Original Investigation

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Effect of Varying Repositioning Frequency on Pressure Injury Prevention in Nursing Home Residents: TEAM-UP Trial Results

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ABSTRACT

OBJECTIVE: To investigate the clinical effectiveness of three nursing-home-wide repositioning intervals (2-, 3-, or 4-hour) without compromising pressure injury (PrI) incidence in 4 weeks.

METHODS: An embedded pragmatic cluster randomized controlled trial was conducted in nine nursing homes (NHs) that were randomly assigned to one of three repositioning intervals. Baseline (12 months) and 4-week intervention data were provided during the TEAM-UP (Turn Everyone And Move for Ulcer Prevention) study. Intervention residents were without current PrIs, had PrI risk (Braden Scale score) ≥10 (not severe risk), and used viable 7-inch high-density foam mattresses. Each arm includes three NHs with an assigned single repositioning interval (2-, 3-, or 4-hour) as standard care during the intervention. A wireless patient monitoring system, using wearable single-use patient sensors, cued nursing staff by displaying resident repositioning needs on conveniently placed monitors. The primary outcome was PrI incidence; the secondary outcome was staff repositioning compliance fidelity.

RESULTS: From May 2017 to October 2019, 1,100 residents from nine NHs were fitted with sensors; 108 of these were ineligible for some analyses because of missing baseline data. The effective sample size included 992 residents (mean age, 78 ± 13 years; 63% women). The PrI incidence during the intervention was 0.0% compared with 5.24% at baseline, even though intervention resident clinical risk scores were significantly higher ($P < .001$). Repositioning compliance for the 4-hour repositioning interval (95%) was significantly better than for the 2-hour (80%) or 3-hour (90%) intervals ($P < .001$).

CONCLUSIONS: Findings suggest that current 2-hour protocols can be relaxed for many NH residents without compromising PrI prevention. A causal link was not established between repositioning interval treatments and PrI outcome; however, no new PrIs developed. Compliance improved as repositioning interval lengthened.

KEYWORDS: compliance, cueing, geriatrics, nursing home, pressure injury, pressure ulcer, prevention, repositioning

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INTRODUCTION

Pressure injuries (PrIs; localized damage to skin and/or underlying tissues over bony prominences from pressure or shear forces) are common, yet seemingly intractable geriatric conditions that are mostly preventable complications in nursing home (NH) residents,[1] who are typically older, with multiple comorbidities, mobility challenges, and severely compromised health.[2–4] Annual PrI prevalence of 7.3% in long-stay and 2.3% in short-stay residents[5] and incidence up to 59% have been reported,[1] hence the emphasis on PrI prevention. Pressure injuries have severe negative impacts on patients (eg, pain, infection, death), healthcare settings, and insurers,[1,6] potentially exceeding $26 billion in costs annually.[7]

Assessment of PrI risk is standard practice in NHs,[8–10] but prevention has proved elusive.[11] There is limited evidence for PrI prevention,[12] with support surfaces and manual repositioning having been the focus. High-specification foam alternatives to standard hospital foam mattresses significantly reduce PrI incidence.[2,13,14] Repositioning ("turning people to change body position"[11]) reduces pressure duration and tissue hypoxia and has theoretical appeal as a preventive approach; however, it also increases nursing workload and disrupts sleep.[1,11] No conclusive evidence for either an optimal repositioning frequency[13,14] or angle/position has emerged,[11] relegating practice settings to use status quo 2-hour intervals based on 60-year-old findings.[15] Staff compliance with 2-hour repositioning is challenging to achieve; the impact of cueing staff to reposition on time is not established.

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The repositioning intervention of the clinical trial protocol for the Turn Everyone And Move for Ulcer Prevention (TEAM-UP) trial[16] was derived from the International Pressure Injury Prevention Guidelines[1] every 2-hour standard for repositioning residents that allows individualization of repositioning intervals of up to 4 hours; the protocol was used by all participating NHs. The TEAM-UP trial examines 2-, 3-, and 4-hour repositioning intervals (prompted by wearable patient position sensors) and the 28-day PrI incidence among NH residents using viable 7-inch high-density foam mattresses and having PrI risk scores of low, mild, moderate, or high (not severe) as measured by the Braden Scale (≥10). The final study results were intended to provide evidence of overall repositioning effectiveness among the three repositioning intervals.

METHODS

This study aimed to determine whether the repositioning interval can be extended from 2 to 3 or 4 hours for NH residents without compromising PrI incidence. An embedded pragmatic cluster randomized controlled trial design was selected because these studies are designed to inform decision-makers regarding the comparative balance of benefits, burdens, and risks of using biomedical or behavioral health interventions.[17] The study was designed with input from healthcare stakeholders[18] and was intended to represent the real-world NH environment that included (1) a diverse representative study population, (2) an intervention that could be incorporated easily into routine clinical workflow as standard of care, (3) outcomes important to decision-makers (in this case, PrI and compliance), and (4) comprehensive data collected through standard documentation in an electronic health record (EHR) within the healthcare setting.

Prior to NH selection, three arms (arm 1 = 2-hour, arm 2 = 3-hour, arm 3 = 4-hour) were determined, with planned assignment of three NHs to each arm by applying a randomized sequencing of the arm assignments according to the chronologic order identified for NHs. The repositioning intervals were implemented in chronologic sequence after completing one round of arm 1, arm 2, and arm 3 to ensure all three intervals could be safely implemented; then, a predetermined sequence was followed, resulting in NHs 1, 6, and 8 in arm 1; NHs 2, 4, and 9 in arm 2; and NHs 3, 5, and 7 in arm 3.

Nine NHs from a large proprietary system in 34 states met the eligibility requirements, accepted the invitation to participate, and were assigned to one of the three NH-wide repositioning interval arms as described previously. The magnitude of within-cluster (arm) dependence was quantified by the intraclass correlation coefficient (ICC), and the precision of this measure was quantified by its confidence interval (CI).

During the intervention, a patient monitoring system cued staff to reposition residents and tracked events. Four-week incidence of new PrI was compared among the three arms, controlling for resident characteristics and staffing levels. Details of the trial design were published previously.[16]

Study Setting, Residents, and Procedures

All Medicare-certified NHs providing intermediate and skilled nursing care within the proprietary company (n = 473) were eligible for randomization. Inclusion criteria for NHs were: over 100 beds; standard use of high-density foam mattresses determined to be viable or replaced within 2 months of study implementation; adequate internet bandwidth capacity to support real-time data collection and storage; and full EHR capability including activities of daily living, laboratory, and radiology results (Table 1). The requirement for NHs to have full electronic record capabilities was essential to facilitate data collection and ensured that the study would have robust data sets.

Investigators invited 83 eligible NHs meeting eligibility to participate in the trial, which required mandatory staff in-service training to explain the study and patient monitoring system implementation. The sample size power requirement (95%) was satisfied by the first nine NHs that agreed to participate based on total residents to be recruited. The nine study NHs (1) had the same standard care delivery policies, (2) were of typical size and characteristics of the other eligible sites, (3) signed implementation agreements, (4) received a nominal stipend to support project implementation, and (5) were randomized via a predetermined random sequencing procedure[16] to one of three repositioning intervals (arms).

Eligible study participants met the following criteria: 18 years or older, without PrIs (on admission or within 72 hours), Braden Scale score ≥ 10 (assessed weekly), and without adhesive allergy or other clinical contraindications (paranoia, dermatitis, personal defibrillator garment and monitor, or "do-not-turn" order). Residents

Table 1. INCLUSION CRITERIA FOR NURSING HOMES AND RESIDENTS

Nursing Home Inclusion Criteria	Resident Inclusion Criteria
>100 beds	Aged ≥18 y
Standard use of high-density foam mattresses	No pressure injury on admission or within 72 h
Adequate internet bandwidth capacity to support real-time data collection and storage	Braden Scale score ≥ 10
Full electronic health record capability	No adhesive allergy or other clinical contraindications

at severe PrI risk (Braden Scale score < 10) were excluded because of unique repositioning and surface needs.

Available electronic historic data for study residents were retrieved for the 12-month baseline period prior to the intervention start at each NH. Residents with both intervention and baseline EHR, Minimum Data Set, and NH Risk Management System data formed the effective sample for pre-post analyses.

Intervention

Each arm included three NHs assigned a NH-wide repositioning interval (2, 3, or 4 hours) during the 4-week intervention. A wireless patient monitoring system using a wearable, resident-specific sensor worn on the upper chest tracked position/movement and cued staff compliance with the prescribed NH-wide repositioning interval.[19] Health Insurance Portability and Accountability Act-compliant visual cues displayed each resident's time-stamped repositioning history and status on unit desk and hallway monitors. Patient monitoring system fidelity checks (6 per week) ensured accuracy.

Standard PrI prevention care other than repositioning intervals was provided in all three arms in accordance with International Pressure Injury Prevention Guidelines[1] (head-of-bed elevation, position angle, and duration and use of pillows/wedges to maintain position, turning sheets, and lift devices as appropriate).[1] Staff assisted non-bedfast residents to stand/move/reposition and used preventive seating cushions as needed. All residents/families received information about the study, repositioning protocol, and their right to refuse care and/or receive a more frequent repositioning interval.

Outcomes

The primary outcome was PrI incidence during the intervention. Daily and weekly NH staff skin assessments were recorded using NH system policies.[1] Certified nursing assistants observed skin daily over bony prominences, between skin folds, in genitalia/buttocks areas, and at sensor sites. Change in skin appearance was reported to licensed staff with oversight for repositioning, safety, weekly skin care checks, and EHR documentation related to PrI status (stage and manifestations). Safety algorithms were published previously.[16]

The secondary outcome was fidelity of staff repositioning compliance tracked by wearable patient sensors, enhanced by NH-mandated in-service training for full- and part-time RNs, LPNs, and Certified Nursing Assistants (79% participation). The required education focused on PrI etiology, Braden Scale risk assessment, evidence-based prevention practices, repositioning benefits, roles and responsibilities, staff workflow, trial protocol, and patient monitoring system information. A researcher visited the NH each shift during week 1 and at least daily during the second through fourth weeks to ensure the patient monitoring system was functioning, answer staff questions, and stock supplies.

Assessments

All NHs and eligible residents were assessed retrospectively for the baseline period (maximum 365 days) before the intervention start date and prospectively for the 4-week intervention period. The NH parent company provided all EHR, Minimum Data Set, and Risk Management System data for the full 28-day intervention period regardless of the number of days repositioning was monitored. Assessments of all eligible residents were extracted from the EHR, Minimum Data Set, or NH Risk Management System. The EHR provided demographic characteristics, medical diagnoses as *International Classification of Diseases* version 9 (baseline period data) and/or *International Classification of Diseases* version 10 codes (most frequently occurring codes were grouped into the most common diagnosis categories), height/weight, vital signs, and laboratory data.

The EHR data were supplemented by the Minimum Data Set, a federally mandated, comprehensive, standardized assessment of NH residents' functional and health needs conducted quarterly and/or at condition change. The NH assessments (location, specialty units, Medicare-certified beds, census, occupancy, staff hours, and payor type) for intervention and baseline were extracted as reported to the CMS. Braden Scale assessments produced the only data for which the data extraction/collection schedule varied between baseline and intervention periods. During baseline, Braden Scale risk scores (10–12, high; 13–14, moderate; 15–18, mild; 19–23, low) were assessed on admission, four times weekly, quarterly, and upon condition change. During the intervention, Braden Scale scores were assessed weekly; no residents were withdrawn because of a Braden Scale score of 9 or less.

The PrI incidence for eligible residents during the 12-month baseline period was extracted retrospectively from the NH Risk Management System and supplemented by the Minimum Data Set and EHR, as previously described.[16] The PrI incidence was determined through standard weekly licensed nursing staff skin assessments for the 4-week intervention, directly reported to researchers, and documented as an adverse event through the NH company's Risk Management System. Researchers ensured study fidelity by randomly verifying assessments and receipt in real time of secure email notification triggered by the reported event.

The patient monitoring system served as a repositioning fidelity measure and assessed several factors for each resident: days with active sensors worn, number of Turn Alert cues, Turn Alert overdue hours, and degree angle of repositioning with ±2.5% accuracy. Turn Alert cues

appeared on screens to notify staff that a resident had not had a position change and was due for repositioning within the allocated interval. Turn Alert overdue hours counted time beyond prescribed repositioning interval that a resident remained in the same position. The 24-hour on-time repositioning compliance was calculated as (1 – [# Turn Alert overdue hours for period of interest]/[total hours monitored for period of interest]) and indicated the degree to which the expected repositioning interval was being achieved.

Statistical Analysis

Primary analyses of PrI outcomes were performed according to the intention-to-treat principle. Analyses were conducted using Statistical Analysis Software (SAS version 9.4, Cary, North Carolina).

Analysis of Intervention Outcomes. The initial analysis plan to test whether the PrI rate during intervention was higher for 3- or 4-hour repositioning compared with 2-hour is reported elsewhere.[16] Overlap between the 95% CIs of rates of PrI and the 2-hour repositioning would confirm the hypothesis for no group difference. However, given that no PrIs developed during the intervention, the trial's original analysis plan was modified to report the trial's characteristics and pre-post comparative analyses by testing baseline (pretest, 2-hour repositioning) versus intervention (posttest, 3-hour, and 4-hour protocols) PrI rates.

Analysis of Differences in Baseline and Intervention Risk. Propensity score logistic regression analysis based on baseline data was used to account for an imbalance in PrI risk associated with significant differences in NH and resident characteristics across arms. The adequacy of the final model fit was ensured by generating a 70% random sample to train/build the model and a 30% random sample to validate the model. Regression coefficients from the fitted training data set model provided unbiased risk predictions of developing a PrI during the intervention. Contribution of each variable to likelihood of developing a PrI was determined by odds ratios (ORs) generated from the model. C statistics were used to assess goodness of fit.

Differences in first Braden Scale scores and mean total Braden Scale scores across arms within the intervention period were compared separately using either analysis of variance or χ^2 analyses. Paired t tests evaluated differences in mean total Braden Scale scores between baseline and intervention cohorts by arm. Two-sided tests ($P < .05$) were used for all analyses.

Power Analyses. Statistical power and sample size analyses are published elsewhere.[16] The expected PrI incidence for this study's 4-week intervention was 3.5% based on the TURN study's[13] highest rate (for moderate-risk patients) during that 3-week intervention. Target sample size was 951 residents (≥317 per arm) to detect minimum detectable effect size of 0.38 difference between study arms with a power of 0.95 based on a one-sided rather than a two-sided test to determine if PrI incidence with 3- or 4-hour repositioning frequency was greater than with 2-hour repositioning; detection of a decrease in PrI was not of concern. Stopping boundaries were maintained during the trial as described in the Data Safety Monitoring Plan; no safety concerns were identified, and the trial was completed. Power was adjusted postintervention after taking into consideration the ICC of the NHs in the three treatment arms. Intraclass correlation coefficient and its CI were calculated.

Ethics

The trial was approved by Duke University Institutional Review Board (#Pro00069413). The Board approved a waiver of informed consent per the US Department of Health and Human Services guidelines 21 CFR 46 because (1) an NH-wide repositioning schedule was provided to the entire cluster of low-, mild-, moderate-, and high-risk residents; (2) the intervention-assigned repositioning interval was adopted as part of NH-wide practice that standardized the repositioning workflow; (3) minimal risk was involved in the arm-level intervention, and (4) a coded data set was created with assigned study identification (ID) number for resident data extracted from the patient monitoring system database, Minimum Data Set, and EHR, and the coded data set was placed directly into a secured network folder. Also, fliers summarizing the project noting NH Medical Director approval were mailed to residents and their family member/responsible party informing them of the option to choose not to participate; the principal investigator's mobile phone number was included for concerns and questions. The principal investigator guided onsite data collection with the project director, who was responsible for implementation fidelity. The research team was responsible for data quality control/analyses. A business associates' agreement was signed between the NH corporation and patient monitoring system company. All methods were performed in accordance with the relevant guidelines and regulations (Declaration of Helsinki).

Data Sharing Statement. The data used in this publication include protected health information and therefore cannot be freely shared. Data sharing will be possible with case-by-case approval from the authors' institutional review board; requests may be directed to the principal investigator.

RESULTS

Repositioning intervals were implemented in the randomly ordered sequence as planned to ascertain whether repositioning interval could be extended from 2 to 3 or 4 hours for NH residents. No PrIs developed among participating residents, even though the preintervention PrI

incidence at the nine NHs ranged from 2.3% to 18.3%. Intervention results are described related to NH and resident characteristics and primary and secondary outcomes. Additional analyses were performed to examine PrI risk and repositioning compliance.

Nursing Homes

Characteristics of the three NHs in each arm during baseline are presented in Table 2; the ICC and its CI are 0.056 (CI, −0.78 to 0.89). The NHs were primarily suburban, with 126 to 238 Medicare-certified beds; some NHs had dementia and/or transitional resident specialty units. The average census ranged from approximately 143 to 162 residents, with Medicare-certified bed occupancy between 79% and 90%. Certified Nursing Assistants provided most care hours to residents, who were primarily Medicaid supported.

Residents

From May 2017 to October 2019, 1,100 residents were fitted with sensors; 108 of these were ineligible for some analyses because of missing baseline data or other disqualifying conditions. The effective sample size included 992 residents. The NH enrollment and randomization, resident assessment and allocation, follow-up, and analysis are shown in the Figure and were developed according to the cluster trial's extension of the CONSORT (Consolidated Standards of Reporting Trials) Statement.

Table 3 presents characteristics of the 1,100 residents allocated to the three intervention arms; 108 residents were excluded from the pre-post analyses, and the remaining 992 residents were analyzed by arms. The 108 excluded residents did not form a PrI; they were significantly younger ($P < .001$), were primarily men ($P = .002$) and had less cerebrovascular disease ($P = .004$), gastroesophageal reflux disease ($P = .026$), Alzheimer disease and related dementias ($P < .001$), and difficulty swallowing ($P < .001$), but had more hypertension ($P < .001$) and diabetes ($P = .003$) than the 992 residents analyzed in the intervention population.

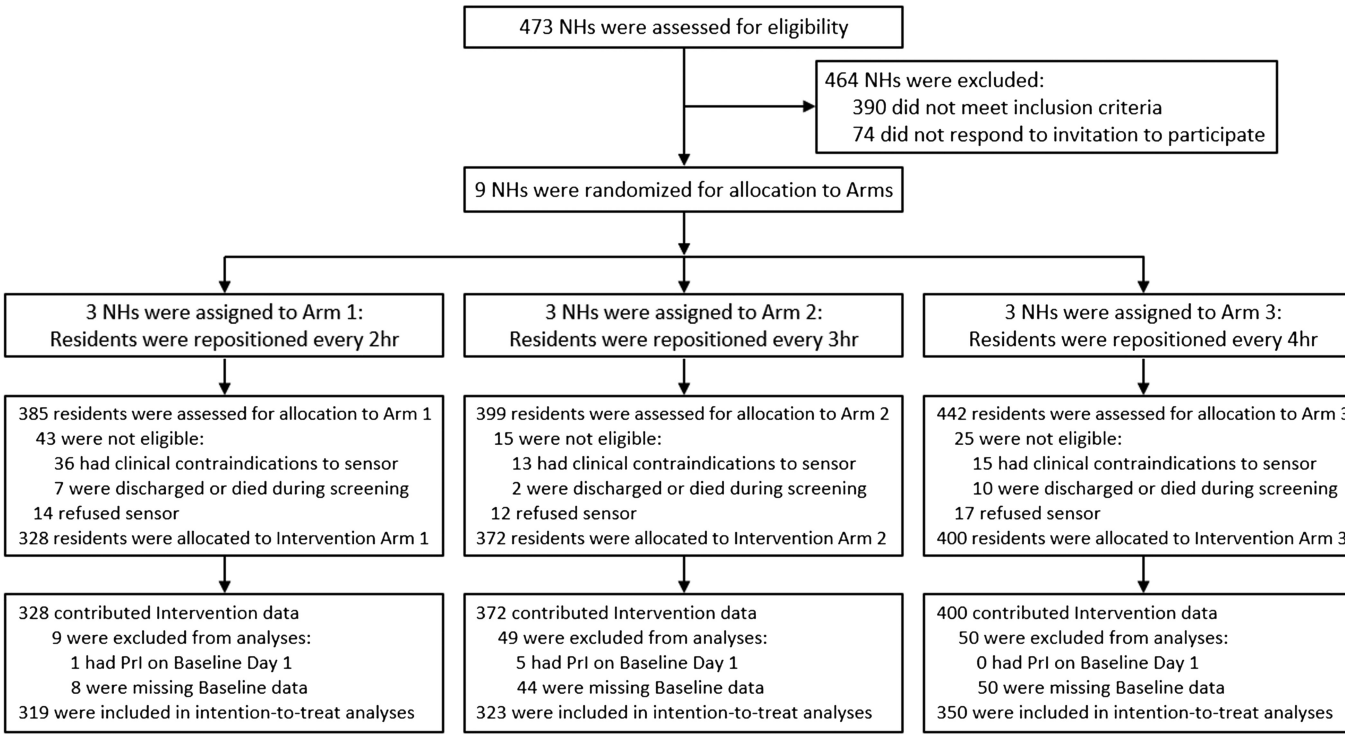
Differences in age, race, ethnicity, diagnosis categories, and intervention length of stay (LOS) were statistically significant across arms (Table 3); this imbalance was addressed using propensity analyses (Table 4). Black residents comprised 53% of arm 2 compared with less than 18% in arms 1 and 3. Fifty-two residents (27% of whom were Black) had one or more incident baseline PrIs that healed prior to intervention start (untabled). Total LOS reflects the time from admission that could have occurred during or before baseline period until the intervention end date or resident discharge from NH. The LOS for only the intervention period (intervention-only LOS) was 1 day shorter in arm 3, which was statistically

Table 2. NURSING HOME (N = 9) CHARACTERISTICS AT BASELINE BY ARM

Characteristics	Arm 1 2 h[a] (n = 319)	Arm 2 3 h[a] (n = 323)	Arm 3 4 h[a] (n = 350)
Location	S, S, S	S, U, S	S, U, S
Specialty units	None, D/T, D	T, D, T	D/T, T, T
No. of Medicare-certified beds per facility, mean (range)	181.0 (180–183)	178.7 (176–180)	180.3 (126–238)
Patient census,[b] mean (SD)	143.2 (37.9)	161.5 (4.3)	159.1 (47.7)
% Occupancy[b] (census-certified beds), mean (SD)	79.2 (17.6)	90.3 (2.3)	88.5 (3.0)
No. of staff hours per resident, d[b] mean[c] (SD)			
RN	1.6 (0.20)	2.1 (0.53)	2.4 (0.53)
LPN	2.9 (0.70)	2.6 (0.49)	2.7 (0.93)
Certified nursing assistant	6.5 (1.40)	7.5 (0.36)	7.6 (0.57)
Resident payor type, mean (% coverage by payor type)			
Managed care	3.8 (2.6)	7.9 (4.9)	11.2 (7.0)
Medicaid	112.7 (78.7)	131.9 (81.7)	115.4 (72.5)
Medicare A	17.9 (12.5)	10.1 (6.2)	18.4 (11.6)
Private pay	4.5 (3.2)	5.4 (3.4)	3.3 (2.1)
Other payor	4.3 (3.0)	6.2 (3.8)	10.8 (6.8)

Abbreviations: D, dementia unit; NH, nursing home; S, suburban; T, transitional care unit; U, urban.
Note: Percentages may not sum to 100 because of rounding.
[a]Repositioning interval for each intervention arm.
[b]Baseline values are for the 6-month period prior to the intervention.
[c]No. of monthly hours/NH monthly census, by staff category.

Figure. NURSING HOME ENROLLMENT AND RANDOMIZATION, RESIDENT ASSESSMENT AND ALLOCATION, FOLLOW-UP, AND ANALYSIS



Abbreviation: NH, nursing home.

significant, but a single-day difference is not considered clinically relevant to the outcome.

PrI Risk Across and Within Arms

Baseline. Table 4 presents clinical risk (Braden Scale) comparisons, predicted propensity, and observed PrI incidence among residents at baseline and during the intervention. At baseline, neither first nor mean total Braden Scale scores differed significantly by arm, although risk differed slightly across mean Braden categories ($P = .03$). Propensity for a resident to develop a PrI at baseline (Table 4) was significantly higher in arm 2 ($P < .001$) than either arm 1 or 3 (Tukey honestly significant difference, $P \leq .05$); arms 1 and 3 did not differ significantly. The ORs for PrI development during baseline (propensity model C statistic, 0.76) included: Black race (OR, 2.24; CI, 1.04–4.80); mild Braden risk category (OR, 3.96; CI, 1.57–9.94); and moderate Braden risk category (OR, 4.69; CI, 1.48–14.91). No other resident characteristics (age, sex, diagnoses) or NH or staffing characteristics were significant predictors for developing a PrI. Observed annual PrI incidence across all NHs during baseline was 5.24% (52/992; range, 2.3%–18.3% across NHs); the overall monthly expected number of PrIs was 4.33.

Intervention. No new PrIs developed during the intervention regardless of NH allocation to 2-, 3-, or 4-hour repositioning interval. Despite significant differences in propensity to develop PrIs, the incidence was 0.0% across all arms, which included 52 residents with a prior baseline PrI that had healed before the start of the intervention. Propensity to develop a PrI during the intervention was significantly greater (50%) at 3 hours (Tukey honestly significant difference, $P \leq .05$) than at 2 or 4 hours, which were not different.

During the intervention, neither first nor mean Braden total risk scores differed by arm. However, both first ($P = .003$) and mean ($P = .001$) Braden Scale score categories (low, mild, moderate, high) differed significantly by arm. Arm 2 included fewer residents at high risk than arms 1 and 3.

Baseline Versus Intervention Across and Within Arms. Pairwise comparisons of baseline and intervention mean total Braden Scale scores were calculated for each arm (Table 4). Mean Braden Scale score was significantly worse (PrI risk was higher) during the intervention: arm 1 ($t = -0.544$, $P < .001$); arm 2 ($t = -0.224$, $P = .015$); and arm 3 ($t = -0.643$, $P < .001$). Residents were more likely to score as high-risk during the intervention overall (n = 66 [6.7%]) than in baseline overall (n = 14 [1.4%]).

The baseline PrIs showed that the majority of PrIs were among residents with mild and moderate Braden risk. Mean Braden risk score categories of baseline

Table 3. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF RESIDENTS ALLOCATED TO INTERVENTION (N = 1,100) AND INCLUDED IN PRE-POST ANALYSES

Resident Characteristics[a]	Allocated to Intervention Arms (N = 1,100)	Excluded from Pre-Post Analyses[b] (n = 108)	Residents Eligible for Pre-Post Analysis[b] (N = 992)				
			Arm 1 2 h[c] (n = 319)	Arm 2 3 h[c] (n = 323)	Arm 3 4 h[c] (n = 350)	*P*[d]	*F* Statistic or χ^2
Resident age, mean (SD), y	77.39 (13.23)	73.17 (14.06)	76.23 (13.32)	79.42 (12.84)	77.87 (12.86)	.008	4.84[e]
Mean differences by arm (CI)[f]			1–2; –3.20 (–5.61, –0.78)	2–3; 1.56 (–0.80, 3.91)	1–3; –1.64 (–4.00, 0.73)		
Resident age distribution, n (%)							
≤64 y	201 (18.27)	34 (31.48)	57 (17.87)	46 (14.24)	64 (18.29)		
65–70 y	130 (11.82)	12 (11.11)	41 (12.85)	38 (11.76)	39 (11.14)		
71–80 y	257 (23.36)	21 (19.44)	92 (22.29)	66 (20.43)	78 (28.84)	.046	18.61[g]
81–85 y	147 (13.36)	16 (14.81)	41 (12.85)	43 (13.31)	47 (13.43)		
86–89 y	134 (12.18)	10 (9.26)	34 (10.66)	40 (12.38)	50 (14.29)		
≥90 y	231 (21.00)	15 (13.89)	54 (16.93)	90 (27.86)	72 (20.57)		
Sex, n (%)							
Female	681 (61.91)	52 (48.15)	207 (64.89)	201 (62.23)	221 (63.14)	.51	0.78[g]
Male	419 (38.09)	56 (51.85)	112 (35.11)	122 (37.77)	129 (36.86)		
Race,[h] n (%)							
Asian	3 (0.27)	2 (1.85)	0 (0.00)	1 (0.31)	0 (0.00)		
Black	293 (26.64)	26 (24.07)	55 (17.24)	170 (52.63)	42 (12.00)	<.001	168.94[g]
White	738 (67.09)	61 (56.48)	248 (77.74)	146 (45.20)	283 (80.86)		
Other, unknown	66 (6.00)	19 (17.59)	16 (5.03)	6 (1.86)	25 (7.14)		
Ethnicity, n (%)							
Hispanic or Latino	24 (2.18)	0 (0.00)	7 (2.19)	3 (0.93)	14 (4.00)	.033	6.18[g]
Not Hispanic or Latino	1076 (97.82)	108 (100.00)	312 (97.81)	320 (99.07)	336 (96.00)		
Top diagnoses for intervention sample, n (%)							
Difficulty walking	939 (85.36)	96 (88.89)	249 (78.06)	278 (86.07)	316 (90.29)	<.001	20.00[g]
Muscle weakness/wasting	903 (82.09)	87 (80.56)	264 (82.76)	239 (73.99)	313 (89.43)	<.001	27.50[g]
Difficulty with swallowing or speech	594 (54.00)	26 (24.07)	213 (66.77)	143 (44.27)	212 (60.57)	<.001	35.62[g]
Hypertension	516 (46.91)	72 (66.67)	149 (46.71)	183 (56.66)	112 (32.00)	<.001	42.03[g]
Atherosclerotic heart disease	483 (43.91)	52 (48.15)	149 (46.71)	150 (46.44)	132 (37.71)	.027	7.24[g]
Alzheimer disease or related dementias	320 (29.09)	12 (11.11)	110 (34.48)	136 (42.11)	62 (17.71)	<.001	49.27[g]
Gastroesophageal reflux disease	315 (28.64)	21 (19.44)	124 (38.87)	105 (32.51)	65 (18.57)	<.001	34.87[g]
Depression	257 (23.36)	25 (23.15)	80 (25.08)	94 (29.10)	58 (16.57)	<.001	15.91[g]
Type 2 diabetes	236 (21.45)	35 (32.41)	73 (22.88)	77 (23.84)	51 (14.57)	.004	10.93[g]
Cerebrovascular disease	228 (20.73)	11 (10.19)	54 (16.93)	74 (22.91)	89 (25.43)	.025	7.36[g]
Intervention-only length of stay, mean (SD), d	25.79 (5.85)	17.80 (7.89)	26.99 (4.09)	27.07 (4.18)	25.98 (5.89)	.0047	5.39[e]
Mean differences by arms (CI)[f]			1–2; –0.081 (–0.975, 0.814)	2–3; 1.091 (0.217, 1.966)	1–3; 1.011 (0.133, 1.888)		
Total length of stay, mean (SD), d	1,122.11 (1,299.14)	18.25 (7.95)	1,288.60 (1,435.59)	1,214.55 (1,262.10)	1,225.69 (1,243.45)	.7424	0.30[e]
Mean differences by arms (CI)[f]			1–2; 74.04 (–169, 318)	2–3; –11.13 (–249, 227)	1–3; 62.91 (–176, 302)		

Abbreviation: CI, confidence interval.
[a]Percentages may not sum to 100 because of rounding.
[b]Eligibility for pre-post analyses required data from both baseline and intervention time periods. The 108 residents not included in pre-post analyses did not have baseline data.
[c]Indicates repositioning interval for each Intervention arm. Each arm included 3 nursing homes.
[d]Denotes arm differences.
[e]Analysis of variance used to test for differences among arms.
[f]Mean difference displayed pairwise: arm "x" – arm "y"; value of actual pairwise mean difference; confidence interval (a, b).
[g]χ^2 Used to test for differences among arms.
[h]American Indian/Alaska Native, 0%; more than one race, 0%; Native Hawaiian or Other Pacific Islander, 0%.

Table 4. PRE-POST COMPARISON OF PREDICTED AND OBSERVED RISK OF PRESSURE INJURY FOR RESIDENTS AT BASELINE AND INTERVENTION BY ARM (N = 992)

	Baseline[b]				Intervention[c]			
Resident Characteristics[a]	**Arm 1 2 h[d] (n = 319)**	**Arm 2 3 h[d] (n = 323)**	**Arm 3 4 h[d] (n = 350)**	***P|F* Statistic or χ^2**	**Arm 1 2 h[d] (n = 319)**	**Arm 2 3 h[d] (n = 323)**	**Arm 3 4hr[d] (n = 350)**	***P|F* Statistic or χ^2**
First total Braden Scale score, mean (SD)	18.40 (3.04)	18.10 (2.62)	18.21 (2.57)	.38/0.97[e]	17.48 (3.39)	17.34 (2.94)	17.37 (3.02)	.84/0.18[e]
Mean difference in first total Braden Scale score by arms (CI)[f]	1–2; 0.299 (–0.210, 0.808)	2–3; –0.115 (–0.612, 0.382)	1–3; 0.184 (–0.315, 0.683)		1–2; 0.139 (–0.439, 0.717)	2–3; –0.028 (–0.593, 0.537)	1–3; 0.111 (–0.456, 0.678)	
19–23 (Low risk), n (%)	167 (52.4)	145 (44.9)	176 (50.3)	.09/11.07[g]	138 (43.3)	109 (33.8)	134 (38.3)	.003/20.01[g]
15–18 (Mild risk), n (%)	119 (37.3)	149 (46.1)	153 (43.7)		110 (34.5)	158 (48.9)	150 (42.9)	
13–14 (Moderate risk), n (%)	23 (7.2)	23 (7.1)	18 (5.1)		44 (13.8)	43 (13.3)	36 (10.3)	
10–12 (High risk), n (%)	10 (3.1)	6 (1.9)	3 (0.9)		27 (8.5)	13 (4.0)	30 (8.6)	
Mean total Braden Scale score, mean (SD)	18.07 (2.77)	17.73 (2.25)	17.89 (2.51)	.23/1.45[e]	17.53 (3.32)	17.51 (2.79)	17.25 (2.94)	.40/0.92[e]
Mean difference in mean total Braden Scale score by arms (CI)[f]	1–2; 0.338 (–0.128, 0.804)	2–3; –0.157 (–0.613, 0.298)	1–3; 0.181 (–0.276, 0.638)		1–2; 0.014 (–0.545, 0.574)	2–3; 0.265 (–0.282, 0.812)	1–3; 0.280 (–0.269, 0.828)	
19–23 (Low risk), n (%)	135 (42.3)	104 (32.2)	132 (37.7)	.03/14.01[g]	126 (39.5)	111(34.4)	113 (32.3)	.001/24.08 [g]
15–18 (Mild risk), n (%)	139 (43.6)	181 (56.0)	167 (47.7)		118 (37.0)	160 (49.5)	163 (46.6)	
13–14 (Moderate risk), n (%)	39 (12.2)	37 (11.5)	44 (12.6)		52 (16.3)	43 (13.3)	40 (11.4)	
10–12 (High risk), n (%)	6 (1.9)	1 (0.3)	7 (2.0)		23 (7.2)	9 (2.8)	34 (9.7)	
Pressure injury propensity score for sample during time period[h]	0.044	0.066	0.048	<.001/17.81[e]	0.044	0.063	0.045	<.001/13.94[e]
Mean difference in pressure injury propensity score by arms (CI)[f]	1–2; –0.023 (–0.032, –0.013)	2–3; 0.019 (0.009, 0.028)	1–3; –0.004 (–0.013, 0.005)		1–2; –0.018 (–0.028, –0.009)	2–3; 0.017 (0.008, 0.026)	1–3; –0.001 (–0.010, 0.008)	
Overall pressure injury incidence for 9 sites, n (%)	52 (5.24)				0 (0)			
Pressure injury incidence by arm, n (%)	13 (4.08)	23 (7.12)	16 (4.57)	.18/1.74[g]	0 (0)	0 (0)	0 (0)	Not applicable[i]
Mean difference in pressure injury incidence by arms (CI)[f]	1–2; –3.046 (–7.174, 1.083)	2–3; 2.549 (–1.486, 6.585)	1–3; –0.496 (–4.545, 3.552)					
Pressure injury incidence by mean total Braden Scale score category by arm								
19–23 (Low risk), n (%)	3 (2.2)	3 (2.9)	1 (0.8)	.47/5.62[g]	0 (0)	0 (0)	0 (0)	Not applicable[i]
15–18 (Mild risk), n (%)	6 (4.3)	16 (8.8)	11 (6.6)		0 (0)	0 (0)	0 (0)	
13–14 (Moderate risk), n (%)	3 (7.7)	4 (10.8)	4 (9.1)		0 (0)	0 (0)	0 (0)	
10–12 (High risk), n (%)	1 (16.7)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)	

Abbreviation: CI, confidence interval.
[a]Percentages may not sum to 100 because of rounding.
[b]Baseline values are for the 12-month period prior to the start of the intervention.
[c]Intervention values are for the 4-week intervention period.
[d]Repositioning interval for each intervention arm. Each arm included three nursing homes.
[e]Analysis of variance used to test for differences among arms.
[f]Mean difference displayed pairwise: arm "x" – arm "y"; value of actual pairwise mean difference; CI (a, b).
[g]χ^2 Used to test for differences among arms.
[h]Propensity score derived from logistic regression with C-statistic = 0.762.
[i]Testing is not applicable to pressure injury incidence during the intervention because testing incidence of zero events is not possible.

residents with PrIs that healed prior to continuing into the intervention (n = 52) were low (n = 7), mild (n = 33), moderate (n = 11), or high (n = 1) risk.

Compliance with Repositioning Schedule

Fidelity to the assigned repositioning interval is presented in Table 5. Of the 992 included residents, 369 wore sensors without interruption for 28 days and 623 wore sensors intermittently because of skin irritation, short-term discharge, refusal, permanent discharge, or death. Intervention residents wore patient monitoring system sensors for an average of 16.06 to 17.44 days. However, all intervention residents were observed for PrI development as part of standard care throughout the 28-day intervention period (Table 3).

Overall, 24-hour average repositioning cues and average overdue hours were significantly higher for the 2-hour arm compared with less frequent repositioning intervals ($P < .001$). Overdue hours were twice as high, and Turn Alert cues were more than twice as high for 2-hour compared with 4-hour repositioning.

Daily on-time repositioning compliance was significantly better as the assigned hourly repositioning interval lengthened. That is, NHs allocated to the 4-hour interval had significantly greater compliance (95%) compared with 3-hour (90%) or 2-hour (80%) intervals ($P < .001$). Daily average on-time repositioning compliance was lower across all Braden Scale risk categories for the 2-hour arm compared with 3- or 4-hour repositioning schedules ($P < .001$).

Table 5. REPOSITIONING CHARACTERISTICS OF RESIDENTS (N = 992) DURING THE 4-WEEK INTERVENTION PERIOD

Repositioning Characteristics	Arm 1 2 h[a] (n = 319)	Arm 2 3 h[a] (n = 323)	Arm 3 4 h[a] (n = 350)	*P*	*F* Statistic
No. of days sensor worn,[b] mean (SD)	16.35 (10.86)	17.44 (10.52)	16.06 (10.95)	.224	1.50[c]
Mean difference by arm (CI)[d]	1–2; –1.096 (–3.098, 0.906)	2–3; 1.381 (–0.578, 3.339)	1–3; 0.285 (–1.675, 2.245)		
Overall resident daily (24 h) average no. of repositioning Turn Alert cues, mean (SD)	4.98 (3.41), n = 297[e]	3.08 (1.72), n = 292[e]	1.98 (1.12), n = 281[e]	<.001	124.07[c]
Mean difference by arm (CI)[d]	1–2; 1.899 (1.450, 2.347)	2–3; 1.096 (0.641, 1.551)	1–3; 2.995 (2.542, 3.448)		
Overall resident daily average repositioning Turn Alert overdue hours per 24 h, mean (SD)	5.14 (3.59), n = 297[e]	3.43 (2.48), n = 292[e]	2.54 (1.79), n = 281[e]	<.001	67.66[c]
Mean difference by arm (CI)[d]	1–2; 1.711 (1.181, 2.240)	2–3; 0.889 (0.351, 1.426)	1–3; 2.599 (2.064, 3.134)		
Overall resident daily (24 h) on–time repositioning compliance,[b,f] mean (SD)	0.80 (0.15)	0.90 (0.11)	0.95 (0.07)	<.001	134.50[c]
Mean difference by arm (CI)[d]	1–2; –0.095 (–0.116, –0.074)	2–3; –0.047 (–0.067, –0.026)	1–3; –0.141 (–0.162, –0.121)		
Overall resident daily (24 h) on–time repositioning compliance[b,f] (by Braden risk category[g]), mean (SD)					
Braden Scale score 19–23 (low risk)	0.86 (0.10)	0.93 (0.10)	0.97 (0.05)	<.001	54.03[c]
Mean difference by arm (CI)[d]	1–2; –0.068 (–0.094, –0.043)	2–3; –0.038 (–0.064, –0.012)	1–3; –0.106 (–0.131, –0.082)		
Braden Scale score 15–18 (mild risk)	0.79 (0.16)	0.89 (0.11)	0.95 (0.06)	<.001	59.86[c]
Mean difference by arm (CI)[d]	1–2; –0.099 (–0.133, –0.065)	2–3; –0.059 (–0.090, –0.028)	1–3; –0.158 (–0.192, –0.124)		
Braden Scale score 13–14 (moderate risk)	0.73 (0.16)	0.88 (0.13)	0.89 (0.10)	<.001	18.32[c]
Mean difference by arm (CI)[d]	1–2; –0.149 (–0.218, –0.080)	2–3; –0.009 (–0.082, 0.063)	1–3; –0.159 (–0.230, –0.087)		
Braden Scale score 10–12 (high risk)	0.72 (0.16)	0.89 (0.09)	0.93 (0.06)	<.001	24.86[c]
Mean difference by arm (CI)[d]	1–2; –0.169 (–0.261, –0.076)	2–3; –0.040 (–0.131, 0.051)	1–3; –0.209 (–0.282, –0.136)		

Abbreviation: CI, confidence interval.
[a]Repositioning interval for each intervention arm. Each arm included 3 nursing homes.
[b]Total N = 988 because of missing movement data for four residents: arm 2 missing three residents (n = 320); arm 3 missing one resident (n = 349).
[c]Analysis of variance used to test for differences among arms.
[d]Mean difference displayed pairwise: arm "x" – arm "y"; value of actual pairwise mean difference; CI (a, b).
[e]No. of residents with one or more overdue repositioning Turn Alert cues.
[f]Mean compliance values imputed for four missing residents after determining there is no difference in statistical significance between the analysis of variance results with and without imputation.
[g]Braden Scale risk category determined from baseline Braden Scale risk scores for the week prior to the Intervention.

DISCUSSION

No PrIs developed during the intervention in this embedded pragmatic cluster randomized trial involving staff cued to reposition NH residents at 2-, 3-, or 4-hour interval. This represents a decrease from baseline 4.33 PrI monthly incidence to zero in the intervention despite significantly greater risk (ie, lower mean total Braden Scale scores), a greater number of Braden Scale high-risk residents than in baseline, and 52 residents (27% Black) who had previously healed PrIs. The null hypothesis of no increase in PrI rates when extending the repositioning interval to 3 or 4 hours cannot be rejected.

Despite this, propensities for PrI development across arms coupled with absence of PrIs during the intervention suggest the potential to safely extend repositioning requirements from every 2 hours to every 3 or even 4 hours for most residents, thus facilitating uninterrupted sleep, which is critical to overall health.[20] Two-hour repositioning is the standard of care implemented during the baseline. Thus, the 2-hour intervention arm could not be directly compared with 3- or 4-hour protocol because no change occurred in its repositioning interval between baseline and intervention. However, study results support relaxation of this 2-hour arm protocol based on its similar propensity for PrI development compared with the 4-hour arm.

The TEAM-UP study suggests that resident repositioning intervals can be safely extended up to every 4 hours without increasing PrI incidence among residents at a wide range of clinical risk, if residents are supported by viable high-density foam mattresses and staff are compliant with repositioning. Defloor and colleagues[14] found that those turned every 4 hours on high-density foam mattresses experienced significantly fewer PrIs than those turned every 2 or 3 hours on standard hospital mattresses. Prior research studying only moderate- and high-risk residents using high-density foam mattresses found no significant difference in PrI incidence with repositioning at 2, 3, or 4 hours.[13] Residents deemed to be low risk are not commonly studied; yet, these residents develop PrIs;[13–15] thus, low/mild-risk residents were included in TEAM-UP. Fifty-two residents with healed baseline PrIs who participated in the intervention included 77% who were of low or mild risk.

The TEAM-UP study supports evidence for the efficacy of high-density foam mattresses in preventing PrIs for 28 days, even with extended repositioning intervals that were associated with significantly better staff compliance. Also, on-time repositioning was supported by staff education and cueing. Education sessions refreshed staff on the etiology of PrIs, the importance of tissue offloading, and proper repositioning techniques, leading to a heightened awareness of prevention standard protocols already in place. This increased awareness was present across all study arms; yet, compliance was lower in the 2-hour interval because nursing staff had difficulty achieving that frequency.

A variety of cueing reminders have been used to improve staff repositioning compliance, for example, bedside logs,[14] musical cues,[21] and paper clocks.[13] Cueing used in TEAM-UP is thought to be a factor that helped facilitate nursing staff in repositioning on time. A comparison of repositioning compliance between the monitored every-2-hour intervention interval and the nonmonitored baseline repositioning was not possible. However, a prior pilot study by Yap and colleagues[19] that used the same patient monitoring system reported a mean of 61.4% repositioning compliance during a 3-day blinded every 2-hour repositioning baseline without cueing. Repositioning compliance improved to 81.5% during 18 days of monitoring with cueing, which is similar to TEAM-UP finding of mean 80% repositioning compliance for the 2-hour arm. Also, Pickham and colleagues[22] found a 54% repositioning compliance in a 2-hour control group of hospitalized acutely ill adults. Similar to TEAM-UP, staff repositioning compliance for hospitalized acutely ill adults was improved by displaying on monitors (visual cues) repositioning information received from wearable sensors.[22]

Limitations

Cluster trials in a healthcare setting without extensive preliminary analyses have a large degree of uncertainty related to the within-cluster correlation and between cluster variation. Small differences in an ICC can result in substantial differences in estimates of the required sample size and number of clusters. The ICC estimate indicated that this study required five NHs per arm; however, the wide CI (−0.78 to 0.89) is evidence of a lack of precision in this measure and does not provide sufficient guidance to determine the optimum number of required NHs. The use of many NHs is problematic when the goal is to efficiently test multiple repositioning intervals in a real-world setting. Accordingly, the number of NHs in the TEAM-UP trial was limited to nine to adhere to the 5-year study period and budget parameters imposed by the funding mechanism while ensuring that the embedded pragmatic cluster randomized trial design requirements were met. This was especially true for implementing the NH-wide intervention that could be incorporated easily into routine clinical workflow as standard of care.

Propensity score analysis partially addressed differences in resident characteristics between NHs in arms 1, 2, and 3. One source of imbalance in arms was associated with Black residents being more likely to develop a PrI; yet, no PrIs developed among Black residents during the intervention. Propensity analysis did not control for variation in a resident's LOS. Potential bias that might have been introduced by differences in short-

stay (LOS <100 days) and long-stay (LOS >100 days) residents as defined according to the CMS could not be fully identified based on available data.

This trial excluded NH residents with severe PrI risk because their care delivery is highly individualized using specialized surfaces and repositioning intervals. Evidence regarding median time to PrI development varies; for example, recent acute care evidence shows a 2- to 5-day median time to PrI development when using high-density foam mattresses and 4-hour repositioning.[23] The TEAM-UP's 28-day follow-up period was longer than prior NH randomized controlled trials' intervention periods.[13,14] Prior research supports the adequacy of the 4-week intervention time period to permit development of PrIs in the sample studied.[13,14] However, this may still be insufficient time to fully demonstrate PrI outcomes, precluding using time-to-development as an analysis strategy, as in the PRESSURE2 study.[24]

It was not possible to blind nursing staff to the intervention. Staff knowledge of the NH-wide repositioning interval was essential but may have contributed to a Hawthorne effect because the patient monitoring system made staff continually aware of resident repositioning needs.

CONCLUSIONS

This study found that a large group of residents could have repositioning protocols relaxed without compromising PrI incidence, although this embedded cluster randomized clinical trial could not establish a true causal link between three repositioning interval treatments and PrI outcomes. This trial is the third study to demonstrate that PrI incidence is not compromised by repositioning most NH residents at 3- or 4-hour interval;[13,14,16] also, the intervention period was longer than that in previous studies. Residents did not develop new PrIs while using viable high-density foam mattresses, and staff were cued to perform scheduled repositioning, demonstrating, as in prior research,[19,25] that consistently implemented prevention strategies can be effective. Successful application of these results NH-wide would free staff for additional care activities and reduce resident sleep disruptions. Additional research is needed to identify specific factors of race and risk differences in PrI incidence. Establishing PrI causative factors will enhance quality of NH care delivery. ●

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