

The Efficacy of Goodmark Medical's Solution Using the BAM Labs[®] Smart Bed TechnologyTM in the Prevention of Pressure Ulcers

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Abstract

Pressure ulcers are a largely preventable, yet prevalent problem in long-term care facilities, causing pain and discomfort for residents and the potential for litigation for the care facility. This study had two major goals, to assess the effects of an every two-hour repositioning schedule on the development of pressure ulcers and to assess the efficacy of the BAM Labs[®] Smart Bed TechnologyTM solution in providing the ability to drive compliance to the repositioning schedule, thereby reducing the number of pressure ulcers in a long-term care bed-bound population. Ninety four residents from three long-term care facilities in Kentucky, deemed at risk for the development of pressure ulcers participated in this study. Over a period of 12 weeks, participant's number of validated bed turns were monitored using the Smart Bed TechnologyTM solution and the number of new pressure ulcers was recorded. Results found that the overall number of pressure ulcers decreased by 50% from baseline to the end of the study period. Additionally, there was a dramatic 85% decrease in new pressure ulcer development during the study. This improvement may be a result of the additional accountability provided by customizes reporting produced by Goodmark Medical's Solution based on data pulled from the BAM Lab[®] Smart Bed TechnologyTM solution.

Keywords: Wounds; Aging; Pressure Ulcers; Smart Bed Technology; Long Term Care

Introduction

Pressure ulcers are defined as a "localized area of tissue necrosis that tends to develop when soft tissue is compressed between a bony prominence and an external surface for a prolonged period of time" [1]. While not all pressure ulcers can be prevented, research indicates that most are preventable [2-4]. As a "reportable event", pressure ulcers are directly linked with quality of care in nursing facilities [4]. Combined with the ever increasing litigious society in which we live today, it is imperative that nursing facilities manage quality improvement initiatives to promote prevention of pressure ulcers through staff accountability and demonstrate that evidence-based practices were utilized, especially in cases where development of a pressure ulcer occurred.

There is a growing body of evidence showing many pressure ulcers are preventable [1]. Black and colleagues [4] reported that, based on a multidisciplinary conference comprised of stakeholders from 34 organizations, most but not all pressure ulcers are avoidable. There is on-going debate as to whether all pressure ulcers can be prevented and further research is indicated.

The National Pressure Ulcer Advisory Panel [1] reported that while a precise number of individuals who develop pressure ulcers were not available in 1989, it is estimated to be over 1 million. More recently, the Institute for Healthcare Improvement [3] estimated that approximately 2.5 million individuals are treated for pressure ulcers annually. In acute care settings, 0.4% to 38% of individuals develop a pressure ulcer while 2% to 24% develop pressure ulcers in long-term care settings and 0% to 17% in home care [3]. The direct consequences of pressure ulcers extend beyond the immediate wound to issues related to quality of life and economic direct and indirect costs for the resident, insurers and the facility. From an individual perspective, pressure ulcers may cause extreme discomfort and pain [5-8] and place the patient at significantly increased risk for life threatening infections [8], and death [6,8-10].

Pressure ulcers are associated with hospitalizations, longer lengths of stay [5,8], discharged to a long-term care facility [8] and decreased quality of life [6].

In-direct consequences of pressure ulcers include litigation associated with development of a pressure ulcer. One study reported that 87% of litigation cases for failure to prevent pressure ulcers favored the long-term care resident based on data collected between 1999 and 2002 [6]. There have been increases in the number of cases settled outside of court and those resulting in confidential settlement arrangements as well [6].

Pressure ulcers create significant increases in cost for residents, insurers and facilities [4]. Treatment costs were \$11.0 billion in 2006 for hospital stays related to pressure ulcers, which was approximately \$1,200 per day on average [8]. Javitz and colleagues [11] reviewed the cost of treating pressure ulcers into 11 cost drivers for Stage III and Stage IV pressure ulcers. Cost driver categories ranged from provider services, devices, surgical and non-surgical treatments, medications, room, length of stay, and hospitalization charges. Costs based on these drivers resulted in estimated daily cost of \$469.83 per day per pressure ulcer; monthly costs of approximately \$5,637.96 and annual costs of approximately \$67,655.52 per pressure ulcer in 2008 dollars.

Utilizing the 2013 Consumer Price Index Calculator (Bureau of Labor Statistics) these costs increase to a daily cost of \$697.54, monthly cost of \$8,370.52, and yearly cost of \$100,446.24.

The current standard for pressure ulcer prevention is repositioning (turning) every two hours to relieve pressure on bony prominences [3,12]. However, following reposition schedules individualized to residents can be challenging in a long-term care environment. In an attempt to standardize repositioning, a frequent practice is for staff to start at the end of one hallway every two hours and reposition residents in an assembly-line approach. However, this practice becomes inefficient and possibly harmful if a resident had just recently been repositioned for any reason. In this case, this approach may result in a resident unknowingly being positioned back to where they recently were too soon. Additionally, compliance to repositioning schedules and last position utilized is difficult to validate and relies solely on staff documentation of repositioning events. Time between the actual event and time of documentation can vary significantly.

Given the importance of quality care at long-term facilities, it is important to consider methods and equipment that may improve staff ability to schedule and comply with "patient-specific" customized repositioning schedules. The Smart Bed TechnologyTM solution developed by BAMTM Labs is one such innovation. This solution can be used to create customized repositioning schedules, leading to improved care and hence reduce the prevalence of pressure ulcers in long-term care facilities and therefore was selected for inclusion in this research.

The major objective of this research study was two-fold. The first objective was to assess the effects of an every two-hour repositioning schedule on the development of pressure ulcers. The second was to assess the efficacy of the Smart Bed TechnologyTM solution in providing the ability to drive compliance to the repositioning schedule, thereby reducing the number of pressure ulcers in a long-term care bed-bound population. The study hypothesis was that facilities utilizing the Smart Bed TechnologyTM solution to schedule and execute two-hour repositioning schedules would report a significantly lower prevalence of new pressure ulcers than the control group [13].

The research questions are formally stated as:

Is there a relationship between two-hour repositioning compliance and the number of pressure ulcers?

How is every two-hour repositioning compliance affected by the introduction of scheduling via the BAM Labs $^{\circ}$ Smart Bed TechnologyTM solution?

How is the prevalence of pressure ulcers affected by the introduction of scheduled repositioning via the Smart Bed TechnologyTM solution?

How is the cost of pressure ulcer treatment affected by the introduction of scheduled repositioning via the Smart Bed TechnologyTM solution?

What are the perceived strengths and weaknesses of the utilization of scheduled repositioning via the Smart Bed TechnologyTM solution reported by key stakeholders?

Method

Instruments/Equipment

The Mini-Mental State Examination (MMSE): The MMSE is a 30 point questionnaire test used to screen for cognitive impairment. Patients are asked questions within the following eight categories: (a)

orientation to time, (b) orientation to place, (c) registration, (d) attention and calculation, (e) recall, (f) language, (g) repetition, and (h) complex commands. Lower scores indicate higher cognitive impairment, with the following descriptors applied to scores: (a) questionably significant: score of 25-30, (b) mild impairment: score of 20-24, (c) moderate impairment: score of 10-19, and (d) severe impairment: score less than 10 [14]. The MMSE has demonstrated high reliability [15,16] and validity [15,16].

Brief Interview for Mental Status (BIMS): The three item BIMS is similar to the MMSE in that it is used to screen for cognitive impairment. The instrument assesses the patient's ability to repeat stated words, temporal orientation, and to recall the previously stated and repeated words. Scores range from 0 to 15, with lower scores indicating more severe cognitive impairment. The BIMS has demonstrated high reliability [17] and validity [18].

The Patient Health Questionnaire (PHQ-9): The PHQ-9 Patient Depression Questionnaire is a 10 item measure of depression. Patients are asked to indicate on four point scale (not at all, several days, more than half of the days, and nearly every day) how often in the past two weeks nine problems have afflicted them. These problems include: (a) feeling tired, (b) poor appetite or overeating, and (c) feeling down, depressed, or hopeless. A tenth item asks the patient to indicate how difficult the problems have made it for the patient to do work, take care of things at home, or get along with other people. Higher frequencies of problems result in higher scores, with higher scores indicating higher levels of depression. The PHQ-9 Patient Depression Questionnaire has demonstrated high reliability [19] and validity [19].

The Minimum Data Set- Activities of Daily Living (MDS-ADL) Scale: The MDS-ADL scale is an eight item scale contained within the Minimum Data Set, is a mandatory data collection tool used in nursing homes in the United States. The ADL items assess the patient's daily functioning in the following areas: (a) bed mobility, (b) transfer, (c) locomotion, (d) dressing, (e) eating, (f) toilet use, and (g) personal hygiene. Each facet is scored on a four point Likert-type scale, from 0 (total independence- minimal staff participation in activity) to 4 (total dependence-full staff participation in activity). The MDS has demonstrated high reliability and validity [20].

Braden Scale: The Braden Scale for Predicting Pressure Sore Risk is a rubric instrument comprised of 6 subscales: (a) sensory perception; (b) skin moisture; (c) activity; (d) mobility; (e) friction and shear; and (f) nutritional status. Each subscale is rated on a scale from 1 to 4, with the exception of friction and shear which is rated on a three point scale. Lower scores indicate greater impairment or higher risk developing a pressure sore. This is a widely used scale to assess patient risk of developing pressure ulcers and has demonstrated high reliability (r = .83 to .94 when used by CNAs and LPNs; r = .99 when used by RNs) and validity [13].

Smart Bed Technology: The BAM Labs[®] Smart Bed TechnologyTM solution is a non-invasive platform consisting of a sensor mat installed under the resident's mattress providing data on motion in bed, heart and respiratory rate trends.

The solution has no leads or wires attached to the resident; and make no direct contact with the body. Biometric sensors in the mat detect heart rate (HR), respiratory rate (RR) (HR and RR used for trend data only) and motion through the mattress. These data are sent via a cloud-based, HIPAA compliant stream, via wireless internet connection. The cloud based program for this study was provided by the BAM Labs^{*} licensee, Goodmark Medical, LLC. The BAM Labs^{*}

Page 2 of 8

Page 3 of 8

Smart Bed TechnologyTM is comprised of a biometric sensor mat. The sensor mat is a self-inflating air bladder that goes underneath the mattress or sleep surface. The air bladder has an air valve in one corner and an air pressure transducer in another corner. The air pressure transducer is complemented by BAM Labs analog design which provides filtering and amplification to produce the desired raw data signal from air pressure changes in the sensor mat. The analog design is optimized for frequency levels in the heart rate and respiration rate ranges and for the collection of motion events of the body.

The raw data signal is sampled every 10 milliseconds (1/1000th of a second) and processed by proprietary BAM Labs algorithms. The algorithms calculate motion, heart rate trends, respiration rate trends, and bed presence based on pressure changes in air pressure of the air bladder. Motion is then further aggregated every ten seconds.

The sensor mat can further filter out motion caused by bed articulation via bed angle measurements. In addition, motors, ambient room noise, building vibration and mechanical noise are filtered from the signal. The biometric motions are filtered, analyzed and returned to the caregiver on an internet connected device. With this data, BAM Labs^{*} has created multiple applications. The Position Change application enables caregivers to set individual resident turn schedules, providing timed prompts to drive position changes. The application also records directional position changes, determines the duration since the last position change and provides automated reminders for the next position change. All position changes are automatically recorded and can be validated by the caregiver to ensure compliance.

Participants

Sample: The sample included 94 residents from three long-term care facilities in the State of Kentucky (Pikeville: n = 33, 35%; Prestonsburg: n = 17, 18%; Riverview: n = 44, 47%). All of the participants were Caucasian and a majority (78%) were female (n = 73). With respect to age, participants ranged in age from 26 to 97, with the average age being 78.12 (SD = 13.26). Participants were assessed on their risk of developing a pressure ulcer using the Braden Scale for Predicting Pressure Sore Risk. Participants scored between 8 and 18 on the Braden Scale with a mean score of 12.86 (SD = 1.79). The Brief Interview for Mental Status (BIMS) and the Mini Mental Status Exam (MMSE) were utilized to determine cognition. On the BIMS, participant scores ranged from 0 to 15, with an average score of 5.81 (SD = 5.30). Participant scores on the MMSE ranged from 3 to 29, with an average score of 13.91 (SD = 9.38). The Patient Health Questionnaire (PHQ-9) was utilized to measure depression. Scores on the PHQ-9 ranged from 0 to 18, with an average score of 2.78 (SD = 3.93), for participants in this study. Lastly, activities of daily living functioning was measured using an ADL function score. Participants scored between 9 and 16, with an average score of 14.24 (SD = 1.48).

Chi-square analyses and one-way analysis of variance (ANOVAs) were conducted in order to determine if the samples from three facilities were similar. Based on the analyses, the all three facilities were similar with respect to participant characteristics, with the exception of the Braden Scale. Results showed the differences in Pikeville Braden scores (Mean 12.06 [SD = 1.71]) and Riverview (Mean 13.57 [SD = 1.89]) were statistically significant (F = 7.931, p = 0.001). This shows that, at baseline, residents at Pikeville scored lower on the Braden than those at Riverview, indicating a higher pressure ulcer risk at Pikeville.

Sampling: A purposive convenience sampling technique was utilized to determine the sample for this study. Residents at 3 long-

term care facilities in the State of Kentucky were evaluated for risk of developing a pressure ulcer. Residents were deemed at risk for developing a pressure ulcer based on their Braden Scale for Predicting Pressure Sore Risk [13]. Possible scores on the Braden Scale range from 6 to 23, with a high risk cut-off point of 16. Lower scores are indicative of higher risk. Residents with scores of 16 or below were deemed to be at-risk of developing a pressure ulcer and were offered participation in this study. All residents who gave verbal assent and could themselves or via proxy provide signed informed consent were enrolled.

Data collection

Quantitative data: Baseline data were collected over a four week period using the facility database and paper records with respect to demographic attributes and prevalence of pressure ulcers. Pressure ulcer data were then collected at the end of the study period to determine the number of residents who developed new pressure ulcers and the number of residents with non-healing pressure ulcers on a weekly basis over the 12 weeks of BAM Labs^{*} Smart Bed TechnologyTM data collection.

With respect to turns, the BAM Labs^{*} Smart Bed TechnologyTM solution captures data in real time. These data were stored in the BAM Lab^{*}/Goodmark system and aggregated weekly by the research team. Weekly compliance percentages were calculated by dividing the number of validated turns (i.e., those above the threshold) by the number of required turns (hours in bed divided by 2) to determine how frequently residents were turned within a two-hour window.

Qualitative data: Brief follow-up interviews were conducted with key stakeholders at the three facilities who were intimately involved with the BAM Labs^{*} bed mats. Key stakeholders were questioned related to their experience with the BAM Labs^{*} bed mats. The questions were as follows: (a) what, if any, was your most memorable story or experience with respect to the bed mats?; (b) what do you perceive are the barriers with respect to the bed mats?; (c) what do you have any suggestions for improvement?; (e) what, if any, difficulties did you have with CNA/staff utilization?; and (f) what is your overall impression of the bed mats?

Procedures

Following the completion of the data collection period, follow-up interviews were conducted with key stakeholders at the 3 facilities in order to ascertain a front-line view of the efficacy of the BAM Labs^{*} bed mats.

Assent and/or informed consent were obtained from all participants included in this study. Only residents determined to be cognitively intact (i.e., MMSE score greater than 14) were permitted to sign the informed consent. For those residents with an MMSE score less than 15, the resident was asked to sign the assent while a family member or power of attorney (POA) was asked to sign the informed consent. ICH GCP guidelines were strictly adhered to throughout this study. The study was approved by the Sterling Institutional Review Board (IRB).

Data analysis

Data were entered into the Statistical Package for the Social Sciences (SPSS) and inspected for "missingness". In total 10% of data on

Page 4 of 8

compliance demonstrated missingness; therefore, mean substitution was utilized to replace missing values on this variable.

Basic descriptive analyses (e.g., frequencies) were conducted on relevant demographic, clinical, and outcome variables. The relationship between compliance and the number of pressure ulcers was examined using bivariate analyses (Pearson product moment correlation analyses). A dependent samples t-test was conducted to assess the treatment effect of the Smart Bed TechnologyTM solution on compliance. An additional dependent samples t-test was conducted to assess the treatment effect of the Smart Bed TechnologyTM solution on the prevalence of pressure ulcers. The qualitative data were analyzed by reporting the frequency at which themes occurred in the data.

Results

The total incidence of new pressure ulcers in the four weeks of baseline measurement prior to study implementation was eight new pressure ulcers. Over the course of 12-weeks, there were only 14 new pressure ulcers in total. This is a dramatic 85% decrease in new pressure ulcer development from baseline (average of 8 new pressure ulcers per week) to the completion of the study period (average of 1.17 new pressure ulcers per week during 12 week intervention). These numbers do not include residents who were admitted with pressure ulcers.

Descriptive statistics

The 94 participants in this study experienced between 0 and 65 pressure ulcers over the 12-week period, with the average being 2.07 pressure ulcers (SD = 7.87). Of the 94 participants, only 34%

experienced a pressure ulcer over the 12-week period (n = 32). However, not all of the pressure ulcers experienced were new wounds. Please note that if the participant currently had a pressure ulcer at baseline, this was considered a new pressure ulcer for the purposes of this study. Of the 32 participants with pressure ulcers, 78% experienced a new wound (n = 25) and 47% of those with pressure ulcers demonstrated improvement during the course of this study (n = 15). These pressure ulcers included the spectrum of possibilities with respect to staging. Of the 94 participants, 34% experienced an Unstageable pressure ulcer (n = 11), 9% experienced a Stage I pressure ulcer (n = 2), and 6% experienced a Stage IV pressure ulcer (n = 2).

It is also important to examine the number and characteristics of pressure ulcers experienced over the 1,222 measurement occasions. Overall, the participants experienced a total of 195 wounds, indicating that a resident experienced more than 1 pressure ulcer over the course of this study or experienced multiple pressure ulcers at one time while others did not experience any pressure ulcers. Of the 195 pressure ulcers, only 18% were new wounds (n = 36), a majority (61%) of these occurring at baseline (n = 22). With respect to healing, a majority (56%) of the reported wounds were improving over the course of this study (n = 110). Further, of the 195 wounds, 48% were unstageable (n = 93), 2% were Stage I (n = 4), 28% were Stage II (n = 54), 11% were Stage III (n = 22).

Table 1 below summarizes the prevalence and characteristics of pressure ulcers overall and by facility, while Table 2 presents a summary table of all of the characteristics discussed above by time period (Tables 1 and 2).

Variable	Overall	Pikeville	Prestonsburg	Riverview	
#PU	195	76	17	102	
(%)		(39.0)	(8.7)	(52.3)	
#New	36	14	6	16	
(%)	(18.5)	(38.9)	(16.7)	(44.4)	
#Heal	110	35	11	64	
(%)	(56.4)	(31.8)	(10.0)	(58.2)	
#Unstageable	93	33	2	58	
(%)	(47.4)	(35.5)	()2.2	(62.4)	
#Stage I	4	1	2	1	
(%)	(2.1)	(25.0)	(50.0)	(25.0)	
#Stage II	54	25	13	16	
(%)	(27.7)	(46.3)	(24.1)	(29.6)	
#Stage III	22	6	0	16	
(%)	(11.3)	(27.3)	(0.0)	(72.2)	
#Stage IV	22	11	0	11	
(%)	(11.3)	(50.0)	(0.0)	(50.0)	
Avg Compliance	48.46	55.06	59.13 39.40		

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Page 5 of 8

(8D)	(21 51)	(22.90)	(44.40)	(10.80)	
(30)	(31.31)	(32.80)	(44.49)	(19.09)	

Table 1: Summary of Prevalence and Characteristics of Pressure Ulcers

Time	#PU	#New	#Heal	#Unstg	#S1	#S2	#S3	#S4	Avg Comp
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(SD)
0	22	22	n/a	11	2	7	1	1	13.00
	(11.3)	(100.0)		(50.0)	(9.1)	(31.8)	(4.5)	(4.5)	(19.05)
1	17	2	8	8	0	7	1	1	31.24
	(8.7)	(11.8)	(47.1)	(47.1)	(0.0)	(41.2)	(5.9)	(5.9)	(24.33)
2	15	0	12	6	0	5	2	2	51.88
	(7.7)	(0.0)	(80.0)	(40.0)	(0.0)	(33.3)	(13.3)	(13.3)	(56.04)
3	12	0	9	6	0	2	2	2	43.10
	(6.2)	(0.0)	(75.0)	(50.0)	(0.0)	(16.7)	(16.7)	(16.7)	(23.04)
4	14	2	9	7	0	3	2	2	48.12
	(7.2)	(14.3)	(64.3)	(50.0)	(0.0)	(21.4)	(14.3)	(14.3)	(21.55)
5	14	2	9	8	0	2	2	2	55.32
	(7.2)	(14.3)	(64.3)	(57.1)	(0.0)	(14.3)	(14.3)	(14.3)	(21.99)
6	19	6	8	9	0	4	2	2	57.06
	(9.7)	(31.6)	(42.1)	(47.4)	(0.0)	(21.1)	(10.5)	(10.5)	(25.92)
7	17	0	10	7	2	6	2	2	52.79
	(8.7)	(0.0)	(58.8)	(41.2)	(11.8)	(35.3)	(11.8)	(11.8)	(27.28)
8	15	0	11	6	0	4	3	2	52.34
	(7.7)	(0.0)	(73.3)	(40.0)	(0.0)	(26.7)	(20.0)	(13.3)	(29.00)
9	12	1	6	6	0	2	2	1	61.54
	(6.2)	(8.3)	(50.0)	(50.0)	(0.0)	(16.7)	(16.7)	(8.3)	(27.83)
10	16	1	13	8	0	5	1	2	54.99
	(8.2)	(6.3)	(81.3)	(50.0)	(0.0)	(31.3)	(6.3)	(12.5)	(32.82)
11	11	0	7	6	0	3	1	1	51.97
	(5.6)	(0.0)	(63.6)	(54.5)	(0.0)	(27.3)	(9.1)	(9.1)	(23.31)
12	11	0	8	5	0	3	1	2	56.67
	(5.6)	(0.0)	(72.7)	(45.5)	(0.0)	(27.3)	(9.1)	(18.2)	(27.31)
Total	195	36	110	93	4	54	22	22	48.46
		(18.5)	(56.4)	(47.7)	(2.1)	(27.7)	(11.3)	(11.3)	(31.51)

Table 2: Summary of Prevalence and Characteristics of Pressure Ulcers over 12 weeks

Research Question One: Is there a relationship between repositioning compliance and the number of new or worsening? Pressure ulcers?

Repositioning compliance ranged from 0% to over 100% (this is possible due to turns being completed repeatedly throughout a 2-hour period), with an average compliance rate of 48% (SD = 31.51). Compliance increased from baseline (Mean = 13.0; SD = 19.05) to the end of the study period (Mean = 56.7; SD = 27.31).

To assess the relationship between compliance and the total number of pressure ulcers a correlation analyses between the number of new pressure ulcers and number of healing pressure ulcers were conducted. Results demonstrate no statistically significant correlation between compliance and the number of pressure ulcers, the number of new pressure ulcers, or number of healing pressure ulcers. However, there was a trend with respect to compliance and the number of pressure ulcers that were indicated as "healing" (r = 0.052; p = 0.069) which may be interesting for further research. When looking at

average compliance over the 13 time periods and the same variables,

Research Question Two: How is compliance affected by the introduction of the Smart Bed TechnologyTM?

In order to assess the effect of the Smart Bed TechnologyTM solution on compliance a dependent samples t-test was conducted to compare the baseline mean compliance rate to the mean at the conclusion of the study (week 12). Results indicated that there was a statistically significant change (t = -14.209; p < 0.001) from baseline to conclusion, with a significantly higher mean compliance rate at the conclusion of the study (M = 56.7) than the beginning (M = 13).

Research Question Three: How is the prevalence of pressure ulcers affected by the introduction of the Smart Bed TechnologyTM solution?

Similar to research question two, in order to assess the effect of the Smart Bed TechnologyTM on the number of pressure ulcers, a dependent samples t-test was conducted to compare the baseline number of pressure ulcers to the number of pressure ulcers at the conclusion of the study (week 12). Results indicated that there was a statistically significant decrease (t = -2.25 p =.03) in the number of pressure ulcers from the baseline (22) to conclusion of the study (11). Similarly, there was a statistically significant decrease (t = -2.1 p = .04) in the number of new pressure ulcers developed from the baseline (22) to conclusion of the study (Tables 1 and 2).

Research Question Four: What are the perceived strengths and weaknesses of the utilization of the Smart Bed TechnologyTM solution reported by key stakeholders?

Brief face-to-face interviews were conducted with six key stakeholders from the three included facilities. Of the six interviews, two (33%) were Directors of Nursing (DONs) or Assistant DONs, two (33%) were administrators, one (17%) was a Staff Development Coordinator (SDC), and one (17%) was a certified nursing assistant CNA). All interviewees were Caucasian, with a majority (67%) being female (n = 4) and 33% being male (n = 2).

The first question posed by researchers focused on the stakeholder's most memorable experience since implementing the BAM Labs[®] bed mats. Three stakeholders were able to recall a significant experience. One stakeholder commented on a resident who was accidently given a mat. When that stakeholder realized the mistake and went to remove the mat from this resident, CNAs pleaded with stakeholder to leave the mat because the resident was susceptible to falls. The stakeholder recounted that the resident has had no falls since the implementation of the BAM Labs' bed mats. Another stakeholder spoke of a resident who had recently passed away. This stakeholder reported that staff from Goodmark Medical (the supplier and service provider of the BAM Labs[®] Smart Bed TechnologyTM solutions), while remotely monitoring the mats, called to report that this particular resident's vital signs were concerning and asked that someone check on that resident (as noted, the BAM Labs Smart Bed $\rm Technology^{\rm TM}$ solution is not intended for use as a real-time vital sign monitoring solution, but trend data is available for review). Unfortunately, the resident passed away a few hours after this call was made. Lastly, one stakeholder reported on a prevented hospitalization. This stakeholder was monitoring the system from home when they noticed the resident's heart rate steadily increasing. The stakeholder contacted staff at the facility and they were able to assess the resident then contact the doctor to order antibiotics and fluids. As a result, the resident did not have to go out to the hospital.

The second question focused on barriers with respect to the bed mats. The major barrier presented by all six stakeholders was the Wi-Fi in the buildings. All stakeholders remarked that lack of consistent connectivity was a major barrier. Other barriers mentioned by stakeholders included staff buy-in (n = 3), inconsistent use (n = 2), training on why to use the BAM Labs^{\circ} bed mats (n = 1), having to micro manage (n = 1), confusing symbolism on iPods (n = 1), having the plugs behind the bed (n = 1), and failure to get alerts when iPod is locked or closed (n = 1).

All stakeholders interviewed spoke of the strengths of the BAM Labs^{*} bed mats. Specifically, a majority (n = 4, 67%) of stakeholders mentioned the additional applications of the BAM Labs[®] Smart Bed TechnologyTM solution (e.g., vital sign trends, bed exits, heart rate trends, movement, etc.) as a major strength of the BAM Labs[®] solution. Three stakeholders mentioned that the BAM Labs' Smart Bed TechnologyTM solution can validate that care is given. Other strengths noted were early intervention (n = 2), ability to monitor at all times regardless of location (n = 2), made turning/repositioning better (n = 1), decreased pressure ulcers (n = 1), and improved quality of care and awareness (n = 1).

With respect to suggestions for improvement, all stakeholders mentioned getting the WiFi and/or connectivity to consistently work. Two stakeholders expressed concern with respect to the launching of the product and/or research study and commented that they would have liked to have seen it phased in on a smaller scale and then grow larger. Two stakeholders mentioned that while the training on how to use the BAM Labs $^{\circ}$ Smart Bed Technology $^{\rm TM}$ solution was good, more training was needed on the importance of using the BAM Labs[®] Smart Bed TechnologyTM solution and why it is so important. Two stakeholders commented on the additional applications available with the BAM Labs[®] solution and suggested more emphasis be placed on these applications. One stakeholder suggested that the same type of solution be developed and added to the current iPod related to activities of daily living.

All but one stakeholder discussed difficulties they had with CNA/ staff utilization. Those stakeholders that did mention difficulties primarily focused on the lack of consistent use due to the lack of consistency with WiFi connectivity (n = 4). One stakeholder mentioned that difficulty with CNA/staff utilization was due to the fact that "nobody was standing over them making sure they used it." One stakeholder commented that a difficulty was that the CNAs were busy. Another stakeholder reported that "fear of change" was a major difficulty related to CNA/staff utilization, especially among older staff. With respect to the one stakeholder that did not report any difficulties with CNA/staff utilization, the stakeholder reported "we have a great staff, it's about letting them know up front what it is all about."

The overall impression of the BAM Labs[®] Smart Bed TechnologyTM solution was positive. All but one stakeholder reported that the BAM Labs[°] Smart Bed TechnologyTM solution was great but reiterated the concerns with Wi-Fi and connectivity. One stakeholder reported that they are "not seeing the full advantage of it" due to the lack of consistent connectivity. Two stakeholders reported on how they wanted more of the BAM Labs[®] Smart Bed TechnologyTM solution in their facilities, but due to funding, they could not implement any additional mats at this time. One stakeholder reported that the BAM Labs[®] Smart Bed TechnologyTM solution "dramatically changes how we do business...as it becomes effective it will change what we do forever." The one stakeholder that reported that they were "torn" stated that it was a "great product" and they liked the concept, but

Page 7 of 8

wished they could have eased into it and received appropriate training and had the connectivity to use it properly.

Discussion

Most importantly, there is evidence of a treatment effect of the BAM Labs^{*} solution on the number of pressure ulcers. As Table 2 illustrates, the overall number of pressure ulcers decreased 50% from baseline to the end of the study period. This does not take into account pressure ulcers that were present upon admission due to the fact that this data was not consistently reported by the facilities. Therefore, it is plausible to assume that the decrease in the percentage of pressure ulcers was even higher. Because of the low number of stage 3 and stage 4 pressure ulcers in the sample (Table 2), it is difficult to speculate about the effectiveness of the BAM Labs^{*} solution in decreasing these pressure ulcers.

With increasing litigation, it is going to be imperative that turning residents within a specified time period is validated. The BAM Labs[®] solution is able to give a long-term care facility that validation. With this, it is also important to note that while CNAs were not given the iPODS or fully trained yet on the BAM Labs[®] solution, the solution was still collecting data. This means that at baseline, the percentage of validated turns was normal practice in these facilities was before the BAM Labs' solution was implemented and this percentage was not good. Overall, the average compliance with 2-hour turn intervals was 13% at baseline, which increased to 48% by the end of the intervention period. While neither of these numbers should be acceptable by best practice standards, and leave an agency open to litigation in the event that a pressure ulcer develops, it is still an improvement. This improvement may be a result of the additional accountability provided by customizes reporting produced by Goodmark Medical's Solution based on data pulled from the BAM Labs[®] solution [21].

Interestingly, the results of this study found that there was not a statistically significant relationship between compliance and the number of pressure ulcers. This finding is in stark contrast to the significant positive relationship between the introduction of the BAM Labs^{*} solution and compliance and the negative relationship between the introduction of the BAM Labs^{*} solution and the prevalence of bed sores. This anomaly may due to the fact that the correlation analyses used all of the measurements, potentially allowing the high prevalence and low prevalence of pressure ulcers at the beginning and end of the study to wash out the relationship. Dependent samples t-tests results provide strong evidence of a treatment effect of the BAM Labs^{*} solution on reducing the number of pressure ulcers and increasing compliance.

Lastly, the non-statistically significant results may be due to the length of the study or the selection of participants. In order to fully test out the significance of the BAM Labs^{*} solution, it will be imperative to design a much larger study where a randomized sample selection is utilized as well as a comparison or control group. Improving the study design may improve the results presented in this white paper, but still, there were significant results present for both social work practice as well as long-term care administration. Regardless, further research is recommended to more carefully examine the impact of the BAM Labs^{*} solution on pressure ulcers.

Strengths and weaknesses of the study design

A weakness with respect to longitudinal design was participant attrition as a result of death. However, with longitudinal studies, a major strength of this design is being able to capture change over time.

This study found that the overall number of pressure ulcers decreased by 50% from baseline to the end of the study period. Additionally, there was a dramatic 85% decrease in new pressure ulcer development during the study period. Finally, the average compliance with two-hour turn intervals increased by 35% during the course of the study. This improvement may be a result of the additional accountability provided by customizes reporting produced by Goodmark Medical's solution based on data pulled from the BAM Lab^{*} Smart Bed TechnologyTM solution. Future studies should be conducted in order to validate these findings. Future studies may want to focus on individuals with stage 3 and 4 pressure ulcers that were not well represented in the current study.

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Page 8 of 8

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