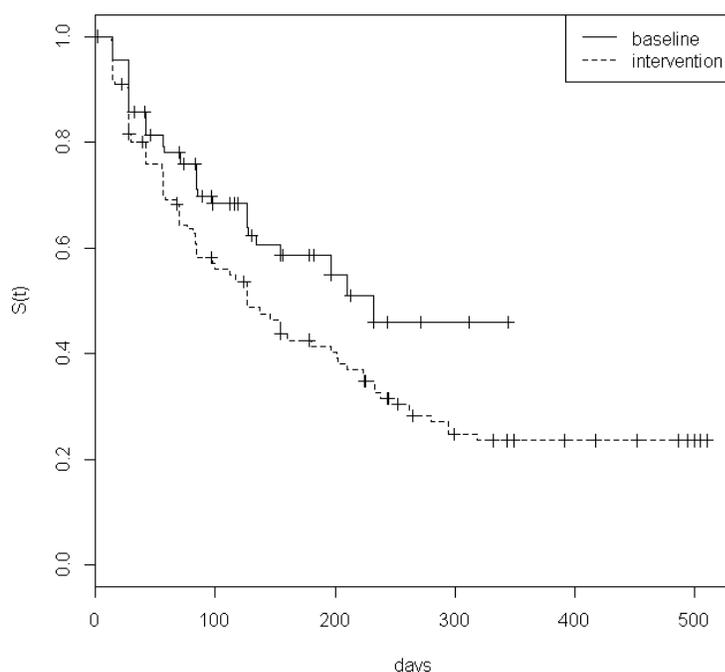


Figure 6: Kaplan-Meier “Survival” Plots—Unadjusted Time to Healing

Table 7 reports the results of a proportional hazards model of wound healing, using prespecified covariates including the wound surface area, the presence of paraplegia/hemiplegia or stroke, comorbidity, and recurrence status (recurrent vs primary ulcer). Hazard ratios for all variables

and their 95% CIs, where the event is healing and hazard corresponds to probability of healing, are reported in Table 7. Hazard ratios larger than 1 indicate a positive effect of the intervention.

Our survival model shows the same result as the primary analysis: there is no statistically significant benefit associated with the intervention. There is, however, in this secondary analysis, a trend toward benefit rather than harm.

Table 7: Hazard Ratios for Covariates of PH Model for Time to Healing

Variable	Hazard Ratio (95% CI)	P Value ^a
Intervention	1.48 (0.79–2.78)	0.22
Log(initial PrU area)	0.65 (0.51–0.83)	0.00045
Paraplegia/hemiplegia or CVA	0.76 (0.43–1.36)	0.36
CCI = 3–5 vs CCI = 0–2	1.54 (0.90–2.64)	0.12
CCI ≥ 6 vs CCI = 0–2	0.68 (0.31–1.49)	0.34
Recurrent ulcer	1.55 (0.41–5.85)	0.52

Abbreviations: CCI, Charlson Comorbidity Index; CI, confidence interval; CVA, cerebrovascular accident; PrU, pressure ulcer.
^aThe intervention effect is not statistically significant at the 0.05 level.

We also used a survival model to explore home-level effects. We present the exponentiated random effects for the intervention coefficient (“slope”) for each of the homes in Table 8. The exponentiated random effect for the slope corresponds to how the hazard ratio for the intervention for the specific home is compared to the average, where *hazard* corresponds to wound healing. More specifically, values larger than 1 indicate a better performance than the average.

Table 8: Exponentiated Random Effects for the Intervention Covariate

Home	Effect of the Intervention Covariate
1	0.94
2	0.48
3	1.62
4	1.94
5	0.93
6	2.20
7	2.29
8	0.49
9	0.64
10	0.92
11	0.68
12	0.76

For example, the intervention in home 6 had a 2.20 times higher effect (hazard ratio for PrU healing) than the average, whereas in home 8 the effect size was less than half than the average. Because of the small sample size, these subanalyses must be interpreted with caution.

We also performed preplanned subgroup analyses by wound stage. There was no effect of the intervention on stage II wounds (in comparison with control wounds of stage II) as intervention wounds in that stage healed 1.02 times faster (95% CI, 0.40–2.63; $P = 0.96$). Stage III wounds healed 2.16 times faster in the intervention (95% CI, 0.87–5.34; $P = .09$); stage IV wounds healed 1.58 times faster (95% CI, 0.20–12.67; $P = 0.66$). Both results were not statistically significant. The hazard ratio for unstageable wounds was 1.00 (95% CI 0.24–4.17; $P = 1.0$).

Incidence Rate

Crude estimates of the incidence rates for each home for the 2 phases were calculated as ratios of the total number of incidents (new residents with wounds) over the total amount of resident time at risk, corresponding to events per 100 resident-years (Table 9).

Table 9: Home-Specific and Overall Incidence Rate Estimates for Baseline and Intervention Phases

Home	Baseline	Intervention
1	8.28	1.71
2	2.93	7.17
3	4.03	4.68
4	2.00	0.72
5	3.09	2.60
6	2.60	1.84
7	1.03	4.21
8	6.02	1.30
9	1.36	3.01
10	1.26	3.66
11	1.19	0.00
12	2.11	0.00
Total	2.62	2.85

To investigate the effect of the intervention, we fitted a random effects model for the estimation of the IRR between control and intervention. The model estimated the IRR of the intervention over the control to be 1.12 (95% CI 0.74–1.68; $P = 0.59$). The model did not find evidence of a significant difference of the incidence rate between the control and the intervention periods. Additionally, the model did not identify a significant heterogeneity among the homes ($I^2 = 10\%$; $P = 0.38$).

Wound-Related Pain

We fitted linear mixed models for the resident-reported VAS wound-specific pain scores. The intervention effect was not significant ($P = 0.5$), potentially due to the very small sample size for this analysis ($n = 24$) as the VAS for pain assessment required mental competence. We also investigated the potential effect of the intervention on the mean pain scores from the proxy-

administered EQ-5D questionnaire, which was administered to the clinician most familiar with every resident, by fitting a mixed-effects proportional odds model. The model did not show any evidence of difference in pain scores between control and intervention ($P = 0.9$).

In summary, we did not detect a difference overall in the rate of PrU healing between the control and intervention arms. We found that the ulcers detected in the intervention period appeared to heal slightly more slowly (5%) than those detected in the control period. When the same ulcer was tracked from the control period through the intervention period, the healing rate was slightly faster in the intervention period. We also did not detect a statistically significant difference overall in the time to healing. No differences were detected in PrU incidence rates or wound-related pain between control and intervention arms.

QUALITATIVE METHODS

Purposive sampling (maximum variation) was employed to select homes that varied in PrU prevalence, location (i.e., LHIN), home size, resident mix, corporate structure, staff turnover, and length of exposure to the intervention. Five of the 12 sites were selected for in-depth observation and interviews. At each of the 5 sites, a qualitative researcher collected data during the intervention period: 14 to 19 hours of ethnographic observation (included informal discussions with staff) and 4 to 6 semistructured in-depth interviews. For every home, APNs kept field notes related to staff perceptions of, and experiences with, the intervention throughout the intervention period (n = 12). Qualitative data were not collected during the control period to minimize both the presence of study personnel and the potential for a Hawthorne effect.

Data collection and analysis followed an iterative process. The qualitative study team met regularly during the data collection process in order to reflect on emerging themes and to discuss how emerging questions might be addressed through further data collection. After reading through transcripts multiple times, the team decided on a coding scheme. The coding scheme was revised to account for new themes and concepts that arose from the re-reading of the transcripts. Key concepts and an analytical framework were developed that interpreted and accounted for the empirical data.

Data were obtained from multiple sources to ensure rigour and data quality: researcher observation, in-depth and informal interviews, APN observations, and bedside audit data. Ethnographic observation was conducted on multiple floors in homes and at various times throughout the day and evening to increase our understanding of organizational context. The iterative collection and analysis of data ensured that we could test hypotheses or explore unexpected findings as they emerged in the analysis. In addition, the report was sent to the APNs for feedback, and their comments were incorporated.

QUALITATIVE RESULTS

Purposive sampling (maximum variation) was employed to identify 5 homes in which to conduct observations and interviews (Table 10).

Table 10: Home Sampling for Qualitative Data Collection

Characteristic	Home No.											
	1 ^a	2 ^a	3	4	5	6 ^a	7 ^a	8	9	10	11 ^a	12
Location	TC	C	C	TC	TC	TC	TC	TC	C	C	C	C
Home size	M	L	S	L	M	L	S	M	S	M	M	L
For-profit funding (Y/N)	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y
PrU prevalence rate Q4 2009 MDS	9.9	10.2	5.9	7.0	8.4	6.3	7.9	6.8	12.3	6.7	9.5	6.8
Turnover in leadership team or wound care lead during study (Y/N)	Y: DOC, WCL	Y: admin, DOC, ADOC, WCL (x3)	Y: DOC, WCL	N	N	N	N	Y: admin (x2), DOC, ADOC, WCL	N	Y: admin, DOC	N	Y: DOC, WCL
Length of exposure (mo) to intervention (determined by randomization)	14	13	12	11	10	9	8	7	6	5	6	4

Abbreviations: admin, home administrator; ADOC, assistant director of care; C, Central Local Health Integration Network; DOC, director of care; L, large (171–250 beds); M, medium (131–170 beds); MDS, Minimum Data Set of the Canadian Institute for Health Information; N, no; PrU, pressure ulcer; Q4, fourth quarter; S, small (100–130 beds); TC, Toronto Central Local Health Integration Network; WCL, wound care lead; Y, yes.

^aSelected for in-depth qualitative data collection.

Note: Parts of this material are based on data and information provided by the Canadian Institute for Health Information. However, the analyses, conclusions, opinions, and statements expressed herein are those of the author, and not necessarily those of the Canadian Institute for Health Information.

Qualitative analyses provided insight into the interactions between context and process in LTC, and how these interactions affected the intervention. We observed differences in homes in terms of their treatment of PrUs. Below we report on the structures and processes that were associated with a proactive approach to wound care. By *proactive*, we are referring to an approach in which there is an emphasis on prevention, on the early identification of PrUs before they become severe, and on rapid identification of PrUs in newly admitted residents, and a treatment approach that is consistent and effective for all PrUs in the home. Only a few homes in this study employed a proactive approach to wound care; in these homes, the study APNs witnessed a strong wound care program in which prevention and treatment strategies were generally concordant with best practice guidelines, and bedside audit rates were relatively low.

Technical Conditions Related to Pressure Ulcer Management

In terms of *technical material* conditions, the data from this study indicate the importance of adequate medical supplies, skills, and time to prevent and treat PrUs. These conditions are influenced at 3 levels (front-line, organizational, and provincial), with interactions between these levels impacting resident care.

The data from this study indicate that a proactive approach to wound care requires front-line staff to have adequate time, medical supplies, and skills to effectively treat and prevent PrUs. In many homes, these conditions were lacking, as illustrated by the quotation below:

...Nurses do not take on the wound care role at all. A major issue remains with limited supplies to no supplies for basic wound care cleansing. This has been mentioned numerous times to the RAI [Resident Assessment Instrument] coordinator and recently to the DOC [director of care]. It is rare to see the DOC up on the floors interacting with staff. I have been floored on occasions with the way residents have been repositioned and transferred to their beds. The occasional PSW does not seem to speak and update the resident that they are going to be moved or care if they are calling out in pain. It is extremely upsetting to watch this type of care when it does occur. It is not often but has occurred a few times when I have been present. It is as if the resident is an object opposed [sic] to being a person and that the care that is being done is a chore oppose [sic] to an act of kindness. The staff seem more distant from the residents than [sic] being a part of their every day care providers.

(APN field notes, February 7, 2012)

Front-line staff efforts were highly dependent on an effective management team that needed to ensure reasonable workloads for front-line staff (such as reasonable nurse-to-resident ratios of 1 to 25 or 30, not 1 to 60) and that medical supplies were well stocked, accessible, and well organized. In addition, the study APNs tended to observe better wound care in organizations that valued ongoing education (a learning culture). Study participants explained that they did not learn their wound care skills in nursing school, as that training just provided them with the “basics.” Therefore, the LTC home plays a central role in providing an environment in which this learning can be either facilitated (e.g., through bedside monitoring, financial commitment to education) or impeded. Most administrators and DOCs in this study did not think that there was a significant difference between RNs and RPNs with regards to wound care. A study APN explained that regardless of whether a nurse is trained as an RN or an RPN, “nursing education programs provide minimal education about wound care.” Therefore, the leadership team of the LTC home can play a central role in developing the skills of their nurses by instituting bedside mentoring with wound care experts, and teaching front-line staff how to place a dressing on a

wound correctly and how to clean the wound to prevent cross-contamination. However, in many homes, the home staff explained that this mentorship did not occur.

The provincial program that provides support to LTC homes to meet the care needs of high-needs residents was discussed by many participants in this study. They felt that the current strategy for funding high-intensity needs in the province encouraged LTC homes to adopt a reactive rather than a proactive approach to the procurement of pertinent medical supplies. Some managers and administrators commented on this during interviews:

“I wish the Ministry of Health would not wait until a person has stage three pressure ulcers to give us an air mattress....They should actually give it to the person way before that so it doesn’t get worse. Then we could get rid of the mattress and the person would not have as much pain or suffering, wouldn’t take as long to heal, and really wouldn’t cost as much in the long run. I wish that we could educate the government around that. That would help.”

(Interview with assistant director of care [ADOC], June 17, 2011)

“If ministry gave [money] for 10 mattresses, instead of waiting for a P.U. [pressure ulcer] to develop. Then you could be more proactive. Beds are a problem. Should have funding for supplies. Should have it right then and there instead of waiting for an order ... It delays the whole treatment.”

(Interview with wound care manager, February 21, 2012)

In many homes, nurses explained that the residents in LTC had more serious medical issues than were seen 10 or 20 years ago and were also physically heavier. Further, some staff noted that documentation requirements had increased, but staffing levels had not been adjusted upwards to compensate for this increased workload. These frustrations were voiced by a staff nurse as follows:

She stated that she had been at the facility for over 20 years and that the workload increased tremendously in the last few years. She stated that the care required for residents was much heavier than it used to be. She had more medications to dispense, more treatments to do and many of the residents were now requiring total care. The biggest challenge that she identified was the amount of documentation that she must now do.

(Pressure ulcer multidisciplinary teams via telemedicine [PUMTT] field notes, February 22, 2011)

Nurse workloads are particularly important for the care of PrUs in LTC because front-line nurses play a pivotal role in the prevention, assessment, and management of PrUs in the LTC context. Front-line nurses supervise PSWs and can ensure that vulnerable residents are repositioned frequently to prevent the development of PrUs. In addition, in some cases front-line nurses explained that they were vigilant at establishing good communication patterns with PSWs so that PSWs would alert them to any redness on a resident’s body that could signify an early (stage I) PrU. Early-stage wounds generally heal faster than later-stage wounds. Although physicians visit each floor of a home once a week, they explained that they rely on the front-line nurses to alert them to the PrU cases that require their attention (e.g., infected wounds are referred to a physician, who can prescribe antibiotics). In addition, advanced-stage PrUs need to be assessed by nurses and then referred to ET nurses so that they can provide appropriate dressing recommendations (physicians sign the order but, according to study participants, physicians always defer to the judgment of the ET nurses). Also, respondents explained that

optimal wound care is time consuming. It requires the nurse to reposition the resident, locate appropriate dressings, and employ clean and sterile techniques throughout.

Nurses conceded to the PUMTT research team that if you are rushed, “you will be cutting corners” (PUMTT field notes, March 19, 2011). In this study, homes that had more reasonable workloads for nurses were generally observed to provide better wound care (as observed by study APNs) and had lower bedside audit PrU rates. In these situations, management had taken a number of steps to protect the workload of their front-line nursing staff, such as instituting reasonable staffing ratios (nurse-to-resident ratios of 1 to 25 or 1 to 30) and making efforts to equalize workloads between shifts and across floors. Unfortunately, in many homes, nurses were given large workloads (nurse-to-resident ratios of 1 to 40 or 1 to 60), and the study APNs witnessed that wound care was suboptimal in these homes. These homes still met the provincial staffing levels in LTC, however, since the only stipulated provincial requirement is to have 1 RN in the home for each shift.

In this study, the staffing ratios of PSWs to residents were more similar from one home to another, (about 1 PSW for 8 residents). However, PSWs were frustrated that they did not have more time to spend talking with residents and that the personal care that they delivered was rushed. In 1 home, however, a PSW described that part of her new responsibilities was delivering restorative care to residents (their regular care was provided by other PSWs). She was pleased that by spending 30 minutes helping the residents walk or eat, she had the time to develop a relationship with them, which she thought was beneficial to their psychosocial health, as well as their physical health. A number of staff members (PSWs and nurses) thought that talking to residents can be beneficial for PrU care, since talking to residents and developing a relationship with them can help prevent and ameliorate resident depression, and depressed patients are more likely to stay in bed (and therefore develop PrUs).

Social Processes Related to Pressure Ulcer Management

The data revealed that the following set of social processes were associated with effective PrU management: (a) high accountability, (b) high responsiveness, and (c) collaborative and consultative decision-making. These factors interacted and played a role at multiple levels (front-line, organizational, and provincial), each having an influence on PrU management in LTC.

The data from this study revealed that different patterns of accountability were associated with different staff behaviours, and that these could have consequences for PrU care. For instance, homes that delegated the management and treatment of all upper-stage wounds to dedicated wound care nurses tended to have front-line nurses that put little effort into prevention. However, in other homes, front-line nurses who were held responsible for treating all stages of wounds could be very motivated at wound prevention and “catching” wounds at stage I, since they did not want to deal with the increased workload caused by treating complex, upper-stage PrUs. But this scenario tended to occur only in a high-accountability culture in which a very competent wound care manager expected high standards of care from front-line staff, and had the capacity to mentor them to help them achieve this goal. In a home with a high-accountability culture, home leadership explained how they used their management team to ensure good-quality wound care. In 1 of these homes, the DOC emphasized that the success of her wound care team could be attributed in part to reasonable manager workloads:

“I think the two new unit managers, X has been with us a year, and X only joined about six months ago, brought their own level of knowledge around wounds, and

their whole focus is different than it was when I first came. So this team is really a wound team. They really like wounds, and they're interested in wounds, and they monitor them. Whereas the team I had in place when I first arrived, there was one person who really focused on it, but they had all 165 residents to worry about, and they were overseeing the whole home as a support to the person, me. And I felt that was going to result in our inability to truly effectively monitor ... the quality of care we hoped to achieved was impossible with one person. Like, I have three people doing this job and it's yielding its return in that regard, but it was very difficult before ... [because] the unit managers now have 64 Residents to monitor, instead of one person monitoring 165."

(Interview with DOC, November 14, 2011)

The data in this study revealed that good wound care tended to occur in the context of a highly responsive organizational culture. In a context of responsiveness, newly identified PrUs were treated as quickly as possible, and PrUs that were deteriorating had treatment regimens altered as soon as possible. In the scenario described below, a nurse explained patterns of responsiveness that went both ways between her and her manager:

She explained what occurred when she had complicated dressings. She would do a weekly wound assessment, and if she saw "something different" then she would ask Lily, the wound care manager, to see it. If it was "going good" she would ask Lily to see it. If it was "going bad" then she would also ask her to see it. Or, sometimes Lily would ask her to "please see me when you do this dressing." Therefore, she explained that the process went both ways. She would seek Lily's input, and Lily would contact her as well. She noted, "The sooner I get rid of the dressing, the better for me."

(Field notes, March 28, 2012)

However, we found that a responsive culture was contingent on a respectful environment as staff were hesitant to raise concerns in a punitive environment. Further, we found that a responsive culture appeared to contribute to staff satisfaction and staff retention, which could also be beneficial for PrU care.

The data revealed that better wound care occurred in a context of consultative decision-making. Further, study APNs witnessed that LTC leaders who consulted with staff about their interests and passions could be rewarded with wound care nurses who were very dedicated and effective in their role.

Participants described that while falls are seen as "incidents" requiring LTC homes to complete forms and notify the Ministry of Health and Long-Term Care (MOHLTC) immediately, there is no such consequence for excessively high rates of PrUs. If homes have repeated problems with skin and wound care, the MOHLTC may be alerted to this and may issue a complaint; but there is no formal process for follow-up if problems are not resolved.

In this study, 14 (35%) of the 49 study participants who were hospitalized during the study period returned to homes with additional PrUs that had developed during their hospital stay, with many of these residents having developed multiple new PrUs. One staff person quipped that if a resident goes to hospital for "more than 3 days," he "will return with at least 1 hospital-acquired PrU." The issue of hospital-acquired PrUs was not discussed by LTC staff at all homes in the study, but it was raised in particular by those in homes that were farthest from the downtown core. The following accounts were recorded during a wound care meeting at an LTC home:

Resident y has ulcers. The resident's daughter is a nurse. Resident was in emergency for 10 hours. 'Can you change her because she is incontinent?' the daughter asked. But in those 10 hours, he was not changed, he was not turned – she asked nurses 'where can we get diapers?' The resident came back with two ulcers – right and left buttocks.

(Field notes, January 19, 2012)

Third week of December, two ulcers but came back from hospital with 9 ulcers... Second admission, came back with 15 ulcers ... just turned to palliative when he came back

(Field notes, January 19, 2012)

When LTC residents acquire PrUs during hospital stays, hospitals are not held responsible as residents are typically discharged back to LTC homes.

Referrals to the Expert Multidisciplinary Team

The study APN consulted the EMDT following the study referral rubric. In the majority of cases (100 of 137 residents [73%]), referral to the EMDT was not indicated. Twelve of the 37 residents (32%) were not referred to the EMDT despite meeting referral criteria, with APNs describing the reason for nonreferral in some cases as being due to a lack of adherence at the home level to treatment recommendations made:

Referral not sent to (E)MDT as treatment recommendations often not followed and wound often infected which was either treated by antibiotics that the bacteria (heavy growth MRSA [methicillin-resistant Staphylococcus aureus]) were resistant to according to sensitivity results, or MD declined to (prescribe) Rx antibiotics as he didn't feel it was necessary unless resident had a fever, cellulitis [sic] and increased white blood cell count. Wound continued to decline due to inadequate management of pressure and wound infection ... Not sent to (E)MDT due to frequent occurrences of wound being left open and contaminated with stool.

(APN referral notes)

Members of the EMDT thought that in *most* cases, the study APN had the expertise to advise on the appropriate course of treatment to support healing:

The cases that were presented to us, the PUMTT ET nurses knew what to do but the problems were in terms of barriers. They would suggest a strategy and it was not implemented by LTC or the family did not want it implemented. I was glad they [the resident] did not come in [to the hospital] because it would have been a waste of time, a waste of resources and it would have stressed out the LTC resident.

(NP from EMDT, April 30, 2012)

APN knew 90% of what we were going to recommend.

(OT from EMDT, May 1, 2012)

Nonetheless, the EMDT did play an important role in a couple of cases. The chiropodist (a member of the EMDT) explained how a patient with diabetes was brought in with a PrU on her foot, and the chiropodist was able to prescribe footwear to help heal the wound. However, it

appears that the study APN did have the expertise to know when referral to a chiropodist was appropriate. She went beyond the requirements of the written study protocol as she personally advocated for this patient to be seen in person by the chiropodist.

The chiropodist noted that it was possible to do an assessment of a patient via video link, but that it was not possible via telephone supported with a digital photo. Similarly, the OT noted that a wheelchair recommendation was challenging to provide via telephone, despite the accompanying photos.

Leadership in Long-Term Care

The intervention consisted of a number of different processes, such as education (in-services, bedside mentoring), comprehensive assessment of PrUs, and development and implementation of recommendations. Each of these processes was contingent on support from the leadership of the LTC home.

In this study, the data indicated that LTC homes with leadership teams that were most supportive of the PUMTT intervention also appeared to provide the best care (according to the clinical observations of the study APNs) to their residents. In these homes, LTC home leadership actively supported and promoted the educational component of the intervention, and ensured that treatment recommendations suggested by the PUMTT team were acted upon. Leadership teams in the least-well-run homes, in which standards of care appeared to be weakest (as observed by the study APNs), were also those that were the least supportive of the intervention. In these cases, managers or DOCs often postponed dates for in-services, did not ensure that their staff attended the in-services, and did not free up staff time to ensure that a wound care nurse was available to receive bedside mentoring. In this latter situation, the study APNs also witnessed unsterile practices and a lack of management follow-up, which contributed to infectious disease outbreaks that tended to interfere with the PUMTT intervention.

In 1 home, the leadership team was supportive of both the educational component of the study (bedside mentoring and in-services) and the implementation of recommendations:

Supportive leadership team: Assigned staff member to participate in the study and provided her with 2 days per month to dedicate to wound assessment. Leadership team receptive to discuss [sic] issues related to aseptic technique and the prevention of wound infection. They were quick to act and obtained dressing trays for staff to use when caring for deep wounds. They informed staff of the change in practice and enlisted me to provide the education. They also acted promptly to investigate a resident with a wound infection so that treatment could be started quickly ... The DOC recognized the need to update the management of stage 1 and 2 P.U. and asked me to make recommendations and teach the staff. The ADOC was very supportive of the PUMTT program and phoned me regularly to review educational needs of staff and to plan the in-service for the following week. She would post a notice on the units the day before the in-service, would [send an] overhead page to announce the in-service and would then go unit to unit to invite staff to attend. Every in-service was attended by most staff on duty for the day.

(APN field notes, June 13, 2011)

In contrast, at 2 of the 12 homes no one came to the bedside to receive mentoring from the study APN. At 1 of these homes, the study APN documented poor wound care and a lack of

follow-up regarding treatment recommendations. It is likely that the very heavy workloads of nurses at this home (1 front-line nurse for every 60 residents, contrasted to 1 front-line nurse for 25 or 30 residents, which was more typical in the other LTC homes) contributed to the suboptimal care as nurses were constrained by their excessive workloads from having the time to change dressings appropriately:

Wound care does not seem to be a priority for the wound nurse or management at the facility. Dressings are changed whenever it suits the nurse, the wrong products are used, wounds are not cleansed or packed appropriately, some wounds are left open and contaminated, recommendations are not followed, endless delays in obtaining supplies, no regard re obtaining or using equipment correctly. Wound nurse does not have an understanding re the principles of wound healing, assessment of wound parameters, identification and management of infection, how and when to use products etc. The goal in my opinion seems to be to change the dressing as quickly as possible – doesn't matter how it is done or what is used or if it is effective or stays on just check off that it has been done. There is no accountability re the outcomes for wound care. No one monitors resident outcomes or follows up if recommendations have been followed ie no wound cultures taken when requested, cultures lost, MD not even advised that I had suggested an x-ray. Heel devices are handled roughly and destroyed.

(APN field notes, June 13, 2011)

In addition, leadership instability was also a problem. In this study, half the homes (n = 6) had leadership turnover during the study period, often at numerous levels simultaneously (e.g., administrator, DOC, ADOC, wound care lead positions all turning over within a short 2-month period). During these periods, the leadership turnover caused a disruption in the PUMTT intervention, as commitment to the study (regarding staff time or staff education) was withdrawn.

Role of the Advanced Practice Nurses in the Study

Wound care managers or wound care nurses from each of the 5 sites explained that the study APNs provided more opportunity for learning compared to their regular enterostomal therapy services, particularly during the on-site part of the study. (Some of them stated that this opportunity for learning was greatly reduced during the remote phase of the study.) Below, a wound care manager explained why she preferred bedside mentoring from the study APN to that of their regular ET nurse:

Because it's less rushed...we communicate more frequently...The [regular] ET nurses are more like a business connection to us, they just come and they do their assessments and then they go and they send us their recommendations.

(Field notes, January 12, 2012)

Study APNs also mentored staff about pressure-reduction strategies (the use of heel booties, pillows, ROHO cushions [The ROHO Group, Belleville, Illinois]) that can prevent new ulcers from occurring; mentored wound care managers about wound care processes, such as the arrangement of the wound cart to reduce cross-contamination; and encouraged other professionals such as physiotherapists to get involved in PrU prevention. By contrast, LTC homes were generally not receiving this type of mentorship from their regular enterostomal therapy services:

The regular ET nurse does not recommend prevention unless you ask. No education sessions about prevention. Whereas, Susie [the study APN] till talk [sic] to RPN and PSW about repositioning.

(Field notes, March 1, 2011)

In this study, most LTC homes used enterostomal therapy services in order to receive an order that could be reimbursed from the High Intensity Needs Fund. These enterostomal therapy services were billed on a fee-per-visit basis, and many of the ET nurses were employed by the company that sold the medical dressings. A wound care manager from 1 home explained that they could call an NP who would provide in-services on prevention to her staff. This NP was employed by the local hospital and worked with LTC homes to help avert hospital transfer. However, only 1 of these 5 homes had that type of relationship with an NP. Further, in a separate interview with this NP, she explained that she wanted to “get off wounds” because it was taking up too much of her time.

The study APNs were the primary point of contact between the EMDT and the LTC home. They were responsible for teaching and mentoring the LTC staff members throughout and for coordinating with the EMDT when needed. Therefore, their professional and personal attributes helped or hindered the intervention. Homes were most satisfied when the study APN was respectful, flexible, and knowledgeable and facilitated teamwork. When the study APNs were respectful of others, home staff persons were eager to work with them and mentorship at the bedside went smoothly:

“Mary [names changed to protect anonymity] – was very approachable – not afraid of her – we can always call her” – “Mary, she respected me.”

(Field notes, February 29, 2012)

On the other hand, problems arose when the study APN was viewed as having a disrespectful manner. In these situations, often the staff at the home resisted working with the study APN:

I had three people who did not want to work with her... I can tell you that my RPN wanted to learn. But she told me ‘I don’t want to have my feelings hurt by Cheryl.’

(Field notes, March 1, 2012)

LTC staff were also appreciative when study APNs were flexible in their approach:

“Liz was more flexible about dressings. She might say ‘This dressing is better, but until you receive it, use this one.’ So, more flexible [than the regular ET nurse].”

(Interview with wound care nurse, home 6, February 29, 2012)

This flexibility was useful in the LTC context, in which optimal dressing supplies often were not available, or in some cases could not be ordered because of exclusive contracts with suppliers. On the other hand, a lack of flexibility hindered teamwork and sometimes led to poorer resident care:

...She was not that flexible...From what I understand about your study, you were interested in a team technique. But, Jen did not work as a team [member]. She just told you what to do...

(Field notes, March 1, 2012)

The data indicated that when LTC home managers were dissatisfied with their study APN, they tended to stop referring new cases to the study and minimized the teaching opportunities provided by the study APN.

In summary, the qualitative data and their analyses increased our understanding of the perceptions and experiences of staff with the intervention, revealing the critical roles that home leadership and personal characteristics of the APN played in this study. In addition, qualitative data and their analyses illustrated how various contextual factors (i.e., materials, skills, staff time, accountability, responsiveness, and decision-making) at multiple levels (i.e., front-line, organizational, and health system) influenced PrU management in LTC.

ECONOMIC EVALUATION

Overview

The objective of the economic evaluation was to compare 2 strategies for the treatment of PrUs in LTC homes in Ontario: the use of EMDTs versus UCTs.

The economic evaluation comprised 2 analyses:

1. The primary analysis was a comparison of the direct care costs associated with EMDTs and UCTs, with the aim of estimating the *additional* direct care costs associated with introducing EMDTs.
2. The secondary analysis was an estimation of the *additional* direct care costs of introducing EMDTs, associated with each *additional* wound-free day provided. This ratio was then compared to a willingness-to-pay (WTP) threshold representing the value associated with an additional wound-free day, to determine whether the introduction of EMDTs appeared to be cost-effective. The uncertainty in this result was then assessed through a bootstrap analysis.

The perspective of each analysis was that of MOHLTC (i.e., the only costs considered were those that are met by MOHLTC). The time horizon of both analyses was time until residents were first in a wound-free state or were censored from the PUMTT study, whichever came first. Costs are reported in 2012 Canadian dollars (CAD). Due to the short time horizon, no discounting has been applied to costs or health outcomes.

Methods

The total mean costs incurred until residents were wound free were estimated for each of the baseline and intervention phases of the study (corresponding to UCTs and EMDTs, respectively) using inverse probability weighting. (50, 51) According to this method, cost data were inflated appropriately in order to account for censoring. Cost data were considered censored if the observations were stopped owing to the end of the study or phase, a resident's death, or a resident dropping out from the study. Costs that were incurred at time points with a higher chance of censoring were inflated more than costs that were incurred at time points with a smaller chance of censoring. Mean costs were estimated for each of a series of approximately 2-week periods (roughly corresponding to the interval between study visits), and these estimates were summed to estimate the total mean cost to wound free for each strategy.

A number of separate cost categories were considered:

- personnel: study nurse, EMDT, enterostomal therapy consultation visits, home nurse, general practitioner (GP)
- treatments and supplies: drugs, dressings, negative pressure wound therapy (NPWT)
- hospitalization: inpatient admissions, ED visits

Data on resource utilization were collected prospectively throughout the study. Where possible, the costs associated with each cost category were estimated by assigning unit costs to this resource utilization, in line with usual methods.

Since each analysis requires an estimate of the *additional* costs associated with EMDTs compared with UCTs (rather than the *total* costs associated with each strategy), we did not consider any costs that would be expected to remain unchanged should EMDTs be adopted into practice. This is standard practice in economic evaluations. (52)

The number of additional wound-free days associated with EMDTs was defined as the mean difference between the intervention and control phases of time to being wound free. Mean differences were estimated from Kaplan-Meier survival curves.

Uncertainty around the estimates of additional costs and additional wound-free days was investigated, and confidence intervals were generated with the use of the bootstrap method. (51) This uncertainty was also used to estimate the *probability* that EMDTs are cost-effective at a specific WTP threshold representing the value associated with an additional wound-free day.

All statistical models were implemented in R language for statistical computing.

Cost Estimates

Personnel

Study Nurse

Each study nurse was instructed to record the amount of time spent with each resident, on each visit, treating each wound, and completing the relevant PrU assessment form. In cases where this time was missing on the form, this time was estimated for each resident using a “last value carried forward” or (where no previous value existed) “next value carried back” method. We estimated the cost of this time by assuming the following:

- Each study nurse is an APN paid an annual salary of \$85,000, plus 24% benefits (\$105,400 total).
- Each study nurse works 8 hours a day for 250 days per year.

This resulted in an estimated cost for the study nurse of \$42.50 per hour.

Expert Multidisciplinary Team

In cases where assistance was required from a member of the EMDT, the study nurse recorded the occupation of the EMDT member and the time spent with the resident. With the exception of the plastic surgeon and orthopedic surgeon, this time was costed by estimating the average annual salary (plus benefits) for each occupation, as defined by Statistics Canada National Occupational Classification codes, and then deriving an average cost for an hour of work for EMDT members of each occupation. It was assumed that all EMDT members worked 35 hours per week for 48 weeks per year, regardless of occupation.

The hourly costs for each occupation were estimated as follows:

- \$16.53 for a PSW (National Occupational Classification code D312) (2006 census, inflated to 2012 CAD using the consumer price index)
- \$25.02 for an RPN (D112) (personal communication with RNAO), 2012
- \$29.36 for an RN (D112) (personal communication with RNAO, 2012)
- \$32.44 for an OT (D043) (2006 census, inflated to 2012 CAD using consumer price index)
- \$40.00 for an APN (D112) (personal communication with Nancy Parslow, 2012)

- \$40.00 for a chiroprapist (D023) (personal communication with Ontario Society of Chiroprapists, 2012)
- \$59.28 for an NP (D112) (personal communication with Laura Teague, 2012)

The costs for plastic surgeon and orthopedic surgeon consultations were estimated on a per-consultation basis according to the most recent Schedule of Benefits issued by MOHLTC. Each plastic surgeon consultation was estimated to cost \$81.10 (A085), while each orthopedic surgeon consultation was estimated to cost \$83.10 (A085).

Although the EMDT included members of additional occupations (including dietitians, physiotherapists, and chiropractors), no assistance was required from these EMDT members during the study, so no costs were incurred.

Enterostomal Therapist

Residents with multiple stage II or single stage III or IV ulcers qualified for access to MOHLTC's High Intensity Needs Fund. LTC homes cannot generally access these funds without a consultation from an ET. However, during the intervention phase the study nurse replaced the ET for this purpose. The costs associated with ET visits may therefore be reduced should EMDTs be adopted in practice.

Records of each ET visit were extracted from resident charts. It was assumed that each ET visit cost \$91 plus \$60 per day for transportation (personal communication with the administrators of 2 LTC homes that participated in the study).

Home Nurses

There are implications for the amount of time spent by home nurses changing dressings if the adoption of EMDTs results in a change in the frequency of dressing changes. Although data on this frequency and the classification of the home nurses conducting each dressing change were extracted from resident charts, no records were made of the amount of time spent on each dressing change.

It was assumed that this time could be approximated by the time spent by the study nurse treating wounds on each visit, as noted by each study nurse on the PrU assessment forms. Separate averages were calculated for wounds of different stages. The estimated dressing times were as follows:

- 10 minutes and 44 seconds (10:44) for stage II wounds
- 14:53 for stage III wounds
- 15:50 for stage IV wounds
- 16:27 for unstageable wounds

The classification of nurses included APNs, ETs, RNs, and RPNs. The cost of the time spent by each home nurse was estimated in the same way described above for the EMDT members.

General Practitioner

The costs associated with GP visits in LTC homes were not proportional to the time spent with each resident. GPs generally billed \$108.85 per month, provided they saw a resident a minimum of 2 times per month; however, if the GP visited a resident more than 4 times per month, they could bill for additional visits at \$35 per visit (personal communication with a GP attached to an LTC home).

Since incremental changes in the frequency of GP visits between 2, 3, or 4 per month had no impact on the costs imposed on the MOHLTC, and since it was difficult in any case to attribute changes in the frequency of GP visits to the strategy used to treat PrUs (UCTs or EMDTs), it was assumed that the introduction of EMDTs would not result in any changes in the costs associated with GP visits.

Treatments and Supplies

Antibiotics

Records on antibiotics prescriptions for each resident were extracted from the charts. The number of pills required for each prescription was estimated based upon the brand names and dosage noted in these charts. The cost of these pills, and in turn the cost of fulfilling each prescription, was then estimated according to the prices published in the MOHLTC's formulary. (53) In cases where the brand name antibiotic stated on the prescription is not an Ontario Drug Benefit—such as in the case of Bactrim (sulfamethoxazole and trimethoprim) or Tazocin (piperacillin and tazobactam) the price of a common generic was used instead.

Dressings and Related Supplies

For each wound, the *type* of dressings and related supplies (including barrier cream, spray, etc) used for dressing changes were extracted from the relevant charts. Since these may have differed between baseline (UCTs) and intervention (EMDTs), and since the frequency of dressing changes may also have changed as a result of the intervention, we attempted to assign a cost to the dressings and supplies used for each dressing change. Unfortunately, no record was made of the *amount*, *size*, or *quantity* of the dressings and related supplies used for each dressing change. Since it was not possible to accurately cost each specific dressing change, an average cost was therefore assigned across all dressing changes.

To calculate this average cost, a sample of 43 photos of wounds were selected. This sample was not random but, rather, was chosen to include an approximately equal number of photos taken in baseline and intervention, and an approximately equal number of photos across each wound stage (stages II, III, and IV and unstageable). One of the study nurses was asked to view each photo, alongside a record of the *type* of dressings and related supplies used for each specific wound at the time the photo was taken. The study nurse provided her expert opinion of the *quantity* of each dressing or supply that was most likely used when changing the dressing on each wound in practice. We then individually costed the dressings and supplies used for each dressing change according to the list prices in Starkmans Health Care Depot catalogue. (54)

The average cost of dressings and related supplies used for each dressing change across the sample of 43 wounds was estimated to be \$10.06. No significant differences were found in the average cost of dressings and related supplies between baseline and intervention, between wounds of difference sizes, or between wounds of different stages, so the overall average was assumed to apply for every dressing change.

Negative Pressure Wound Therapy

It was considered plausible that the use of EMDTs may have resulted in a reduction in the use of NPWT. NPWT requires a vacuum-assisted closure (VAC) therapy unit and VAC therapy disposable dressings. The daily cost for renting a VAC therapy unit and using the VAC therapy disposable dressings was assumed to be \$150 (personal communication with a CCAC manager, verified by a DOC at 1 of the LTC homes in the study where NPWT was used).

Hospitalization: Inpatient Admission and Emergency Department Visits

We used data from the Ontario Case Costing Initiative (OCCI) to cost inpatient admissions and ED visits. For inpatient admissions this was done on a per-diem basis using the most recent data for inpatient services (calculated by dividing the average total cost by the average LOS). For ED visits this was done on a per-visit basis using the most recent data for ambulatory services.

For each inpatient admission or ED visit, the study nurse recorded the date, duration, and reason for hospitalization on the respective PrU assessment form. However, since these forms were not completed during the baseline phase of the study, these data could not be used for a comparison of hospital costs between UCTs and EMDTs. The only consistent data on inpatient admissions and ED visits in both phases of the study were the records extracted from chart data.

The OCCI's estimates of hospital costs are provided separately for each most responsible diagnosis (MRD), as defined by *International Classification of Diseases*, 10th Revision (ICD-10), codes. For each hospitalization we attempted to match the reason for hospitalization recorded in the respective chart to an MRD, but in some cases this was complicated by missing or multiple reasons given for the hospitalization. These were accounted for as follows:

- If multiple reasons were given for an inpatient admission or ED visit, the first reason was used.
- If no reason was given, the per-diem (for inpatient admissions) or per-visit (for ED visits) cost for the hospitalization was assumed to be the mean of the per-diem or per-visit costs for all the inpatient admissions or ED visits for residents in the study for which a reason was given.
- If the reason given in the charts did not correspond to an ICD-10 code in the OCCI data set, or if the relevant cost data for that ICD-10 code could not be provided by the OCCI due to Freedom of Information legislation, then the hospitalization was costed in the same manner as if no reason had been given.

For each inpatient admission, the total cost was assumed to equal the cost per diem multiplied by the LOS recorded in the chart data. Where this was not reported, the mean LOS reported by the OCCI for the respective MRD was used. Where both the LOS and the MRD were not reported in the chart data, the LOS was assumed to be the mean of the LOSs for all the inpatient admissions for residents in the study for which an LOS was given. Where the inpatient admission was due to PrUs, we assumed that the cost per diem was conditional upon the stage of the wound.

Estimation of Willingness to Pay for a Wound-Free Day

Our secondary analysis estimated the *additional* direct care costs of introducing EMDTs, associated with each *additional* wound-free day provided. If EMDTs were found to *reduce* direct care costs and *increase* wound-free days provided to residents, it would follow that EMDTs are cost-effective (EMDTs “dominate” UCTs). Conversely, if EMDTs were found to *increase* direct care costs and provide *fewer* wound-free days than UCTs, then EMDTs would *not* be cost-effective. However, if EMDTs were found to increase (or decrease) *both* the direct care costs and wound-free days, then determining whether EMDTs are cost-effective would require an estimate of the MOHLTC's WTP threshold for an additional wound-free day.

Although such a WTP threshold has not been specified by MOHLTC, we may tentatively infer such a WTP as follows:

- We assume that MOHLTC has a WTP of \$50,000 per additional quality-adjusted life-year (QALY). (55)
- This is equivalent to $\$50,000/365 = \137 per additional quality-adjusted life-day (QALD).
- Previous work by the THETA Collaborative (56) found that the *disutility* associated with a PrU is $0.731 - 0.675 = 0.056$ for residents at high risk of developing PrUs.
- Each additional wound-free day may therefore be assumed to increase a resident's total QALDs by about 0.056.
- This implies that MOHLTC has a WTP threshold of $137 \times 0.056 = \mathbf{\$7.67}$ per additional wound-free day.

Results

Primary Analysis: Comparison of Direct Costs of Care

The results of the primary comparison of direct care costs are given in Table 11. The provision of EMDTs for the treatment of PrUs in LTC homes in Ontario is estimated to reduce the direct care costs incurred until healing by an average of \$649 per resident, compared with the use of UCTs. This decrease in direct care costs is driven by a substantial reduction in NPWT costs (an average of \$3,142 per resident). There is also a reduction in the costs associated with ET visits (\$340 per resident) and a fall in antibiotics costs (\$46 per resident). These costs savings are substantially offset by an increase in hospital costs (\$1,705 per resident). There is also an increase in the costs associated with dressings (\$661 per resident) and home nurses (\$392 per resident). The additional cost of the study nurse and EMDT is estimated to be \$101 and \$20 per resident, respectively.

We have concerns around the 3 largest contributors to the cost difference between the use of EMDTs and UCTs (NPWT, hospitalization, and dressings), which we have tentatively explored through scenario analyses in which each of these costs is removed from the comparison in turn (see Table 11). Our first concern relates to whether the substantial costs savings resulting from eliminating NPWT would occur in practice. In the PUMTT study, the costs associated with NPWT were incurred by just 5 residents, with a single resident incurring observable NPWT costs of \$29,400 (196 days at \$150 per day). This raises 2 issues: first, whether the pattern of NPWT use observed in residents enrolled in the control arm of the study is representative of that in the wider population of residents meeting the criteria for the intervention (and hence whether \$3,142 per resident is a reasonable estimate of NPWT costs incurred by such residents in routine practice); and second, whether the complete elimination of the use of NPWT observed during the intervention phase of the study is representative of the expected reduction in the use of NPWT should EMDTs be adopted in practice in Ontario. This second question is particularly relevant in light of recent evidence that the use of NPWT might be appropriate in some of these residents. (47, 57-68) Excluding all cost savings from NPWT from the analysis resulted in EMDTs appearing to *increase* direct care costs by \$2,493 per resident.

Our second concern relates to the estimated increase in hospital costs. Since relatively few residents in the study experienced a hospitalization, and in many cases these hospitalizations might not have resulted from (or could not be attributed to) PrUs, we were uncertain whether this estimated cost increase would transpire should EMDTs be adopted in practice in Ontario. Excluding hospital costs from the comparison resulted in EMDTs appearing to reduce direct care costs by \$2,354 per resident.

Finally, we are concerned that the estimated costs for dressings and related supplies of \$10.06 per dressing change may overstate the actual costs in practice. Excluding these costs from the

analysis resulted in the adoption of EMDTs appearing to reduce direct care costs by \$1,310 per resident.

Table 11: Cost Comparison of UCTs and EMDTs, per Resident

Cost Category	UCTs (\$CAD)	EMDTs (\$CAD)	Difference
Personnel Costs			
Study nurse	N/A	101	101
EMDT	N/A	20	20
ET	357	18	-340
Home nurse	1,094	1,486	392
Total personnel costs	1,451	1,624	173
Treatments and Supplies Costs			
Antibiotics	84	38	-46
Dressings	1,623	2,284	661
NPWT	3,142	0	-3,142
Total treatments and supplies costs	4,849	2,322	-2,527
Hospital Costs			
Inpatient	4,147	5,792	1,645
Ambulatory (ED)	250	310	60
Total hospital costs	4,397	6,102	1,705
Grand Total	10,697	10,048	-649
Grand total (w/o dressings costs)	9,074	7,764	-1,310
Grand total (w/o NPWT costs)	7,555	10,048	2,493
Grand total (w/o hospital costs)	6,300	3,946	-2,354
Grand total (w/o dressings, NPWT costs)	5,932	7,764	1,832
Grand total (w/o dressings, hospital costs)	4,677	1,662	-3,015
Grand total (w/o NPWT, hospital costs)	3,158	3,946	788
Grand total (w/o dressings, NPWT, hospital costs)	1,535	1,662	127

Abbreviations: ED, emergency department; EMDT, expert multidisciplinary team; ET, enterostomal therapist; NPWT, negative pressure wound therapy; UCT, "usual" care team; w/o, without.

Secondary Analysis: Estimation of Additional Cost per Additional Wound-Free Day

Our statistical model predicted that adopting EMDTs would shorten the mean time to healing, resulting in an average of **45.65 additional wound-free days per resident** compared with the use of UCTs. Our base-case cost comparison estimated that the use of EMDTs would reduce direct care costs until healing by \$649 per resident compared with the use of UCTs. It follows that the EMDT strategy dominates the UCT strategy (i.e., it provides improved health outcomes yet lowers costs, such that the additional cost per additional wound-free day is negative). EMDTs therefore appear to be cost-effective *regardless* of MOHLTC's willingness to pay for an additional wound-free day.

This is also true for those scenario analyses in which only the costs associated with hospitalizations and/or dressings were excluded from the comparison. Since the use of EMDTs resulted in cost savings under these scenarios, EMDTs are cost-effective regardless of MOHLTC's willingness to pay for an additional wound-free day.

Table 12: Additional Cost of EMDTs per Additional Wound-Free Day Provided

Scenario	Cost per Resident (\$CAD)			Cost per Wound-Free Day Provided (\$CAD)
	UCTs	EMDTs	Difference	
Base-case analysis	10,697	10,048	-649	-14.22
Total w/o dressings costs	9,074	7,764	-1,310	-28.70
Total w/o NPWT costs	7,555	10,048	2,493	54.61
Total w/o hospital costs	6,300	3,946	-2,354	-51.57
Total w/o dressings and NPWT costs	5,932	7,764	1,832	40.13
Total w/o dressings and hospital costs	4,677	1,662	-3,015	-66.05
Total w/o NPWT and hospital costs	3,158	3,946	788	17.26
Total w/o dressings, NPWT, and hospital costs	1,535	1,662	127	2.78

Abbreviations: EMDT, expert multidisciplinary team; NPWT, negative wound pressure; UCT, "usual" care team; w/o, without.

The additional cost of the use of EMDTs per additional wound-free day provided under each scenario is shown in Table 12.

If only the cost savings associated with NPWT are excluded from the analysis, EMDTs are estimated to cost \$54.61 per additional wound-free day provided. Since this is greater than the tentative WTP threshold of \$7.67 per additional wound-free day, it follows that EMDTs *do not* appear to be cost-effective compared with UCTs under this scenario. If the cost savings associated with NPWT and the cost increases associated with either dressings or hospitalization are excluded from the analysis, EMDTs are estimated to cost \$40.13 or \$17.26 per additional wound-free day, respectively. Under either scenario EMDTs *do not* appear to be cost-effective compared to UCTs. However, if all the costs associated with NPWT, dressings, and hospitalization are excluded from the analysis, EMDTs *do* appear cost-effective, at an estimated cost of \$2.78 per additional wound-free day provided.

It should be noted that each of these scenarios takes an all-or-nothing approach to each of these cost components. Although we have concerns about our base-case estimates of each of these costs, it may not be appropriate to disregard each cost estimate altogether in any final analysis. Judgment is clearly required in each case, and there are a number of alternative scenarios that may reasonably be considered. In any alternative scenario that may be considered, it follows that **the use of EMDTs appears to be cost-effective if the additional cost compared with the use of UCTs is less than \$350 per resident** (assuming that EMDTs provide 45.65 additional wound-free days per resident, and the WTP for an additional wound-free day is \$7.67).

Results of Bootstrap Analysis

The bootstrap analysis accounts for the uncertainty in our cost and effect estimates. (51) This uncertainty can be attributed in part to the relatively small size of the PUMTT study, which results in large variability in the estimates of cost and effect.

The additional wound-free days provided by EMDTs are estimated to be 44.3 (95% CI, 23.7–107.0).

Revised estimates of the mean additional direct care costs (and 95% CIs) associated with EMDTs for each cost category, and for the total across all categories, are reported in Table 13.

The bootstrap analysis reveals considerable uncertainty in our findings. For both the estimated increase in wound-free days with EMDT use and the estimated reduction in direct care costs, the 95% CI includes 0.

Assuming a WTP for a wound-free day of \$7.67, **the probability that EMDTs are cost-effective is 55.8%.**

Table 13: Additional Cost of EMDTs per Additional Wound-Free Day Provided

Cost Category	Additional Cost of EMDTs per Additional Wound-Free Day Provided (\$CAD)		
	Mean	Lower 95% CL	Upper 95% CL
Personnel costs			
Study nurse	97	64	127
EMDT	20	9	37
ET	-336	-451	-204
Home nurse	348	-302	1,087
Treatments and supplies costs			
Antibiotics	-42	-122	20
Dressings	602	-355	1,705
NPWT	-3,165	-8,446	-160
Hospital costs			
Inpatient	1,689	-3,694	6,563
Ambulatory (ED)	65	-199	331
Grand total	-722	-10,155	6,753

Abbreviations: CL, confidence limit; ED, emergency department; EMDT, expert multidisciplinary team; ET, enterostomal therapist; NPWT, negative pressure wound therapy.

Discussion

We have attempted to estimate the additional direct care costs associated with introducing EMDTs. We estimated that total direct care costs incurred until healing would fall by \$649 per resident. This would be driven by a substantial reduction in costs associated with NPWT, largely offset by an increase in costs associated with hospitalization and dressings. We have concerns about our base-case estimates of each of these cost drivers, which we have explored through scenario analyses. Where the cost savings associated with NPWT are considered, EMDTs always appear to *reduce* total costs; conversely, where the cost savings associated with NPWT are not considered, EMDTs always appear to *increase* total costs. Determining the true extent of savings associated with NPWT in practice is therefore crucial.

It may well be the case that 1 of the primary benefits of the intervention is that it enhances evidence-based wound care, with a key implication for costs being a possible reduction in the use of NPWT. However, recent studies have suggested that the use of NPWT might be appropriate in some residents who meet the criteria for the intervention. (47, 57-68) There may also be other means of achieving the same effect.

It should be noted that there is significant uncertainty in our analyses. Our findings must therefore be interpreted with caution. Some of this uncertainty could potentially be addressed in future work by obtaining more accurate cost estimates from MOHLTC's High Intensity Needs Fund data. Accounting for this uncertainty, the probability that EMDTs are cost-effective is estimated to be 55.8%.

Absence of Cost-Utility Analysis

The design of the PUMTT study raised significant hurdles to carrying out a cost-utility analysis, as is typically performed in economic evaluations. The study adopted a stepped wedge design, with each of 12 LTC homes initially assigned to baseline and then intervention at a different point during the study timeline. Some residents were enrolled part way through the study, and many dropped out or were otherwise censored before the end of the study. As a result, there was considerable variance in the length of time residents spent in the study, with some residents followed up for only a single visit and others followed up for more than a year. This raises issues when choosing an appropriate time horizon for an economic analysis: a time horizon long enough to capture the outcomes of those residents with the longest follow-up would potentially result in substantial censorship bias, whereas a time horizon short enough to avoid this censorship bias would be too short to provide meaningful results. The stepped wedge design of the study also provided no "natural" time horizon to adopt (i.e., the length of each study arm, as might be adopted for a standard RCT). Since the cost-effectiveness analysis we conducted focused on cost per wound-free day, it was judged that the most natural time horizon to adopt was the time until residents were first in a wound-free state (or were censored from the PUMTT study, whichever came first).

This time horizon would clearly not be appropriate to adopt in a cost-utility analysis. In such an analysis, any benefit of the intervention would be realized through the improved health-related quality of life (HRQOL) or "utility" of residents once their wounds healed (assuming the intervention reduced the time to healing). An increase in the number of wound-free days, with higher utility, would in turn lead to an increase in QALYs associated with the intervention. However, if the time horizon of the cost-utility analysis were until residents were first in a wound-free state, then no account would be taken of residents' increased utility following healing. Such an analysis would substantially underestimate the QALYs associated with whichever strategy (intervention or baseline) had the shortest time to healing. (Indeed, it is likely that this strategy would be found to have *fewer* QALYs, even though it was more effective, simply as a result of the time horizon adopted.) The solution to this problem would be to adopt a longer time horizon. However, in the case of the PUMTT study, this would result in 2 problems. First, it would introduce substantial censorship bias (as noted above). Second, in the study no HRQOL data were collected from residents after their wounds healed; as a result, any cost-utility analysis would have to speculate on the HRQOL of residents following healing, which would be complicated by the high morbidity and mortality rates among the residents in the study. It was therefore determined that no cost-utility analysis could be carried out alongside the PUMTT study.

OVERALL DISCUSSION

The primary analysis of the PUMTT study, which focused on the rate at which PrUs healed, did not detect a statistically significant difference in the rate of healing between control and intervention periods. The secondary analyses, which focused on time to healing and the probability of healing, also did not demonstrate statistically significant differences between control and intervention periods. We did not detect a difference between control and intervention periods in self-reported wound-related pain. However, the sample size of the cognitively intact residents who were able to provide a response was relatively small ($n = 24$), necessitating caution in interpreting these results. We did not detect a difference in PrU incidence rates between control and intervention periods. However, we were not able to reliably determine the presence of PrUs during the control period due to these data not being systematically recorded in the charts.

There are several limitations that could potentially explain our inability to detect a statistically significant benefit of our intervention. The study was powered to detect a 40% difference in rate of healing between control and intervention periods, with healing rate calculations used in the model based on average healing rates for stage II PrUs. Healing rates for stage II PrUs are, on average, twice as fast as those for stage IV PrUs. Less than 50% of all PrUs recruited into this study were stage II. Thus, our study may have been underpowered to detect a difference in a mixed population with a prevalence of higher-stage PrUs.

Limiting the study period to 17 months necessitated steps (i.e., time points at which homes were introduced to the intervention) that were 1 month long. The consequence of inadequate step length is a decrease in power, biasing the intervention effect estimate toward the control mean. (69) A larger effect might be detected if a longer period were used.

Another potential limitation of the study design that could contribute to the negative trial results is that the dose of the intervention may have been too low to allow for the detection of an overall effect. In looking at the data displaying between-home differences in time to healing (see Table 8), we see a trend toward a higher probability of healing in homes with longer periods of exposure (homes 1 to 7), suggesting a possible relationship between length of exposure (dose) and time to healing (response). The study period was 17 months, limiting on-site APN time to 3 months at every home, followed by varying lengths of remote support. APNs spent 1 day per week for 3 months at every home during the first phase of the intervention. The intervention was composed of educational and behavioural components that may well have needed 6 months or longer to be adopted, particularly in light of the instability in staffing within homes that necessitated ongoing staff training. In addition, moving to remote support further lowered the dose of the intervention, and was found to be particularly challenging to implement in homes with high rates of staff turnover and poor leadership.

Comparison Between the Intervention Model and the Control Model

The intervention model in this study consisted of an APN who was experienced in wound care, who worked with the EMDT. The APN was new to the homes. She visited each of the 12 homes weekly for 3 months, followed by remote support for variable lengths of time depending on each home's randomization order. In each weekly visit, she gave PrU education to home staff, assessed PrUs, and prescribed treatments and recommendations. She also performed evaluations for referral to the EMDT and referred to the EMDT directly if indicated. The EMDT

was located in an off-site wound care clinic in an acute hospital (St. Michael's Hospital, Toronto).

In comparison, during the control period before the intervention started, wound care in the LTC homes was managed by an internal team led by a designated wound care nurse in 8 of the homes and by the unit RN in 4 of the homes. All of the 12 homes had ongoing enterostomal therapy services for wound care. Six of the homes had contracted enterostomal therapy services that visited the homes biweekly as needed. The other 6 homes used the enterostomal therapy service provided by a CCAC. The ET nurses made a referral if indicated to the EMDT through the residents' attending physicians. The enterostomal therapy service was interrupted for PrU cases only during the intervention period when the study APN took over.

Both the study APNs and the ET nurses were comparable in their education and experience with wound care (personal communication, 2012). Both followed the evidence-based best practice guidelines for the assessment and management of PrUs as recommended by the RNAO best practice guidelines (46) and the international pressure ulcer guidelines issued by the National Pressure Ulcer Advisory Panel. (1) The difference between intervention and control periods was essentially the additional staff education provided by the APNs and the effectiveness of direct systematic referral to the study's EMDT.

Low Frequency of Referral to Expert Multidisciplinary Team

Only 37 of 137 (27%) residents met the referral criteria for assessment by the EMDT, of which 24 (18%) were actually referred. The remainder were managed by the study APNs in collaboration with EMDTs within the homes. It is possible that routine referral for comprehensive multidisciplinary evaluation for all patients might have resulted in better outcomes. The fact that care changed for only 5 of 24 (21%) residents assessed by the EMDT suggests that gains associated with routine full multidisciplinary evaluation in this setting (for PrUs and patients in LTC) may be modest; this is supported by statements from the EMDT members that they felt they played a very minor role.

There are 3 main reasons for this low frequency of referral. First, the sample size was calculated based on CIHI data from the Minimum Data Set for Q4 2009. As seen in Table 4 on PrU prevalence, home PrU prevalence rates obtained from a home-wide bedside audit of every resident by the APN at the start of intervention in 2011 (mean 4.7%, SD = 2.0) were almost half the size of rates obtained from CIHI for Q4 2009 (mean 8.1%, SD = 1.9). Prevalence rates reported at various stages of the study were much lower. In order to ascertain if this drop in prevalence rates was a provincial trend, provincial- and LHIN-level prevalence rates were obtained from CIHI for Q1 2010 to Q1 2012. Provincial, Toronto Central LHIN, and Central LHIN PrU prevalence rates remained steady from Q4 2009 to Q1 2012 and did not reflect the drop in prevalence observed in the homes enrolled in this study. This discrepancy could be explained by a few factors. The first possibility is that the accuracy of classification and documentation of wounds in the Minimum Data Set may be suboptimal, a hypothesis supported by the fact that 12 of 93 wounds (13%) reported to study APNs as PrUs during the intervention period were not actually PrUs. A second possibility is that home staff behaviour may have changed during the control period simply because they knew a study was under way (the Hawthorne effect), thereby lowering PrU rates in the control period. Last, PrUs may have been under-reported to study staff at the study start; however, reported PrU prevalence rates 2 weeks prior to the intervention start were relatively close to those observed at bedside audits in most homes, suggesting under-reporting was not a likely explanation. Prevalence rates appeared to drop further over the 18 months of the study in 11 of 12 homes between the intervention start and study close (4.7% to

3.0%). This further reduction across homes may be another “study effect.” It would be important to see if this reduction in prevalence was sustained in 2012 after the conclusion of the study.

Second, only 37 of 137 (27%) residents met the referral criteria to EMDTs, and for various reasons, 12 of the 37 eligible residents (32%) were not referred to the EMDTs despite meeting referral indications. One of the 25 referred residents died before the consultation appointment, leaving only 24 of the 135 residents (17.8%) actually seen by the EMDTs. This low eligibility for referral is largely due to the high proportion of lower-stage and uncomplicated PrU wounds. As shown in Table 3b, stage II and unstageable wounds made up 52.8% of all the wounds seen in intervention. A higher number of lower-stage ulcers reported in the intervention versus the control period could potentially be explained by increased surveillance. Although not statistically significant, the probability of healing was higher and time to healing was shorter during the intervention period versus the control, likely due to lower-stage PrUs being reported more frequently in the intervention period versus the control period. Consequently, the referral rubric was not likely to be the cause of low referral as the criteria were standard indications for referral to a specialist wound team.

Third, barriers to change in practice in the homes and conflicts between the APN and the home staff also contributed to the low level of referral. For at least 4 potential referrals, the APN did not make the referrals because she felt that the homes had not been adhering to her recommendations and therefore would not comply with the referrals.

In other studies that advocated for an EMDT role in PrU care in the LTC setting, the team was on-site in the home and was composed of the home staff. Fenner (70) described an in-house wound care team led by a wound, ostomy, and continence (WOC) nurse, which is equivalent to the ET nurse in our context. Kennerly et al (71) described a nurse-led interdisciplinary team inside an LTC home for quality improvement in PrU care. A recent study by Temkin-Greener et al (11) demonstrated the effectiveness of self-managed teams in nursing homes on PrU outcomes, showing that self-managed teams had higher penetration (i.e., better staff cohesion, more staff involved in daily care teams, and more staff having consistent assignment) than those teams formally organized by the management.

The PUMTT study attempted to test the effectiveness of an off-site EMDT working through an external APN in LTC homes.

Barriers to Implementation of Recommendations and Education from the APN and EMDT

The effectiveness of the EMDT in this study context was limited not only by the small number of referrals but also by the fact that in 79% of the referrals, the assessment and treatment were unchanged. As described in the qualitative interview, some members of the EMDT felt that they played a superfluous role, stating that the study APN had the expertise to advise on the appropriate course of treatment.

There is a need to further explore the barriers to the implementation of more effective PrU treatment. Some of the barriers were identified in the qualitative interviews. These included unsupportive and weak leadership teams, high leadership turnover, unresponsive organizational culture, a lack of consultative decision-making, low priority assigned to PrU care, a lack of accountability, the heavy workload of front-line staff, and interpersonal conflicts between home staff and study staff.

Our qualitative data revealed great variability in the way in which homes managed PrU treatment and in how staff in these homes experienced the intervention, highlighting the critical role context plays in determining trial outcomes. Most homes (n = 10) struggled with challenges at the leadership level. In 6 of the 12 homes (50%), the leadership team changed during the study period, often simultaneously at multiple levels (administrator, DOC, ADOC, and wound care lead). Even in homes with no turnover at the leadership level, decisions made by leadership teams often negated the efforts of the study APN and EMDT. Homes with strong leadership teams (n = 2) supported the study and followed through on recommendations, helping to explain the between-home variation identified in time to healing and probability of healing (secondary outcomes).

Igarashi et al (72) showed that a low prevalence of PrUs was significantly associated with staff education. In our study, less than half of the homes showed a good staff turnout for the in-service education and bedside teaching sessions. These were also the homes that showed the greatest drop in prevalence at the end of the study, and were the homes where the leadership showed the most active support of the study. The nursing staff in most homes in our study had tight schedules and were overburdened. Unless the home leadership gave them extra time and credit to attend education sessions, there was no incentive to attend. We found that for successful implementation of staff education, the program must not demand extra time and effort on the part of the nursing staff and must not be viewed as imposing on their daily routine chores.

One potential method is to adopt a buddy or apprentice system instead of formal in-service sessions that required most of the staff to interrupt their work. In this scenario, each home appoints a wound care nurse to receive advanced training in wound care; this wound care nurse then trains the other staff in the home. To be successful, the designation of this wound care nurse must be at the RN level. We found that if the designation was RPN, the nurse could not negotiate the hierarchy and effect changes. The home needs to give this RN a leadership role in the EMDT and empower this individual to integrate changes in PrU care into routine care practices.

The APN's interpersonal skills and expertise came under trial when she wanted to make changes to the established culture. In some homes, there was a total lack of co-operation with the APN and a lack of compliance with her recommendations. In such homes, the presence of the APN was counter-productive.

Our qualitative results suggest that a strong, stable, and supportive leadership; an effective, competent wound management team; a high accountability and high responsiveness culture that permits collaborative and consultative decision-making; and proactive front-line staff are crucial factors in the implementation of any quality improvement program. Our observations are consistent with previously reported exemplars of successful implementation of PrU interventions.

Research and Knowledge Transfer in Long-Term Care Setting

Niederhauser et al (73) published a systematic review in 2012 that examined the implementation of programs for preventing PrUs. They identified 24 articles describing comprehensive PrU prevention programs, of which 4 are for the LTC setting. Our study findings are in agreement with their conclusion. A successful outcome is associated with "administrative support with active involvement of clinical staff at the patient care level, bundling of care practices and infusing them into routine care practice, creating system-wide change and

communication that is individualized to the institution's culture, making visible the documentation of PrU prevention practices, and regular education of all levels of staff.”

Clinical research is not common in the LTC setting. Home leadership and staff need to be convinced of the value and educated about the research process. Closer contact and a better understanding by the study APN of each home's unique culture before launching the intervention would have gathered more support from the leadership and potentially increased the effectiveness of intervention. Instead of being viewed as an external agent, the APN could have identified and educated a local champion to lead the home's wound care team. This champion could in turn have educated the rest of the home staff through a buddy system. Instead of implementing our standardized PrU assessment tool as something new that was viewed by the nursing staff as extra forms to fill out, the local champions could have been empowered to integrate the tool into their routine care practice. The more intervention practices are incorporated into routine care, the more likely they are to be implemented regularly and their implementation sustained, even long after the end of the study.

Another strategy to improve compliance with and the sustainability of the PrU prevention program is to avoid making too many changes at one time. Changes should be thoughtfully planned, bundled into existing care practices, and “embedded into the various knowledge reservoirs in the organization.” (74)

Niederhauser et al's (73) systematic review supports an EMDT approach to PrU prevention. However, in-house teams that are empowered within their institutions appear to be more successful. There is no single composition of the EMDT that has been identified as being the best. The team composition should be customized for the needs of the individual institution. (75)

Economic Analysis

The economic evaluation highlighted that a key benefit of adopting EMDTs may be the enhancement of evidence-based wound care. Negative pressure wound therapy was reduced in the intervention period, identifying potential savings as a result of this reduction. Some uncertainty could be addressed in future work by obtaining cost estimates from MOHLTC's High Intensity Needs Fund database to verify if trial results related to the use of NPWT were representative of homes across the province.

This study was limited to 1 EMDT in the Greater Toronto Area and may not be generalizable to other health regions. Although the structure and function of the EMDT in this study reflect those of teams in other acute care centres, alternative team models and locations serving patients in a wider variety of settings (e.g., hospital, home) should be studied in order to evaluate the clinical effectiveness and cost-effectiveness of EMDTs in the treatment of PrUs.

OVERALL CONCLUSIONS

The effectiveness (or lack thereof) of a complex intervention depends on the elements of the intervention, and the interactions between the intervention elements and the context within which the intervention is situated. In this study we did not detect significant differences in healing rates between the control and intervention periods.

This study revealed that wound care within an LTC home is associated with a set of technical, material conditions (staff time, clinical skills, medical supplies) and social processes (decision-making, responsiveness, accountability), all of which are influenced by leadership teams within LTC homes. These factors were evident at a variety of levels (front-line, organizational, and provincial), with interactions between factors across various levels influencing the way in which PrUs were managed.

ACKNOWLEDGEMENTS

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APPENDICES

Appendix 1: Referral Rubric

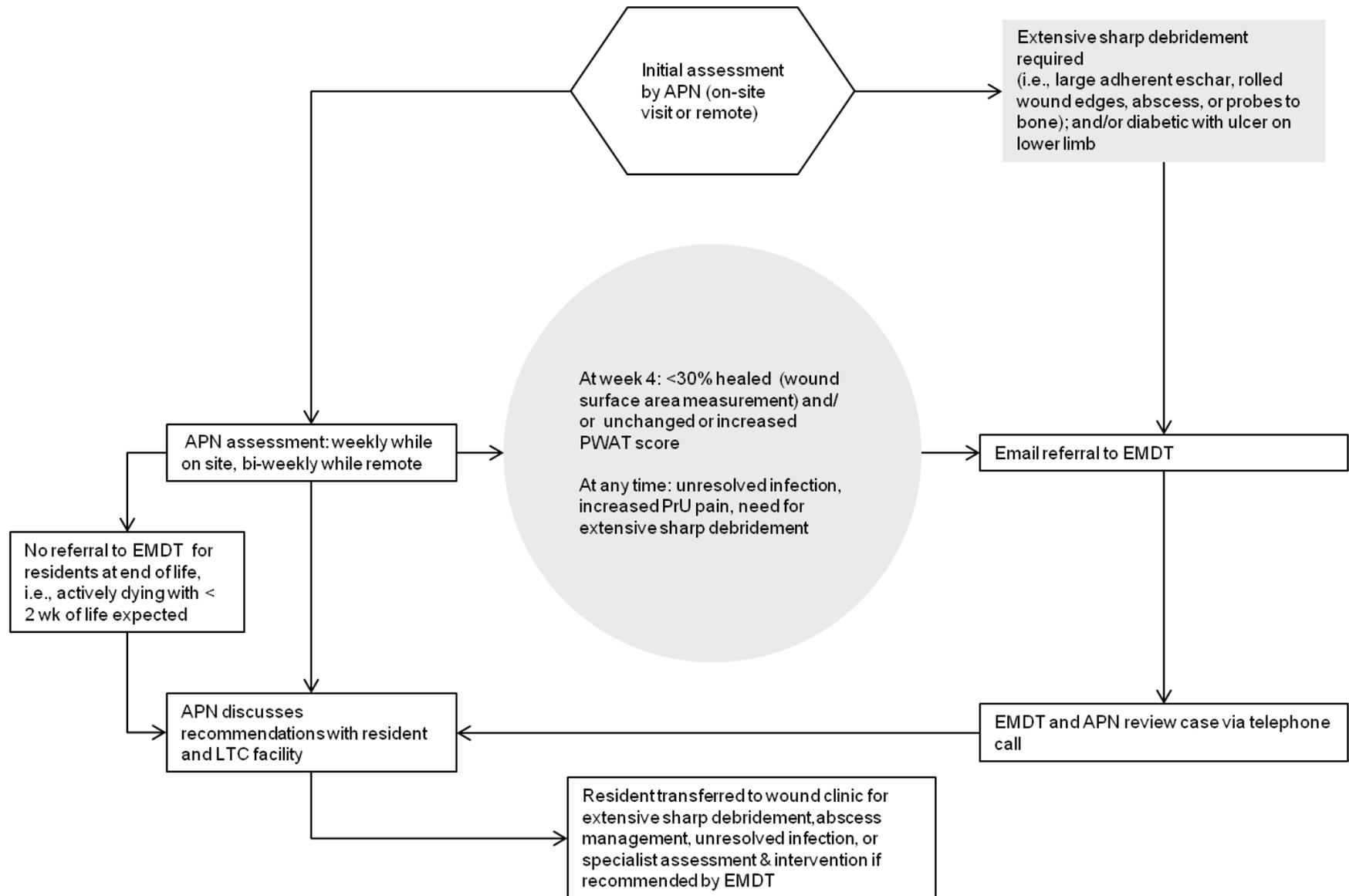


Figure A1: Referral Rubric.

Abbreviations: APN, advanced practice nurse; EMDT, expert multidisciplinary team; LTC, long-term care; PWAT, photographic wound assessment tool.

Appendix 2: Standardized Assessment and Treatment Form

PUMTT TELEMEDICINE PRESSURE ULCER (PrU) ASSESSMENT – Initial Follow-up

Complete pages 1 & 2 ONLY on admission, re-admission, and with a change in condition or a change in information

Study ID. _____ Date ____/____/____ Age: _____ Male Female HIN: yes no

LTC Facility _____ Unit: _____ Phone _____

Contact Nurse: _____

Disease Status: Check all that apply: Spinal cord injury (level) _____, Contractures: Location _____, Spasticity,
 CVA (impact) _____ COPD, ASHD, CHF, Rheumatoid Arthritis, Peripheral Vascular Disease, Diabetes,
 Dialysis, Liver or Renal Disease, Active Cancer, Height _____, Weight _____, Morbid obesity, Emaciated, Recent unintentional
 weight loss, Actively dying, Alzheimer's, Other: _____

Allergies: yes/no. If yes, specify: _____

Past Medical HX (list any not included above)	Current Medical HX: Recent events (list all relevant ie. falls, etc.)	List Current Blood Work (3mons.) & Relevant PrU Investigations (x-ray etc.) <i>(Include copies of reports)</i>	Medications (List or send copy of medication profile)

Recent time out of facility: yes no Date: _____, Length of time out of facility: _____ hrs. Appointment related to PrU? yes no

Recent transfer to emergency, Date: _____ Duration: _____ hrs. Transfer related to PrU? yes, no, Other: _____

Recent hospital admission, Date: _____ Duration: _____ days. Reason for admission related to PrU? yes, no Other: _____

Skin condition on return from hospital: intact, bruised, PrU deterioration, new pressure ulcer: stage: _____, other: _____

Abbreviations: ASHD, arteriosclerotic heart disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; HIN, high-intensity needs; HX, history; ID, identification; PrU, pressure ulcer; PUMTT, pressure ulcer multidisciplinary teams via telemedicine.

PUMTT TELEMEDICINE PRESSURE ULCER (PrU) ASSESSMENT – Initial Follow-up

Study ID _____ Complete: Braden

OR interRAI PURS

Date

____/____/____

Braden Pressure Ulcer Risk Assessment	Score each parameter
Sensory Perception : Ability to respond meaningfully to pressure related discomfort	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/> , 4- <input type="checkbox"/>
Moisture Degree skin is exposed to moisture	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/> , 4- <input type="checkbox"/>
Activity Degree of physical activity	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/> , 4- <input type="checkbox"/>
Mobility Ability to change and control body position	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/> , 4- <input type="checkbox"/>
Nutrition: Usual food intake pattern.	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/> , 4- <input type="checkbox"/>
Friction/Shear	1- <input type="checkbox"/> , 2- <input type="checkbox"/> , 3- <input type="checkbox"/>
Add scores for each parameter to obtain total score (lower score = higher risk)	Total Score :

interRAI PURS Assessment	Score
<input type="checkbox"/> Bed mobility: Ability to move from to and from lying position, turn and position body in bed	0- <input type="checkbox"/> Self performance 1- <input type="checkbox"/> Support required
<input type="checkbox"/> Walk in room: How resident walks between locations in own room	0- <input type="checkbox"/> Self performance 1- <input type="checkbox"/> Support required
<input type="checkbox"/> Bowel Continence: Control of bowel movement, with appliance, or bowel program	0- <input type="checkbox"/> Yes 1- <input type="checkbox"/> No
<input type="checkbox"/> Weight Change : weight loss - 5% or more in last 30 days or 10% or more in last 180 days	0- <input type="checkbox"/> No 1- <input type="checkbox"/> Yes
<input type="checkbox"/> Hx of resolved pressure ulcers: Resident has a PrU that was resolved in last 90 days	0- <input type="checkbox"/> No 2- <input type="checkbox"/> Yes
<input type="checkbox"/> Pain Symptoms: Frequency that resident complains or shows evidence of pain	0- <input type="checkbox"/> No pain 1- <input type="checkbox"/> Pain daily
<input type="checkbox"/> Shortness of Breath	0- <input type="checkbox"/> No 1- <input type="checkbox"/> Yes
Add numbers to obtain Total Score	(higher score = ↑ risk)

Bowel & Bladder	<input type="checkbox"/> Continent	<input type="checkbox"/> Incontinent Urine	<input type="checkbox"/> Indwelling Catheter	<input type="checkbox"/> Incontinent of Feces	<input type="checkbox"/> Fecal containment device		
Mental Status	<input type="checkbox"/> Alert & oriented	<input type="checkbox"/> Confused & easily oriented	<input type="checkbox"/> Disorientated, confused	<input type="checkbox"/> Resistant to care, combative	<input type="checkbox"/> Unresponsive	<input type="checkbox"/> Delirium	<input type="checkbox"/> other

Pressure Management

Bed surface	Chair	Heels	Positioning Routine	Assessment by other Professionals (Indicate Name & phone number)
<input type="checkbox"/> Standard mattress <input type="checkbox"/> High density foam	Cushion: <input type="checkbox"/> yes <input type="checkbox"/> no Type: _____	<input type="checkbox"/> pillows	Bed: Repositioned every _____ hrs Usual position in bed: _____ Total hours in bed: _____ / day	<input type="checkbox"/> OT _____ Date of most recent assessment: _____ Frequency of reassessment: _____
<input type="checkbox"/> Fluid / gel filled mattress (name): <input type="checkbox"/> Static air:(name)	W/C Seating Assess <input type="checkbox"/> yes <input type="checkbox"/> no Date: _____ Completed by: ____	<input type="checkbox"/> Off-loading Boot Type: _____ When worn: _____	Chair: Hours up in chair _____ / day Frequency up in chair: <input type="checkbox"/> OD, <input type="checkbox"/> BID, <input type="checkbox"/> TID, <input type="checkbox"/> QID, <input type="checkbox"/> other: _____ Repositioned in chair every _____ hrs.	<input type="checkbox"/> PT _____ Date of most recent assessment: _____ Frequency of reassessment: _____
<input type="checkbox"/> Low air loss:(name) <input type="checkbox"/> Other: (name)	Tilt Chair <input type="checkbox"/> yes <input type="checkbox"/> no Frequency: _____ <input type="checkbox"/> Geri-chair	<input type="checkbox"/> Padded Heel bootie <input type="checkbox"/> Other:	Positioning devices: <input type="checkbox"/> yes <input type="checkbox"/> no (state device): _____ Transfer devices: Lift <input type="checkbox"/> yes <input type="checkbox"/> no Sliding board <input type="checkbox"/> yes <input type="checkbox"/> no, Other:	<input type="checkbox"/> Dietitian _____ Date of most recent assessment: _____ Frequency of reassessment: _____ <input type="checkbox"/> Other: _____

Nurse's Signature and designation: _____ Date Completed _____

Abbreviations: BID, twice daily; Hx, history; ID, identification; OT, occupational therapist; PrU, pressure ulcer; PT, physiotherapist; PUMTT, pressure ulcer multidisciplinary teams via telemedicine; PURS, Pressure Ulcer Risk Scale; QID, four times a day; TID, three times a day; W/C, wheelchair.

PUMTT TELEMEDICINE PRESSURE ULCER (PrU) ASSESSMENT – Initial Follow-up

Study ID: _____ Date: ____/____/____

Complete Weekly & Use Additional assessment sheets if more than one

PrU

PrU Stage (check one only)	<input type="checkbox"/> DTI	<input type="checkbox"/> I	<input type="checkbox"/> II	<input type="checkbox"/> III	<input type="checkbox"/> IV	<input type="checkbox"/> Unstageable	Total # of PrUs: ____	PrU # if multiple: ____
Wound Location: (Check all that apply)	<input type="checkbox"/> left	<input type="checkbox"/> right	<input type="checkbox"/> front	<input type="checkbox"/> back	<input type="checkbox"/> outside	<input type="checkbox"/> inside	<input type="checkbox"/> bottom of foot	<input type="checkbox"/> top of foot
Wound Location: (Check one location only)	<input type="checkbox"/> coccyx/ sacrum	<input type="checkbox"/> ear <input type="checkbox"/> elbow	<input type="checkbox"/> hip	<input type="checkbox"/> foot <input type="checkbox"/> heel	<input type="checkbox"/> sitting bone (ischium)	<input type="checkbox"/> ankle bone	<input type="checkbox"/> knee	<input type="checkbox"/> Other:
Current PrU Status:	<input type="checkbox"/> Actively healing		<input type="checkbox"/> Delayed healing		<input type="checkbox"/> Deterioration		<input type="checkbox"/> End of life	
Date of PrU onset: _____	Reoccurrence of previous PrU?				<input type="checkbox"/> yes		<input type="checkbox"/> no	
PrU acquired:	<input type="checkbox"/> hospital		<input type="checkbox"/> community		<input type="checkbox"/> Current LTC home		<input type="checkbox"/> Other LTC home	

PWAT (tick 1 per category)	1- Size	2 -Depth	3 -Necrotic Tissue Type	4 -Total Amount Necrotic Tissue	5-Granulation Tissue Type (pick worst)	6- Total Amount Granulation Tissue	7- Edges (directly touching within 0.5cm of edge)	8 -Peri-Skin Viability(10cm from edge)	
	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	<input type="checkbox"/> 0	
	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	
	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Total
	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	<input type="checkbox"/> 3	PWAT
	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Score
Score each									

Peri-Tissue Edema (press skin)	Peri-Tissue Induration (pinch surr. skin)	Peri-wound warmth	Undermining (identify according clock location)	Exudate Type	Exudate Amount	Tissue Type	Odor	Wound Infection Evident	Swab Obtained
<input type="checkbox"/> no	<input type="checkbox"/> no	<input type="checkbox"/> no	<input type="checkbox"/> None: ____	<input type="checkbox"/> None	<input type="checkbox"/> None	<input type="checkbox"/> Closed	<input type="checkbox"/> None	<input type="checkbox"/> no	<input type="checkbox"/> no
<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> yes	<input type="checkbox"/> 12 - 3 ____cm.	<input type="checkbox"/> Serous	<input type="checkbox"/> Light	<input type="checkbox"/> Epithelial Tissue	<input type="checkbox"/> Mild	<input type="checkbox"/> yes	<input type="checkbox"/> yes
<input type="checkbox"/> pitting	<input type="checkbox"/> < 2 cm		<input type="checkbox"/> 3 - 6 ____cm.	<input type="checkbox"/> Bloody	<input type="checkbox"/> Moderate	<input type="checkbox"/> Granulation Tissue	<input type="checkbox"/> Moderate	<input type="checkbox"/> Local	Date:
<input type="checkbox"/> non-pitting	<input type="checkbox"/> 2-4cm		<input type="checkbox"/> 6 - 9 ____cm.	<input type="checkbox"/> S-sang	<input type="checkbox"/> Heavy	<input type="checkbox"/> Slough	<input type="checkbox"/> Pungent	<input type="checkbox"/> Cellulitis	Date:
	<input type="checkbox"/> > 4 cm.		<input type="checkbox"/> 9 - 12 ____cm.	<input type="checkbox"/> Purulent		<input type="checkbox"/> Necrotic Tissue		<input type="checkbox"/> Systemic	Date:
			Total area: <input type="checkbox"/> no <input type="checkbox"/> yes						

<p>Assessment of Constant Pain: Rated by: <input type="checkbox"/> Resident, <input type="checkbox"/> Proxy</p> <p>Indicate level of constant pain: 0 (no pain) → 10 (worst possible pain)</p> <p>Pain Score: _____</p> <p>Location of pain: _____</p> <p>Analgesic order <input type="checkbox"/> no <input type="checkbox"/> yes Effective <input type="checkbox"/> no <input type="checkbox"/> yes</p>	<p>Current Antibiotic Therapy: <input type="checkbox"/> no <input type="checkbox"/> yes</p> <p>Date Started: _____</p> <p>Treatment: _____</p> <p>Duration: _____</p> <p>Response: _____</p>	<p>Past (3 month) Antibiotic Tx: <input type="checkbox"/> no <input type="checkbox"/> yes</p> <p>Date Completed: _____</p> <p>Treatment: _____</p> <p>Duration: _____</p> <p>Response: _____</p>
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Abbreviations: DTI, deep tissue injury; ID, identification; HIN, high-intensity needs; L, length; LTC, long-term care; PrU, pressure ulcer; PUMTT, pressure ulcer multidisciplinary teams via telemedicine; PWAT, photographic wound assessment tool; surr, surrounding; Tx, treatment; W, width.

PUMTT TELEMEDICINE PRESSURE ULCER (PrU) ASSESSMENT – Initial Follow-up

Study ID: _____ Date: ____/____/____ **Complete Weekly & Use Additional assessment sheets if more than one PrU**

Topical Treatments: Tick Current Treatments (CTx), and Past Treatments (PTx).

Primary Dressing	CTx	PTx	Antimicrobial/ Antibacterial	CTx	PTx	Secondary Dressing	CTx	PTx	Cleansing & Debridement	CTx	PTx
None	<input type="checkbox"/>	<input type="checkbox"/>	None	<input type="checkbox"/>	<input type="checkbox"/>	None	<input type="checkbox"/>	<input type="checkbox"/>	None	<input type="checkbox"/>	<input type="checkbox"/>
Dry Gauze	<input type="checkbox"/>	<input type="checkbox"/>	Silver alginate	<input type="checkbox"/>	<input type="checkbox"/>	Gauze	<input type="checkbox"/>	<input type="checkbox"/>	Cleansing 30 cc syringe & 20 g needle	<input type="checkbox"/>	<input type="checkbox"/>
Wet-to-dry	<input type="checkbox"/>	<input type="checkbox"/>	Silver fabric	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal pad	<input type="checkbox"/>	<input type="checkbox"/>	Compress x _____ minutes	<input type="checkbox"/>	<input type="checkbox"/>
Alginate / Hydrofibre	<input type="checkbox"/>	<input type="checkbox"/>	Silver hydrogel	<input type="checkbox"/>	<input type="checkbox"/>	Composite	<input type="checkbox"/>	<input type="checkbox"/>	Cleanse periwound skin	<input type="checkbox"/>	<input type="checkbox"/>
Hydrocolloid	<input type="checkbox"/>	<input type="checkbox"/>	Silver foam	<input type="checkbox"/>	<input type="checkbox"/>	Foam: adhesive	<input type="checkbox"/>	<input type="checkbox"/>	Commercial cleanser	<input type="checkbox"/>	<input type="checkbox"/>
Non-adherent	<input type="checkbox"/>	<input type="checkbox"/>	Cadexomer Iodine / Iodosorb	<input type="checkbox"/>	<input type="checkbox"/>	Foam: Non-adhesive	<input type="checkbox"/>	<input type="checkbox"/>	Normal saline	<input type="checkbox"/>	<input type="checkbox"/>
Honey	<input type="checkbox"/>	<input type="checkbox"/>	Inadine	<input type="checkbox"/>	<input type="checkbox"/>	Hydrocolloid	<input type="checkbox"/>	<input type="checkbox"/>	Sterile H2O	<input type="checkbox"/>	<input type="checkbox"/>
Hydrogel	<input type="checkbox"/>	<input type="checkbox"/>	Hygeol	<input type="checkbox"/>	<input type="checkbox"/>	Transparent Film	<input type="checkbox"/>	<input type="checkbox"/>	Mechanical Debridement	<input type="checkbox"/>	<input type="checkbox"/>
Foam	<input type="checkbox"/>	<input type="checkbox"/>	Buro-Sol	<input type="checkbox"/>	<input type="checkbox"/>	Clear Acrylic Absorbent	<input type="checkbox"/>	<input type="checkbox"/>	Sharp / Surgical Debridement	<input type="checkbox"/>	<input type="checkbox"/>
Composite	<input type="checkbox"/>	<input type="checkbox"/>	Chlorhexidine	<input type="checkbox"/>	<input type="checkbox"/>	Highly absorbent fiber pads	<input type="checkbox"/>	<input type="checkbox"/>	Enzymatic Debridement	<input type="checkbox"/>	<input type="checkbox"/>
Transparent Film	<input type="checkbox"/>	<input type="checkbox"/>	Betadine	<input type="checkbox"/>	<input type="checkbox"/>	Other: (name)	<input type="checkbox"/>	<input type="checkbox"/>	Autolytic Debridement	<input type="checkbox"/>	<input type="checkbox"/>
Other:(name)	<input type="checkbox"/>	<input type="checkbox"/>	Other:(name)	<input type="checkbox"/>	<input type="checkbox"/>				Other: (name)	<input type="checkbox"/>	<input type="checkbox"/>

Adjunctive Tx	CTx	PTx	PrU Skin Protection	CTx	PTx	Other Treatments: CTx	PTx	Total Time for Treatment
None	<input type="checkbox"/>	<input type="checkbox"/>	none	<input type="checkbox"/> < 30 minutes				
NPWT	<input type="checkbox"/>	<input type="checkbox"/>	Liquid Skin sealant	<input type="checkbox"/> 30 - 45 minutes				
E-Stimulation	<input type="checkbox"/>	<input type="checkbox"/>	Barrier cream	<input type="checkbox"/> 45 – 60 minutes				
Laser	<input type="checkbox"/>	<input type="checkbox"/>	Zinc Oxide	<input type="checkbox"/> 60 – 75 minutes				
Other	<input type="checkbox"/>	<input type="checkbox"/>	Moisturizer	<input type="checkbox"/> 75 – 90 minutes				
			Other:	<input type="checkbox"/> > than 90 minutes				

Indicate Current dressing change frequency: Bid, OD, Q2days, Q3 days, Q4 days, once per week, other: _____
Nurse's Signature and designation: _____ Date: _____

Abbreviations: Bid, twice daily; ID, identification; NPWT, negative pressure wound therapy; OD, once daily; PrU, pressure ulcer; PUMTT, pressure ulcer multidisciplinary teams via telemedicine; Q, every.

Recommendations: APN on site APN Telemedicine MDT Telemedicine MDT Clinic visit Date: _____
 Client Study ID: _____ Facility: _____ Total number of PrUs: _____ Pg: ___ of ___

PrU	Pressure Ulcer	Local Wound Care:	Pressure Management†	Additional Comments
# 1	Location: _____ Impression:	<input type="checkbox"/> Recommendations same for all PrU <input type="checkbox"/> Continue current treatment <input type="checkbox"/> Change dressing regimen to: Peri-skin care: _____ Apply : _____ Cover with: _____ Secure with : _____ Debridement method: _____ Adjunctive therapy: <input type="checkbox"/> Negative pressure wound therapy <input type="checkbox"/> Biological wound healing agent <input type="checkbox"/> Other: _____ Dressing frequency: _____	<input type="checkbox"/> Recommendations same for all PrUs <input type="checkbox"/> Continue current pressure management strategies Implement: <input type="checkbox"/> Support surface: _____ <input type="checkbox"/> Heel device: _____ <input type="checkbox"/> Turning and repositioning: _____ <input type="checkbox"/> Wheelchair & Seating: _____ <input type="checkbox"/> Sitting protocol: _____ <input type="checkbox"/> Seating assessment: _____ <input type="checkbox"/> Other equipment (e.g., Commode): _____ <input type="checkbox"/> Mobility aids: _____ <input type="checkbox"/> Other: _____	
# 2	Location: _____ Impression	<input type="checkbox"/> Continue current treatment <input type="checkbox"/> Change dressing regimen to: Peri-skin care: _____ Apply : _____ Cover with: _____ Secure with : _____ Debridement method: _____ Adjunctive therapy: <input type="checkbox"/> Negative pressure wound therapy <input type="checkbox"/> Biological wound healing agent <input type="checkbox"/> Other: _____ Dressing frequency: _____	<input type="checkbox"/> Continue current pressure management strategies Implement: <input type="checkbox"/> Support surface: _____ <input type="checkbox"/> Heel device: _____ <input type="checkbox"/> Turning and repositioning: _____ <input type="checkbox"/> Wheelchair & Seating: _____ <input type="checkbox"/> Sitting protocol: _____ <input type="checkbox"/> Seating assessment: _____ <input type="checkbox"/> Other equipment (e.g., Commode): _____ <input type="checkbox"/> Mobility aids: _____ <input type="checkbox"/> Other: _____	
# 3	Location: _____ Impression	<input type="checkbox"/> Continue current treatment <input type="checkbox"/> Change dressing regimen to: Peri-skin care: _____ Apply : _____ Cover with: _____ Secure with : _____ Debridement method: _____ Adjunctive therapy: <input type="checkbox"/> Negative pressure wound therapy <input type="checkbox"/> Biological wound healing agent <input type="checkbox"/> Other: _____ Dressing frequency: _____	<input type="checkbox"/> Continue current pressure management strategies Implement: <input type="checkbox"/> Support surface: _____ <input type="checkbox"/> Heel device: _____ <input type="checkbox"/> Turning and repositioning: _____ <input type="checkbox"/> Wheelchair & Seating: _____ <input type="checkbox"/> Sitting protocol: _____ <input type="checkbox"/> Seating assessment: _____ <input type="checkbox"/> Other equipment (e.g., Commode): _____ <input type="checkbox"/> Mobility aids: _____ <input type="checkbox"/> Other: _____	

Recommendations: APN on site APN Telemedicine MDT Telemedicine MDT Clinic visit Date: _____
 Client Study ID: _____ Facility: _____ Pg: ___ of ___

Pain Management	Nutrition/ Fluid intake	Activity / Mobility	Moisture Management																														
	<input type="checkbox"/> Dietitian Referral <input type="checkbox"/> Monitor Intake <input type="checkbox"/> Monitor weight	<input type="checkbox"/> PT referral <input type="checkbox"/> OT referral †																															
Specialty Consults	Follow up	Additional Recommendations	Indicate total amount of time for each discipline involved in assessment & care of resident:																														
<p>Consults completed</p> <input type="checkbox"/> Infectious disease <input type="checkbox"/> Plastic surgeon <input type="checkbox"/> Orthopedic surgeon <input type="checkbox"/> Dermatology <input type="checkbox"/> Vascular Surgery <input type="checkbox"/> Hematology <input type="checkbox"/> General Surgeon <input type="checkbox"/> Other: _____ <p>Future Consults Suggested</p> <input type="checkbox"/> Infectious Disease <input type="checkbox"/> Plastic Surgeon <input type="checkbox"/> Orthopedic Surgeon <input type="checkbox"/> Dermatologist <input type="checkbox"/> Vascular Surgeon <input type="checkbox"/> Hematologist <input type="checkbox"/> General Surgeon <input type="checkbox"/> Other: _____ <p>Referral date: _____</p> <input type="checkbox"/> Consult to be arranged by LTC Home	<input type="checkbox"/> Specialty MD consult note forwarded to physician Name of specialist _____ <input type="checkbox"/> APN follow-up <input type="checkbox"/> Multidisciplinary Team: <input type="checkbox"/> Remote <input type="checkbox"/> Clinic visit Date: _____ <input type="checkbox"/> No MDT follow up required		<table border="1"> <thead> <tr> <th data-bbox="1499 581 1562 609"></th> <th data-bbox="1570 581 1829 641">Discipline / Designation</th> <th data-bbox="1837 581 1976 641">Total Time in Minutes</th> </tr> </thead> <tbody> <tr> <td data-bbox="1499 651 1562 683"><input type="checkbox"/></td> <td data-bbox="1570 651 1829 683">Nurse Practitioner</td> <td data-bbox="1837 651 1976 683"></td> </tr> <tr> <td data-bbox="1499 690 1562 722"><input type="checkbox"/></td> <td data-bbox="1570 690 1829 722">Occupational Therapist</td> <td data-bbox="1837 690 1976 722"></td> </tr> <tr> <td data-bbox="1499 729 1562 761"><input type="checkbox"/></td> <td data-bbox="1570 729 1829 761">Chiroprapist</td> <td data-bbox="1837 729 1976 761"></td> </tr> <tr> <td data-bbox="1499 768 1562 800"><input type="checkbox"/></td> <td data-bbox="1570 768 1829 800">APN</td> <td data-bbox="1837 768 1976 800"></td> </tr> <tr> <td data-bbox="1499 807 1562 839"><input type="checkbox"/></td> <td data-bbox="1570 807 1829 839">RN</td> <td data-bbox="1837 807 1976 839"></td> </tr> <tr> <td data-bbox="1499 846 1562 878"><input type="checkbox"/></td> <td data-bbox="1570 846 1829 878">RPN</td> <td data-bbox="1837 846 1976 878"></td> </tr> <tr> <td data-bbox="1499 885 1562 917"><input type="checkbox"/></td> <td data-bbox="1570 885 1829 917">Social Worker</td> <td data-bbox="1837 885 1976 917"></td> </tr> <tr> <td data-bbox="1499 924 1562 1008"><input type="checkbox"/></td> <td data-bbox="1570 924 1829 1008">Physician: (specify are of specialty) _____</td> <td data-bbox="1837 924 1976 1008"></td> </tr> <tr> <td data-bbox="1499 1015 1562 1118"><input type="checkbox"/></td> <td data-bbox="1570 1015 1829 1118">Others: specify _____ _____</td> <td data-bbox="1837 1015 1976 1118"></td> </tr> </tbody> </table>		Discipline / Designation	Total Time in Minutes	<input type="checkbox"/>	Nurse Practitioner		<input type="checkbox"/>	Occupational Therapist		<input type="checkbox"/>	Chiroprapist		<input type="checkbox"/>	APN		<input type="checkbox"/>	RN		<input type="checkbox"/>	RPN		<input type="checkbox"/>	Social Worker		<input type="checkbox"/>	Physician: (specify are of specialty) _____		<input type="checkbox"/>	Others: specify _____ _____	
	Discipline / Designation	Total Time in Minutes																															
<input type="checkbox"/>	Nurse Practitioner																																
<input type="checkbox"/>	Occupational Therapist																																
<input type="checkbox"/>	Chiroprapist																																
<input type="checkbox"/>	APN																																
<input type="checkbox"/>	RN																																
<input type="checkbox"/>	RPN																																
<input type="checkbox"/>	Social Worker																																
<input type="checkbox"/>	Physician: (specify are of specialty) _____																																
<input type="checkbox"/>	Others: specify _____ _____																																

Date: _____ Name & discipline completing recommendations: _____

Abbreviations: APN, advanced practice nurse; ID, identification; MD, physician; MDT, multidisciplinary team; OT, occupational therapist; PrU, pressure ulcer; PT, physiotherapist; RN, registered nurse; RPN, registered practical nurse.

Figure A2: Standardized Assessment and Treatment Form

Appendix 3: Hospitalization, Use of Emergency Departments, and Utility

Table A1: Emergency Department Visits and Hospitalization per Home for Control and Intervention Periods

Home	Control				Intervention			
	No. of ED Visits	No. of Hospitalizations	Hospitalization Days	Patient Days	No. of ED Visits	No. of Hospitalizations	Hospitalization Days	Patient Days
1	4	5	22	387	9	5	53	2,657
2	0	0	0	976	12	11	75	2,705
3	1	1	3	714	4	3	32	2,274
4	0	1	6	674	1	2	10	731
5	4	5	27	1,247	5	7	94	903
6	18	9	29	1,160	4	4	32	884
7	0	0	0	486	6	5	59	662
8	4	5	42	667	14	9	83	1,010
9	1	2	12	994	4	3	31	830
10	5	5	50	1,033	1	2	34	364
11	1	1	21	1,128	2	1	8	588
12	0	0	0	707	0	0	0	399

Abbreviation: ED, emergency department.

Utility

For the analysis of the intervention effect on the utility (proxy-administered EQ-5D utility scores), we employed a 2-level linear mixed model, accounting for the clustering effect of the repeated measures per resident and for the clustering effect of residents belonging to different homes. The model was adjusted for the time since the first visit for each patient (using an incrementing visit number), as well as other possible confounders (age, sex, diabetes, and BMI). The employed mixed-effects model did not identify a statistically significant change in the mean utility between the 2 study phases, as shown in Table A2.

Table A2: Intervention Effect on Utility

	Effect Estimate (95%CI)	P Value
Intervention	-0.030 (-0.088 to 0.029)	0.32
Visit no.	-0.001 (-0.003 to 0.002)	0.7
Age	-0.003 (-0.005 to -0.0002)	0.0303
Sex (male)	-0.000 (-0.055 to 0.054)	0.99
Diabetes	0.009 (-0.047 to 0.066)	0.74
Body mass index	0.004 (0.001 to 0.007)	0.0036

We also found large heterogeneity in the random effects among the homes, regarding the intercept (i.e., baseline utilities) and the intervention effects. We observed the phenomenon that homes with lower baseline utilities benefited more from the intervention, whereas homes with relatively higher baseline utilities seemed to have a larger drop in the utilities when we moved to the intervention phase.

Despite the very small sample size (only 24 residents were cognitively competent and able to complete the questionnaire during some of the visits), we performed similar analyses using EQ-5D scores based on questionnaires completed by the residents whenever those were available and feasible. The results did not show any significant difference between the baseline and intervention ($P = 0.81$).

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