Bundling Interventions to Enhance Pain Care Quality (BITE Pain) in Medical Surgical Patients

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Background: Inadequate pain management and undertreatment remain a serious clinical issue among hospitalized adults, contributing to chronic pain syndromes and opioid dependency. Implementation of individual pain care interventions has been insufficient to improve pain care quality. The purpose of this interprofessional, patient-centered project was to implement a 6-component bundle of evidence-based pain management strategies to improve patients' perception of pain care quality and 24-hour pain experience outcomes.

Methods: A quasi-experimental design was used to test the effect of a bundled pain management intervention on 3 medical surgical units. Baseline outcomes using the Pain Care Quality-Interdisciplinary (PainCQ-I[©]) and Pain Care Quality-Nursing (PainCQ-N[©]) surveys were measured monthly for 4 months preintervention and 30 months postintervention.

Results: A convenience sample of 846 patients was analyzed. The effect of the intervention on pain outcomes could not be tested because unit-based adherence did not meet the goal of 80%. A subsample of 70.2% (594/846) of participants was sufficient to complete a 3-group analysis of preintervention and postintervention participants with confirmed intervention adherence. Participants in the postintervention group who received all 6 components (n=65) had significantly higher odds of higher PainCQ[©] scores than those in the preintervention group (n=141) (PainCQ-I[©]: odds ratio [OR] 2.61, 95% confidence interval [CI] 1.54-4.42; PainCQ-N[©]: OR 3.82, 95% CI 2.06-7.09) or those in the postintervention group receiving ≤5 components (n=388) (PainCQ-I[©]: OR 2.52, 95% CI 1.57-4.03; PainCQ-N[©]: OR 3.84, 95% CI 2.17-6.80).

Conclusion: Medical surgical patients participating in this study who received the bundled 6-component intervention reported significantly higher levels of perceived pain care quality, suggesting that a bundled approach may be more beneficial than unstandardized strategies.

Keywords: *Acute pain, animal assisted therapy, aromatherapy, implementation science, interprofessional relations, music therapy, pain–postoperative, pain management, pain measurement, quality indicators–health care, quality of health care, surveys and questionnaires*

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INTRODUCTION

Pain in the United States is a public health crisis of epidemic proportions.[1] Approximately 100 million Americans suffer from acute and chronic pain at an annual cost reaching $635 billion, more than the combined healthcare expenditures for diabetes, cardiovascular disease, and cancer.[2] Pain management is widely accepted as an important component of high-quality care and a strong contributor to patient satisfaction.[3-5] Despite awareness and therapeutic improvements, inadequate pain management and undertreatment of pain remain a serious clinical issue among hospitalized patients, contributing to chronic pain syndromes and opioid dependency.[6,7] Clearly, implementation of individual pain care interventions has been insufficient to improve patients' perceptions of pain care quality.[8-11] Therefore, there is a need to implement an innovative pain management intervention that (1) actively engages the patient as a partner rather than a passive recipient of treatment; (2) applies bundled interventions that are complementary and conceptually aligned; and (3) improves patients' ability to cope with pain by providing some predictability and engaging them in control regarding the plan of care.[12,13]

LITERATURE REVIEW

A review of the published literature cited in Ovid MEDLINE and CINAHL focused on exploring the effectiveness of

outcomes of pharmacologic and nonpharmacologic nursing interventions in reducing acute and chronic pain in adult hospitalized patients. Four systematic reviews and 21 original research studies published from 2003-2014 were critiqued for level of evidence using the Centre for Evidence-Based Medicine guideline[14] and provided the basis for the intervention in this research study.

The literature synthesis is briefly described beginning with the highest level of evidence (systematic reviews). Four systematic reviews supported a benefit in pain outcomes related to patient pain education,[15] therapy,[16] and nonpharmacologic therapy.[17,18] Six randomized controlled trials described beneficial pain management outcomes from patient education[19] and nonpharmacologic therapy.[20-24] Two quasi-experimental studies supported a benefit in pain outcomes related to structured pain rounds[25] and nonpharmacologic therapy.[26] Thirteen descriptive, comparative, or correlational designs described positive pain care quality outcomes associated with patient pain education,[27] pain and coping assessment strategies,[28-33] communication of pain management plans,[34] pharmacologic therapy,[35] and nonpharmacologic therapy.[36-39]

Although pharmacologic agents have been the mainstay of pain management, synthesis of this body of knowledge suggests that the evidence is insufficient to support a specific nursing intervention that effectively manages pain. Yet case studies that tested individual nonpharmacologic interventions in the 2010 Pain Care Quality Study reported by Potter et al[40] reported a potential benefit for hospitalized adults at single sites. Interventions described in the literature review supporting this study were associated with a potential benefit as adjuncts to pharmacologic therapies that included patient education, clinical pathways, teaching patients coping strategies, and various nonpharmacologic therapies (massage, relaxation, guided imagery, pet therapy, music therapy, prayer, distraction) in improving patients' perceptions of pain management. None of these interventions was found to be harmful or of less benefit than usual care. However, despite the state of knowledge about various adjunctive strategies to individualize pain management in hospitalized adults with acute and chronic pain syndromes, important substantive and theoretical questions exist. These gaps include that little or no knowledge exists regarding the effect of bundling pain care strategies on patients' perceptions of pain care quality.

However, structured quality improvement initiatives and observational cohorts using bundled interventions to improve hospital outcomes in ventilator-associated pneumonia (VAP)[41,42] and septic shock[43,44] support improvement in these outcomes when bundle adherence with completing all bundle components reaches and exceeds 80% over time. Although quality improvement and observational studies are not strong evidence to support the role of bundle adherence in improving quality outcomes in VAP and septic shock, the literature does support a relationship between bundle adherence and quality outcomes.[41-43] Therefore, it seemed plausible to test the same bundling concept using the 80% adherence goal in implementing all 6 pain care strategies as one bundle in an intervention study. This research study addressed the knowledge gap and sought to test an important substantive clinical question: determining the effect of a 6-component bundle of pain care

strategies, BITE Pain Therapy™ (Bundling Interventions to Enhance Pain Care Quality), on patients' perception of pain care quality. The purpose of this nurse-driven, interprofessional, patient-centered project was to implement BITE Pain Therapy™, a standardized bundle of conceptually aligned evidence-based pain care management strategies, to improve patients' perception of pain care quality by actively engaging the patient as a partner rather than a recipient of treatment. Active engagement of the patient as a healthcare team partner using BITE Pain Therapy™ was facilitated by 6 bundle components that (1) defined and communicated pain care expectations and (2) determined appropriate pain care interventions. This study was particularly important because if the hypothesis that the BITE Pain Therapy™ intervention improves medical surgical patients' perceptions of pain care quality was supported, nurses could add a bundle of evidence-based, pragmatic, and readily accessible pain care strategies to their armamentarium in the battle against pain in hospitalized patients.

RESEARCH QUESTIONS

The research questions that guided this scientific inquiry were (1) To what extent does implementation of a unit-based standardized bundle of evidence-based pain care components (BITE Pain Therapy™) improve medical surgical patients' perception of pain care quality over time? and (2) Is there a relationship between BITE Pain Therapy™ intervention adherence, patients' perception of pain care quality, and pain experience outcomes?

METHODS
Design

A quasi-experimental interrupted time series design was used to evaluate the effect of the BITE Pain Therapy™ intervention on patients' perceptions of pain care quality and 24-hour pain experience outcomes. Unit-level pain quality data were collected monthly for 4 months before implementation and 30 months after. Unit intervention adherence data were collected weekly and averaged monthly. The study was performed according to good clinical practice principles and was approved by the participating facility's institutional review board (IRB).

Setting

The study was conducted on 3 medical surgical units in a 550-bed quaternary acute care academic facility in metropolitan New Orleans, LA, with Magnet Recognition® (American Nurses Credentialing Center, Silver Spring, MD). Patients on each of the 3 adult units are primarily specialty populations: gastrointestinal disorders (38 beds), orthopedics (42 beds), and transplant (34 beds). However, all 3 units are similar in that >60% of the patients are admitted for major surgical procedures.

Sample and Sampling Plan

A convenience sample of all patients meeting inclusion criteria on the 3 participating medical surgical units was recruited to participate in the study. The sampling plan involved recruiting patients on a predetermined day of each month during the 4-month preintervention and 30-month postintervention periods. All patients on each unit were screened by study staff for eligibility using the electronic
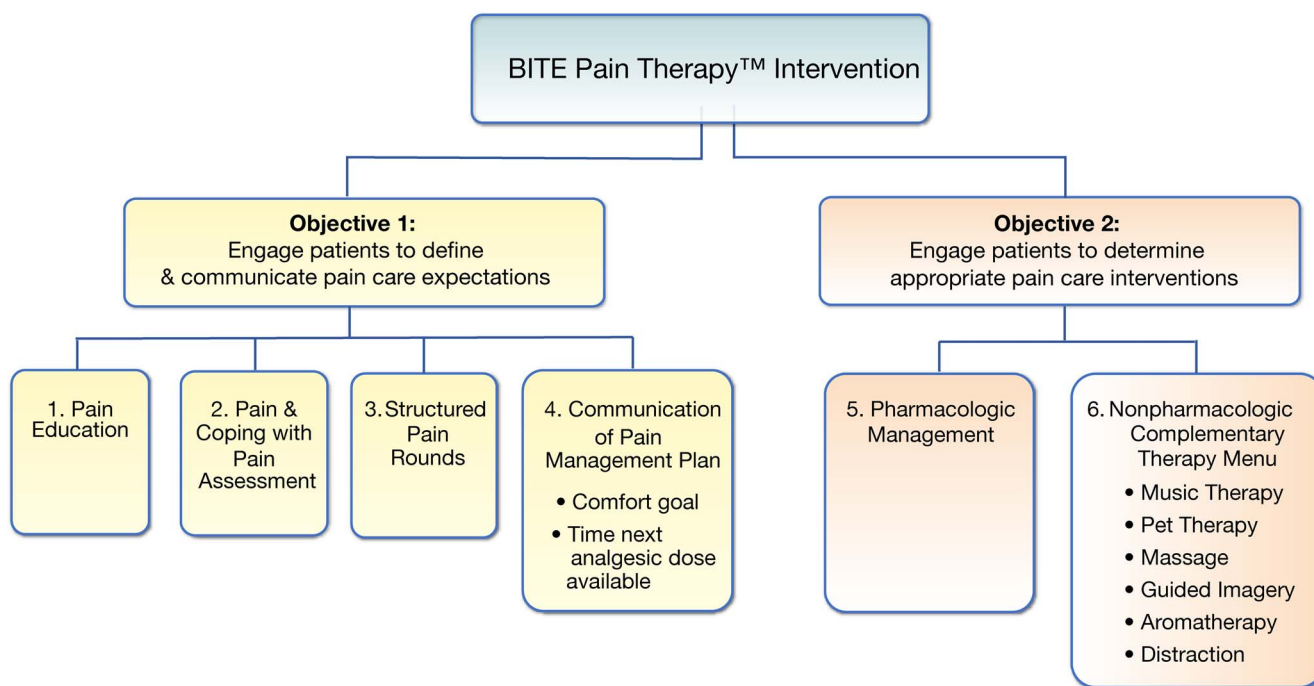
Figure 1. BITE Pain Therapy™ (Bundling Interventions to Enhance Pain Care Quality) objectives and components.

health record and daily unit census reports. All eligible patients were invited to voluntarily consent to participate if the inclusion criteria were met: ≥18 years old, on that unit at least 24 hours, complaint of pain in the last 24 hours with an active order for pharmacologic analgesic, and able to speak and read English. Patients were excluded if they had a history of cognitive dysfunction, an acute mental status change, or a medical condition that precluded their ability to participate in a 15-minute interview for collecting data.

Intervention

The BITE Pain Therapy™ intervention was implemented on November 1, 2014 as a new best practice for the management of acute and chronic pain for all patients hospitalized on the 3 participating units. BITE Pain Therapy™, a 6-component bundled intervention, was developed by the investigators based on the synthesis of evidence previously described in the literature review. The 6 bundle components (Figure 1) included (1) patient education regarding pain and pain management (pain brochure and individualized instruction); (2) pain and coping with pain assessments using the 0-10 numeric rating scale with faces; (3) structured pain rounds every hour during the day and every 2 hours at night if the patient was awake; (4) communication of the pain management plan (comfort goal and time next analgesic dose available) written on the patient's wall-mounted whiteboard; (5) pharmacologic management; and (6) the offer of menu-driven adjunctive nonpharmacologic therapies.

Although these bundle components are congruent with the standard of care, the development of a coping with pain assessment instrument (Figure 2) and a menu for patients to select nonpharmacologic therapy options were innovative additions to the intervention. Patients were provided a menu, Take the BITE Out of Pain, on admission (Figure 3).

The expectation was that all patients with a complaint of pain would be offered the entire 6-component BITE Pain Therapy™ bundled intervention each shift as the new standard of care. Each participating unit was supplied with two supply carts called comfort carts that included nonpharmacologic therapies (ie, essential oils, distraction materials, massagers). Comfort carts were audited, and the supplies were replaced each week or more often if nurses reported a need.

All participating unit-based provider stakeholders (nurses, advanced practice nurses, physicians, physician assistants, clinical pharmacists, social workers, physical and occupational therapists, pastoral care providers) received education regarding the BITE Pain Therapy™ intervention, including information about knowledge and attitudes about pain management and implementation of the pain care bundle. Nurses' competencies in completing all bundle components were validated using role modeling and case study vignette simulations. The institution's Pain Task Force accepted

Figure 2. Ability to cope with pain rating scale.

Take the **BITE** Out of Pain
Nonpharmacologic Therapy Menu

Therapies you and your nurse can do now

Music Therapy
- TV Channel 20
- Listen to your music

Relaxation [1]
- Deep breathing
- Stretching
- Progressive muscle relaxation
- Prayer
- Meditation

Guided Imagery [1]
- Meditate on images on music TV Channel 20
- Create own images

[1]Ask your nurse for instructions

Distraction
- Read
- Electronic games
- Crossword puzzles, word searches
- Board games
- Watch TV

Ask your nurse about arranging the following therapies

Music Therapy [2]
- Live music in your room

Massage Therapy
- Battery operated massage units

Aromatherapy
- Essential oils to smell

Distraction Resources
- Crossword puzzles, word searches
- Checkers/Chess
- Books
- Have someone read to you [2]

Pet Therapy [2]
- Pet visit in your room

Positioning
- Repositioning
- Elevation of extremity

Physical Agents
- Heat or cold

[2] Call Volunteer Services to schedule
  NOTE: Based on availability

Figure 3. Nonpharmacologic therapy menu.

responsibility for facilitating physician and advanced practice clinician (nurse practitioners, physician assistants) pain management education involving the BITE Pain Therapy™ bundle. Ongoing education was facilitated using online intranet-based educational modules, skills fairs, and unit-based huddles.

Measurement and Instruments

Pain Care Quality (PainCQ©). Patients' perception of pain care quality, the primary endpoint, was measured using 2 different surveys: Pain Care Quality-Interdisciplinary (PainCQ-I©) and Pain Care Quality-Nursing (PainCQ-N©) surveys.[45] These surveys collect information about the patient's pain care experience in the context of a specific encounter and provider interactions during hospitalization. The surveys focus on a comprehensive assessment of pain management that impacts the patient, family, and friends, including nonpharmacologic therapies and fear of addiction. Patients' perception of pain care quality was measured using the PainCQ© surveys monthly during 2 periods: preintervention

(4 months) and postintervention (30 months). In addition, demographic information and 5 selected items from the Brief Pain Inventory[46] about participants' pain experience during the previous 24 hours were solicited at the same time the PainCQ© surveys were administered. While demographic items included self-reported type of pain (acute, chronic, or both types), the 5 items eliciting information about patients' pain experience during the previous 24 hours focused on pain outcomes (average pain level, time in severe pain, frequency of pain medication administration, percent pain relief from medications, ability to cope with pain). Preintervention participants completed the same PainCQ© surveys as postintervention participants with one exception. Demographic items in the preintervention survey did not request participants to self-identify the type of pain they were currently experiencing.

Following informed consent, trained data collectors used pen and paper surveys to collect information via structured interview. Permission to use and revise the Pain Care Quality surveys was granted by the developer. The original 20-item

Table 1. Confirmatory Factor Analysis for PainCQ© Survey Data

Test Statistic	Criteria for Good Model Fit	PainCQ-I© (n=846)	PainCQ-N© (n=846)
Number of items		6	15
Chi-square (df)		21.49 (8)	372.79 (83)
P value for chi-square	<0.05	0.006	<0.001
Chi-square ratio	χ^2/df (<3)	2.69	4.48
Comparative fit index	≥0.95	0.99	0.95
Goodness-of-fit index	≥0.95	0.99	0.94
Standardized root mean square residual	≤0.08	0.023	0.050
Root mean square error of approximation	≤0.08	0.045	0.065

Note: Missing data replaced with subscale mean to facilitate complete dataset for confirmatory factor analysis.
df, degrees of freedom; PainCQ-I©, Pain Care Quality-Interdisciplinary; PainCQ-N©, Pain Care Quality-Nursing.

survey includes pain care quality items specific to interdisciplinary care (6 items) and nursing pain care (14 items).[45,47] Altogether, these 20 items specifically measure patients' perception of pain care quality, and they make up the PainCQ-I© and the PainCQ-N© surveys. The 6 items included on the PainCQ-I© survey are categorized under 2 subscales: Partnership with the Health Care Team (3 items) and Comprehensive Interdisciplinary Pain Care (3 items). The 14 items on the PainCQ-N© survey are categorized under 3 subscales: Being Treated Right (7 items), Comprehensive Nursing Pain Care (4 items), and Efficacy of Pain Management (3 items).[47] Both the PainCQ-I© and PainCQ-N© surveys use a 6-point Likert rating scale (1=strongly disagree to 6=strongly agree) to elicit information about pain care quality related to interdisciplinary care since admission to the hospital (ie, PainCQ-I©) and nursing care during the previous 12-hour shift (ie, PainCQ-N©). Higher scores indicate better pain care quality.

Because the BITE Pain intervention included an option of nonpharmacologic therapies thought to improve patients' ability to cope with pain,[17,18,48,49] it was important to assess the patients' baseline coping ability and the impact of nursing care as confounding variables. Therefore, 2 additional questions were developed in collaboration with the instrument developer. One of the items previously mentioned in the 5-item section that assessed the patient's pain experience during the last 24 hours—*Please rate how effectively you are coping with pain on the average during past 24 hours*—uses a numeric rating scale with faces (10=coping all the time to 0=never coping). The second question—*The nurse did a good job helping me to cope with my pain*—was added to the PainCQ-N© Being Treated Right subscale items, increasing this subscale to 8 items. Information from 34 survey items (8 demographic, 5 pain experience, 20 PainCQ©, plus 1 new coping question) were collected from participants.

The 20 items making up the original PainCQ-I© and PainCQ-N© surveys[47] have psychometric estimates to support reliability and validity in measuring patients' perceptions about pain care quality. All 5 subscales have previously reported satisfactory internal consistency reliability and construct validity via confirmatory factor analysis (CFA).[47] Internal consistency reliability for each subscale of the PainCQ-I© (6 items) and revised PainCQ-N© (15 items) surveys used in this study were satisfactory. Cronbach's α for the individual subscales was 0.69 (Partnership with the Health Care

Team), 0.71 (Comprehensive Interdisciplinary Pain Care), 0.87 (Being Treated Right), 0.71 (Comprehensive Nursing Pain Care), and 0.88 (Efficacy of Pain Management). CFA supported the validity of the construct in this study, and the data fit the model for both the PainCQ-I© and revised PainCQ-N© surveys (Table 1).

BITE Pain Therapy™ *Intervention Fidelity*. Measuring intervention adherence is critical to determining whether perceptions of pain care quality are attributable to the intervention or to some other confounding variable. The researchers developed an audit tool to measure patients' perception of nurses' adherence with each of the 6 bundle components using a dichotomous (yes/no) response. Patients were selected for auditing based on the same eligibility criteria used in conducting the PainCQ© surveys. Using the same audit instrument, 2 strategies were used to assess the impact of the intervention on patients' perception of pain care quality and pain outcomes. First, unit-based adherence of the intervention was captured weekly but at a different time than pain care quality and pain outcome data collection. Second, individual participant intervention adherence was collected monthly at the same time as pain care quality and pain outcome data collection, providing paired data for some participants in the postintervention group.

Unit-Based Intervention Adherence Audits. Unit-based audits were conducted by research assistants each week via patient interview and observation. Consented patients were interviewed regarding their recollection that the bundle options were offered during the prior 24 hours and by observation of written communication of the pain management plan on whiteboards in the hospital room. Bundle adherence audits were scored to determine the percentage of adherence for each bundle component and for all 6 bundle components. This information was communicated back to nurses on each participating unit weekly to foster improved adherence with all 6 bundle components over time. In addition, nurses were encouraged to anonymously complete a pocket card weekly to communicate processes that worked well or presented obstacles to bundle adherence (Figure 4).

Individual Participant Intervention Adherence Audits. To investigate the effects of the bundle components on improving the perception of pain care quality, defining and capturing participants' exposure to the intervention were necessary. In June 2015, the protocol was amended and approved by

BITE Pain Therapy
What's Working for Nurses & What's Not

Instructions: Please evaluate whether or not each of the BITE Pain Interventions is working (you can or cannot do it). Include any comments that will help us to improve this project. Use the back of this card for additional comments.

Date:_____ Shift: _____ Unit (circle 1): 1   2   3

BITE Pain Intervention	Is it working?	Comments (especially what is not working)
Pain & coping assessment at same time	YES ☐ NO ☐	
Structured pain rounds per guideline	YES ☐ NO ☐	
Whiteboard to communicate pain therapy	YES ☐ NO ☐	
"Taking the BITE Out of Pain" menu (daily review)	YES ☐ NO ☐	
Access to pharmacologic agents for pain when you needed them	YES ☐ NO ☐	
Able to facilitate complementary therapy options selected by patient	YES ☐ NO ☐ No requests ☐	
Scheduled volunteer services without problem	YES ☐ NO ☐ No requests ☐	

Figure 4. Nurses' pocket card to assess what was working and not working.

the IRB. In addition to the monthly intervention adherence audits, this amendment provided a mechanism to capture individual participant intervention adherence data on some of the postintervention group at the same time as pain care quality and pain outcome data were collected.

Participant data from the entire preintervention (n=141) period and from individual audits (n=453) from some in the postintervention period were categorized into groups according to their exposure to the intervention. Three groups were defined: Group 1 Preintervention (no bundle), Group 2 Postintervention (offered 0-5 bundle components), and Group 3 Postintervention (offered all 6 bundle components). The team's rationale was (1) no one in Group 1 was exposed to the bundle; 2 of the components were not available (ability to cope with pain assessment and nonpharmacologic menu); (2) participants in Group 2 who reported receiving 0-5 components were exposed to at least 1 component (pharmacologic analgesia was an inclusion criterion) during their hospitalization even if they were not consciously aware; and (3) the number of participants in Group 3 who reported receiving all 6 bundle components at the time PainCQ© survey data were collected supports intervention adherence. Therefore, the primary analysis of the effect of the bundled intervention focused on comparing the pain care quality

scores and pain outcomes of 3 participant groups that had paired data to support whether or not exposure to the intervention occurred.

DATA ANALYSES

Exploratory data analysis was conducted to examine the distributions of each study variable, primary and secondary endpoints by means ± standard deviations, and frequencies and percentages. Medians and interquartile ranges were reported when continuous data were not normally distributed. All analyses were completed using SAS/STAT software, v.9.4 of the SAS System for Windows. All tests were performed with significance level $\alpha=0.05$.

Pain experience outcome data were dichotomized into 2 groups of responses for average pain (low=0-4 rating vs high=5-10 rating), time in severe pain (0%-25% vs 26%-100%), amount of relief from pharmacologic analgesia (0%-75% vs 80%-100%), and ability to cope with pain (0-6 rating vs 7-10 rating). Little variability was seen among patients' responses, and dichotomizing allowed us to see the separation between participant responses more clearly. In addition, the dichotomized groups were aligned with existing clinical practice goals for quality improvement of pain care outcomes at this organization.

Data were analyzed using 2 approaches: (1) testing the entire participant sample's demographics, pain care quality and pain experience outcome data, and unit-based monthly mean intervention adherence measures for the 6-component bundle and (2) testing the subsample of participants with individual-level intervention adherence data paired with pain care quality and pain experience outcome data.

Entire Participant Sample Analysis (n=846)

Demographic characteristics for the entire sample are reported as means and standard deviations for continuous measures and as frequencies and percentages for categorical measures. Chi-square tests were used for comparisons of the dichotomized 24-hour pain experience outcomes regarding time in severe pain, relief from pain, and ability to cope between participants reporting low vs high average pain. Additionally, all 3 dichotomized outcomes were compared via chi-square tests between groups defined by the dichotomized type of reported pain. A multinomial ordinal regression model incorporating an interrupted time series design was used to test for changes from preintervention to postintervention in means and time trends in PainCQ© scores across the sample and within each unit. Differences in changes from preintervention to postintervention in means and time trends in PainCQ© scores between units were also tested.

Subsample Analysis (n=594)

A subsample analysis was completed using the preintervention participant data (n=141) and data collected on postintervention participants (n=453) with individual paired data for intervention adherence for the bundle components, PainCQ© and pain experience outcomes. As previously described, participants were categorized into 3 groups (Group 1 Preintervention, Group 2 Postintervention [receiving 0-5 bundle components], and Group 3 Postintervention [receiving all 6 bundle components]) for comparison. Sample size was determined from a power analysis of

PainCQ© scores. To achieve 80% power to detect differences in PainCQ© scores between the 3 adherence groups, a total sample size of n=231 is sufficient. The power and sample size calculations are based on the expectation of observed means equal to 4.0, 4.5, and 5.0 for the preintervention, postintervention with partial intervention adherence, and postintervention with full adherence groups, respectively. A standard deviation of 1.0 was assumed for all participant groups, and the calculations were adjusted to account for multiple comparisons. Because of the non-normality of the actual observed PainCQ© scores in this study, the subsequently described group comparisons utilized nonparametric methods. Although less powerful than analogous parametric tests, we concluded that the amassed sample size of n=594 was sufficient to maintain adequate power.

Using one-way ANOVA for continuous measures and chi-square tests for categorical measures, demographics and type of pain were compared. To test for group differences in the study outcomes, Kruskal-Wallis tests were used for distributions of PainCQ© scores and subscale scores, chi-square tests were used for associations with 24-hour pain care experience responses, and odds ratios (ORs) from a multinomial ordinal regression model were used for odds of higher PainCQ© scores. Finally, intervention adherence data for the 2 postintervention groups (n=453) were tested using chi-square tests for associations between exposure to individual bundle components and 24-hour pain experience outcomes.

RESULTS
Participant Characteristics

A total of 1,290 patients met eligibility criteria over the course of the 34-month study period, with 856 (66.4%) consenting (Figure 5). Ten of 856 participants withdrew without completing the survey because of a change in their medical condition (ie, pain, fatigue, nausea). Data from 846 participants were included in analyses. Participants' self-reported demographic characteristics for the sample (n=846) included a mean age of 54.4 years (SD=14.4) and 50.9% male. Significantly more participants were white (66.1%), not Hispanic or Latino (94.4%), married/partnered (51.8%), and completed at least some college (54.3%) (Table 2).

Of the 846 participants, 141 (16.7%) completed the PainCQ© surveys during the preintervention study period, July through October 2014. As previously stated, the 3 self-reported pain types (acute, chronic, or both) were only collected from postintervention participants, representing 704/846 (83.2%) of the sample, with the majority (413/704 [58.7%]) reporting acute pain compared to 125/704 (17.8%) reporting chronic pain and 166/704 (23.6%) with both acute and chronic pain (Table 2).

A group comparison of all participants (n=846) based on reported 24-hour pain experience was completed. When 24-hour pain experience outcomes were dichotomized by low vs high average pain ratings, participants who reported a lower average daily pain score reported significantly less time in severe pain, greater pain relief from pharmacologic analgesia, and higher ability to cope with pain (Table 3). However, when 24-hour pain experience data were analyzed from the 704 postintervention participants from whom pain type was collected (Table 4), differing patterns of associations were observed between participants reporting acute
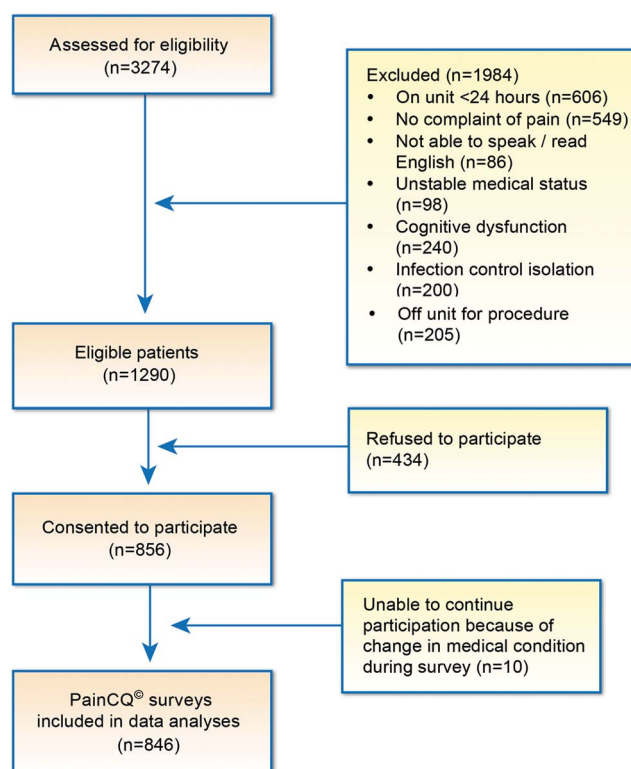

Figure 5. Participant flow chart.

pain compared to participants who reported chronic or acute and chronic pain. Participants reporting acute pain alone had more reports of low average pain scores (22.3%), less time in severe pain (65.4%), and more relief from pharmacologic analgesia (56.7%) than those with chronic or both acute and chronic pain. No significant differences in ability to cope with pain based on type of pain were found.

Pain Care Quality and Unit-Based Intervention Adherence

Incorporating the interrupted time series design, an ordinal regression model was used to answer the research question, *Does implementation of a unit-based standardized bundle of evidence-based pain care interventions (BITE Pain Therapy™) improve medical surgical patients' perception of pain care quality over time?* Figure 6 illustrates that no significant changes occurred in trends of PainCQ-I© ($F[1,836]<0.005$; $P=0.991$) or PainCQ-N© ($F[1,836]=0.08$; $P=0.776$) scores over time or in mean PainCQ-I© ($F[1,836]=0.07$; $P=0.792$) or PainCQ-N© ($F[1,836]=0.01$; $P=0.912$) scores following implementation of the intervention.

Three-Group Participant Findings

Because the BITE Pain Therapy™ unit-based intervention adherence for the 6-component bundle failed to meet the monthly average goal of 80%, we were unable to test the hypotheses that bundle adherence had an effect on patients' perception of pain care quality or pain experience outcomes. Faced with a mean unit-based adherence for the 6-component bundle that did not exceed zero percent during the first 7 months of the postintervention period, the protocol

Table 2. Participant Characteristics

Characteristic	All Participants n=846
Mean age, years ± SD	54.4 ± 14.4
Sex	
Female	415 (49.1)
Male	430 (50.9)
Race	
Black or African American	248 (29.3)
White	559 (66.1)
Other	39 (4.6)
Ethnic background	
Hispanic, Latino, or Spanish origin	47 (5.6)
Not Hispanic or Latino	798 (94.4)
Marital status	
Single	196 (23.2)
Separated or divorced	127 (15.0)
Widow or widower	85 (10.0)
Married or partnered	438 (51.8)
Education	
Technical school graduate and below	386 (45.7)
Some college and above	459 (54.3)
Pain[a]	
Acute	413 (58.7)
Chronic	125 (17.8)
Acute and chronic	166 (23.6)

[a]Pain type was collected only on postintervention participants (n=704).
Note: Data are reported as n (%) unless otherwise indicated.

amendment afforded the opportunity to collect paired pain care quality, pain experience outcome, and bundle component adherence data beginning in the eighth month of the postintervention period. Intervention adherence data were collected on 453/705 (64.3%) postintervention participants who completed PainCQ© surveys. During the 30-month intervention period, participants (n=453) reported receiving a mean of 3.9 BITE Pain Therapy™ bundle components (median 4.0). However, only 65/453 (14.3%) reported receiving all 6 bundle components (Figure 7). Audit data of each bundle component from the 453 participants revealed that 81.0% reported receiving pain education, 55.8% received both pain and coping with pain assessments, 83.8% experienced structured pain rounds, 38.8% had whiteboard communication of their comfort goal and next analgesic dose available, 96.0% were aware they were receiving pharmacologic analgesia, and 41.0% were offered the complementary therapy menu. The 2 bundle components that negatively impacted intervention fidelity were failure to update the whiteboard communication of the pain management plan and offering the complementary therapy menu.

Table 5 describes the demographic characteristics of the 3 participant groups using the sample of 594: Group 1 Preintervention (no bundle), Group 2 Postintervention (offered 0-5 bundle components), and Group 3 Postintervention (offered all 6 bundle components). No differences (P>0.05) were

Table 3. 24-Hour Pain Experience Outcome Comparisons Dichotomized by Low vs High Average Pain Ratings (n=846)

Outcome	Low Average Pain (0-4 rating)	High Average Pain (5-10 rating)	Missing/Unknown	Chi-Square (df)[a]	P Value
Time in severe pain				117.3 (4)	<0.001
0%-25%	129 (86.0)	345 (49.9)	1 (25.0)		
26%-100%	21 (14.0)	344 (49.7)	2 (50.0)		
Missing/unknown	0 (0.0)	3 (0.4)	1 (25.0)		
Amount of relief from pharmacologic analgesia				39.6 (4)	<0.001
0%-75%	32 (21.3)	337 (48.7)	2 (50.0)		
80%-100%	106 (70.7)	331 (47.8)	2 (50.0)		
Missing/unknown	12 (8.0)	24 (3.5)	0 (0.0)		
Average ability to cope with pain				11.1 (4)	0.005
Low (0-6 rating)	39 (26.0)	278 (40.2)	2 (50.0)		
High (7-10 rating)	109 (72.7)	409 (59.1)	2 (50.0)		
Missing/unknown	2 (1.3)	5 (0.7)	0 (0.0)		

[a]Test statistics and P values from chi-square tests for association.
Notes: The Missing/Unknown column label refers to unknown responses for rating of average pain; the Missing/unknown row labels refer to unknown responses for ratings of time in severe pain, amount of pain relief from pharmacologic analgesia, or average ability to cope with pain. Data are reported as n (%). Bold denotes statistical significance.
df, degrees of freedom.

Table 4. 24-Hour Pain Experience Outcome Comparison by Type of Pain (n=704)

Outcome	Acute Pain	Chronic Pain	Acute and Chronic Pain	Chi-Square (df)[a]	P Value
Average pain				18.3 (4)	0.001
Low (0-4 rating)	92 (22.3)	13 (10.4)	16 (9.6)		
High (5-10 rating)	319 (77.2)	111 (88.8)	149 (89.8)		
Missing/unknown	2 (0.5)	1 (0.8)	1 (0.6)		
Time in severe pain				38.3 (4)	<0.001
0%-25%	270 (65.4)	55 (44.0)	69 (41.6)		
26%-100%	140 (33.9)	69 (55.2)	97 (58.4)		
Missing/unknown	3 (0.7)	1 (0.8)	0 (0.0)		
Amount of relief from pharmacologic analgesia				14.2 (4)	0.007
0%-75%	165 (40.0)	64 (51.2)	87 (52.4)		
80%-100%	234 (56.7)	55 (44.0)	69 (41.6)		
Missing/unknown	14 (3.4)	6 (4.8)	10 (6.0)		
Average ability to cope with pain				5.2 (4)	0.267
Low (0-6 rating)	140 (33.9)	49 (39.2)	69 (41.6)		
High (7-10 rating)	270 (65.4)	75 (60.0)	94 (56.6)		
Missing/unknown	3 (0.7)	1 (0.8)	3 (1.8)		

[a]Test statistics and *P* values from chi-square tests for association.
Notes: Data are reported as n (%). Bold denotes statistical significance.
df, degrees of freedom.

seen in age, sex, race, ethnicity, marital status, or highest level of education among the 3 groups. In addition, we found no difference in the distribution of pain types between the 2 postintervention groups.

This 3-group analysis of the preintervention participants and 2 postintervention participant groups identified significant (*P*<0.05) differences between groups for total PainCQ-I© and PainCQ-N© scores, as well as all subscale scores (Table 6). Participants in Group 3 Postintervention who were offered all 6 bundle components had a higher perception of pain care quality compared to either the Group 1 Preintervention participants or the Group 2 Postintervention participants.

Regression analysis of ordered multinomial PainCQ-I© and PainCQ-N© scores by group suggests that the odds of higher pain care quality scores were not statistically different between Group 2 and Group 1 (Table 7). However, Group 3 had significantly higher odds of higher scores for both the PainCQ-I© (OR >2.5) and PainCQ-N© (OR >3.8) surveys vs both Group 1 and Group 2 (Table 7).

We found no significant differences (*P*>0.05) between Group 1 Preintervention participants and participants in the 2 postintervention participant groups for 24-hour pain outcomes (Table 8). Although the majority of participants in all 3 groups reported a high average daily pain score (score >5), the majority also reported less time in severe pain (<26% of the time) and higher abilities to cope with pain (score >6). In contrast, reports of the percentage of pain relief from pharmacologic analgesia for the 3 groups were variable.

Even though participants who received all 6 bundle components did not demonstrate a significant impact on 24-hour pain experience outcomes, a secondary analysis of each bundle component did identify the following findings. When each bundle component was tested for an association with each of the 24-hour pain experience outcomes, one bundle component significantly improved two of the four 24-hour pain outcomes (Table 9). Participants who received the structured Pain Rounds bundle component vs those who did not reported significantly less time in severe pain and a higher ability to cope with pain.

DISCUSSION

To our knowledge, this study is the first to test the effect of a patient-centered bundled pain management intervention on medical surgical patients' perception of pain care quality and 24-hour pain experience outcomes. Yet because unit-based intervention fidelity failed to meet the goal of 80% adherence with the BITE Pain Therapy™ 6-component bundle, we were unable to determine an effect of the unit-based intervention on patients' perception of pain care quality and 24-hour pain experience outcomes comparing the preintervention to postintervention periods as initially proposed. However, the sample size was sufficient to complete a 3-group analysis that allowed us to compare participants' perception of pain care quality and 24-hour pain experience outcomes with confirmed intervention adherence in a subsample of 70.2% (594/846) of participants. This subsample was representative of the patient populations cared for on all 3 participating units for sex, age, and ethnicity, with no significant differences in the distribution of participant characteristics among the 3 groups.

Our subsample findings support that participants receiving the 6-component bundle comprising the BITE Pain Therapy™ intervention reported significantly higher levels of pain care quality delivered by both nurses and interdisciplinary care teams during hospitalization. In contrast, no
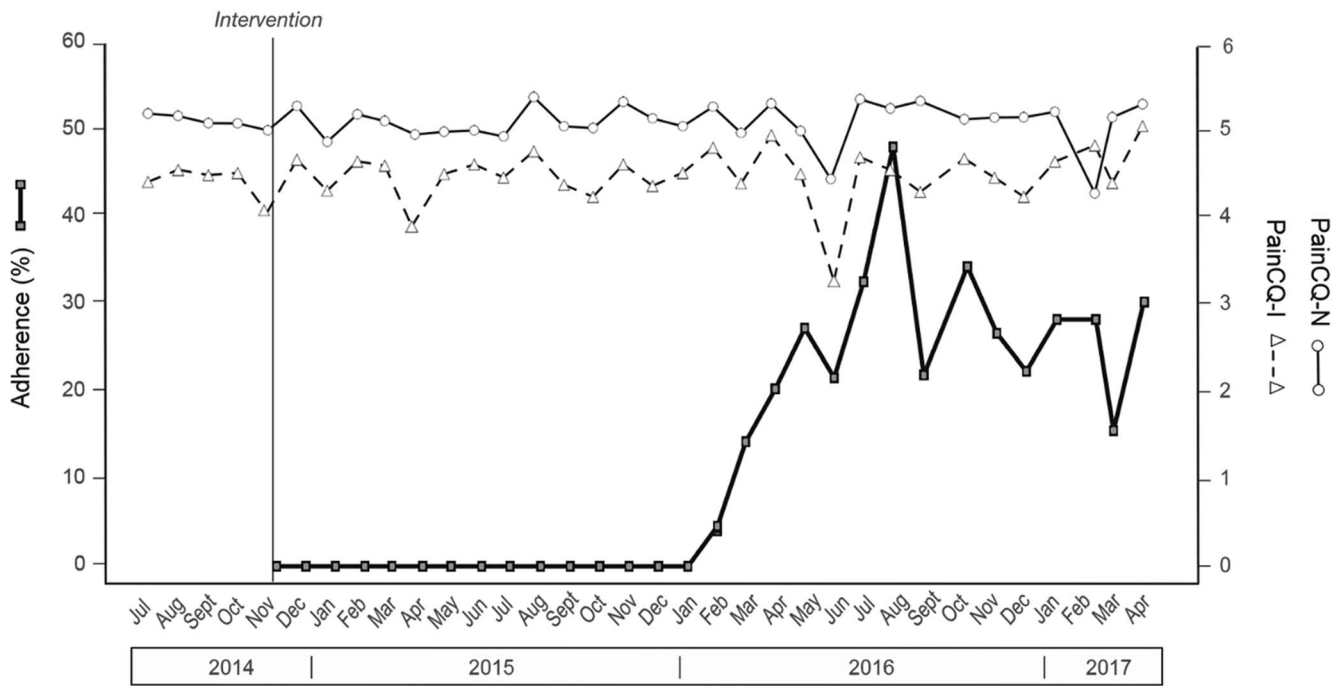
**Figure 6. Run chart showing mean monthly unit-based intervention adherence with the 6-component bundle and PainCQ©
scores for interdisciplinary and nursing surveys during the 34-month study period.** PainCQ-I, Pain Care Quality-Interdisciplinary;
PainCQ-N, Pain Care Quality-Nursing.

differences in perception of pain care quality were detected
between participants in the preintervention group and partic-
ipants in the postintervention group that did not receive all 6
bundle components. Therefore, this study provides support
that using all 6 components comprising BITE Pain Therapy™
significantly improved the perception of pain care quality
in the medical surgical patients who participated in this
study.

No relationships were identified between the preinterven-
tion and 2 postintervention groups for average pain score,
time in severe pain, amount of pain relief from pharmacologic
analgesia, or average ability to cope with pain. Overall, the
majority of participants in all 3 groups reported an average
24-hour pain rating in the moderate to severe range (5-10
rating), yet reports of less percentage of time in severe pain
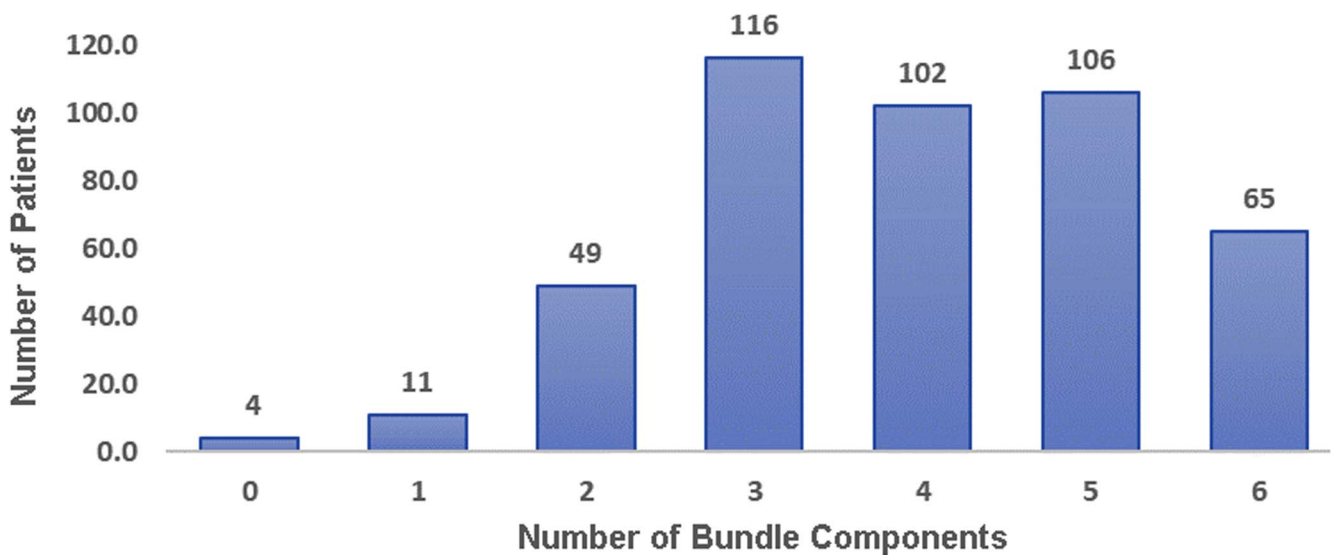(0%-25%) vs more time (26%-100%) in severe pain were

Figure 7. BITE Pain Therapy™ **(Bundling Interventions to Enhance Pain Care Quality) bundle adherence for all 6 components
(n=453).**

Table 5. Participant Characteristics and Bivariate Comparisons for Preintervention and Postintervention Groups (n=594)

Characteristic	Group 1 Preintervention (no bundle) n=141	Group 2 Postintervention (0-5 bundle components) n=388	Group 3 Postintervention (6 bundle components) n=65	Test Statistic[a]	P Value
Mean age, years ± SD	55.5 ± 15.0	55.9 ± 14.1	51.5 ± 15.7	$F_{(2,591)}=2.53$	0.081
Sex				$\chi^2(2)=4.38$	0.112
Female	83 (58.9)	189 (48.7)	32 (49.2)		
Male	58 (41.1)	199 (51.3)	33 (50.8)		
Race				$\chi^2(4)=1.53$	0.821
Black or African American	45 (31.9)	109 (28.1)	21 (32.3)		
White	89 (63.1)	264 (68.0)	41 (63.1)		
Other	7 (5.0)	15 (3.9)	3 (4.6)		
Ethnic background				$\chi^2(2)=1.28$	0.864
Hispanic, Latino, or Spanish origin	9 (6.4)	18 (4.6)	4 (6.2)		
Not Hispanic or Latino	132 (93.6)	369 (95.1)	61 (93.8)		
Missing/unknown	0 (0.0)	1 (0.3)	0 (0.0)		
Marital status				$\chi^2(6)=4.47$	0.614
Single	33 (23.4)	80 (20.6)	17 (26.2)		
Separated or divorced	20 (14.2)	62 (16.0)	5 (7.7)		
Widow or widower	20 (14.2)	50 (12.9)	7 (10.8)		
Married or partnered	68 (48.2)	196 (50.5)	36 (55.4)		
Education				$\chi^2(2)=0.03$	0.987
Technical school graduate and below	64 (45.4)	175 (45.1)	30 (46.2)		
Some college and above	77 (54.6)	213 (54.9)	35 (53.8)		
Pain				$\chi^2(1)=1.40$	0.509
Acute	Not collected	227 (58.5)	43 (66.2)		
Chronic	Not collected	66 (17.0)	9 (13.8)		
Acute and chronic	Not collected	95 (24.5)	13 (20.0)		

[a]Test statistics and P values from one-way ANOVA F-test for age comparison and chi-square tests for association for all categorical variable comparisons.
Note: Data are reported as n (%) unless otherwise indicated.

Table 6. Preinterventional and Postintervention Group Comparisons of PainCQ© and Subscale Scores (n=594)

Survey/Subscale	Group 1 Preintervention (no bundle) n=141	Group 2 Postintervention (0-5 bundle components) n=388	Group 3 Postintervention (6 bundle components) n=65	Chi-Square (df)[a]	P Value
PainCQ-Interdisciplinary© survey	4.5 (3.7-5.3)	4.5 (3.7-5.5)	5.3 (4.8-5.8)	19.8 (2)	<0.001
Subscale 1 – Partnership with the Health Care Team	5.7 (5.0-6.0)	5.7 (5.0-6.0)	6.0 (5.7-6.0)	18.9 (2)	<0.001
Subscale 2 – Comprehensive Interdisciplinary Pain Care	3.7 (2.3-5.0)	4.0 (2.7-5.0)	4.7 (4.0-5.7)	14.9 (2)	<0.001
PainCQ-Nursing© survey	5.2 (4.8-5.7)	5.4 (4.6-5.8)	5.9 (5.3-6.0)	25.3 (2)	<0.001
Subscale 1 – Being Treated Right	6.0 (5.5-6.0)	6.0 (5.5-6.0)	6.0 (6.0-6.0)	14.0 (2)	<0.001
Subscale 2 – Comprehensive Nursing Pain Care	4.8 (3.5-5.6)	4.8 (3.5-5.8)	5.8 (4.8-6.0)	28.9 (2)	<0.001
Subscale 3 – Efficacy of Pain Management	5.7 (5.0-6.0)	5.7 (5.0-6.0)	6.0 (5.3-6.0)	8.6 (2)	**0.014**

[a]Test statistics and *P* values from chi-square tests for association.
Notes: Data are reported as median (25th percentile-75th percentile). Bold denotes statistical significance.
df, degrees of freedom; PainCQ©, pain care quality.

Table 7. Regression Analysis of Ordered Multinomial PainCQ© Scores by Preintervention and Postintervention Group (n=594)

Survey/Comparison Groups	Odds Ratio[a] (95% CI)
PainCQ-Interdisciplinary© survey	
Group 2 Postintervention[b] vs Group 1 Preintervention[c]	1.04 (0.73-1.47)
Group 3 Postintervention[d] vs Group 1 Preintervention[c]	**2.61 (1.54-4.42)**
Group 3 Postintervention[d] vs Group 2 Postintervention[b]	**2.52 (1.57-4.03)**
PainCQ-Nursing© survey	
Group 2 Postintervention[b] vs Group 1 Preintervention[c]	0.99 (0.70-1.42)
Group 3 Postintervention[d] vs Group 1 Preintervention[c]	**3.82 (2.06-7.09)**
Group 3 Postintervention[d] vs Group 2 Postintervention[b]	**3.84 (2.17-6.80)**

[a]Odds ratios represent odds of a higher score on the PainCQ© scale.
[b]Group 2 Postintervention (0-5 bundle components).
[c]Group 1 Preintervention (no bundle).
[d]Group 3 Postintervention (6 bundle components).
CI, confidence interval; PainCQ©, pain care quality.

almost equally split. The incongruence between the majority of participants' reports of moderate to severe pain and less percentage of time in severe pain may be explained by the dichotomization of these measures. Even though others have reported the validity of categorizing numerical pain ratings into 3 groups (mild, moderate, and severe pain),[50,51] we chose to categorize pain ratings into 2 groups based on our institution's quality improvement goals related to pain. The accuracy of participant recall could also have biased pain-related outcome measurement and contributed to the incongruence between average 24-hour pain ratings and percentage of time in severe pain. However, other studies support the validity of patient recall related to reporting average pain scores for both 24-hour[52,53] and 1-week time periods.[54]

In addition, we found no differences between groups in participants' reports of the amount of relief from pharmacologic analgesia. Fifty-seven percent of the preintervention group reported ≥80% relief from pharmacologic analgesia compared to an almost equal split between <80% and ≥80% in the 2 postintervention groups. While the latter finding was not significant, organization-wide strategies to promote adjunctive nonpharmacologic pain management to reduce opioid use were launched at the same time that this research study began. Therefore, pharmacologic analgesia alone would have been the mainstay of pain management during the preintervention period and may have contributed to reports of ≥80% relief from analgesics. Nevertheless, we did not measure opioid use, so we are unable to determine if the differences in opioid administration differed between the preintervention or postintervention groups and contributed to reports of increased pain relief from pharmacologic analgesia in the preintervention group.

The bundled intervention did not have a significant effect on participants' ability to cope with pain. Although the major-

Table 8. Preintervention and Postintervention Group Comparison of Distributions of Dichotomized 24-Hour Pain Experience Outcomes (n=594)

Outcome	Group 1 Preintervention (no bundle) n=141	Group 2 Postintervention (0-5 bundle components) n=388	Group 3 Postintervention (6 bundle components) n=65	Chi-Square (df)[a]	P Value
Average pain				4.9 (4)	0.296
Low (0-4 rating)	29 (20.6)	72 (18.6)	7 (10.8)		
High (5-10 rating)	112 (79.4)	314 (80.9)	57 (87.7)		
Missing/unknown	0 (0.0)	2 (0.5)	1 (1.5)		
Time in severe pain				1.9 (4)	0.754
0%-25%	81 (57.4)	215 (55.4)	37 (56.9)		
26%-100%	60 (42.6)	170 (43.8)	27 (41.5)		
Missing/unknown	0 (0.0)	3 (0.8)	1 (1.5)		
Amount of relief from pharmacologic analgesia				5.6 (4)	0.233
0%-75%	55 (39.0)	182 (46.9)	33 (50.8)		
80%-100%	80 (56.7)	192 (49.5)	32 (49.2)		
Missing/unknown	6 (4.3)	14 (3.6)	0 (0.0)		
Average ability to cope with pain				7.0 (4)	0.137
Low (0-6 rating)	61 (43.3)	134 (34.5)	22 (33.8)		
High (7-10 rating)	80 (56.7)	247 (63.7)	43 (66.2)		
Missing/unknown	0 (0.0)	7 (1.8)	0 (0.0)		

[a]Test statistics and P values from chi-square tests for association.
Note: Data are reported as n (%).
df, degrees of freedom.

Table 9. Comparison of 24-Hour Pain Experience Outcomes by Exposure to Each Bundle Component

Component	Outcome	Yes	No	Chi-Square (df)[a]	*P* Value
Component 1. Pain Education	Average pain			0.42 (1)	0.519
	Low (0-4 rating)	18.3	15.3		
	High (5-10 rating)	81.7	84.7		
	Time in severe pain			0.12 (1)	0.729
	0%-25%	56.7	54.7		
	26%-100%	43.3	45.3		
	Amount of relief from pharmacologic analgesia			0.23 (1)	0.229
	0%-75%	47.5	54.8		
	80%-100%	52.5	45.2		
	Average ability to cope with pain			1.04 (1)	0.307
	Low (0-6 rating)	33.7	39.5		
	High (7-10 rating)	66.3	60.5		
Component 2. Pain and Coping With Pain Assessment	Average pain			2.13 (1)	0.144
	Low (0-4 rating)	15.4	20.7		
	High (5-10 rating)	84.6	79.3		
	Time in severe pain			0.00 (1)	0.963
	0%-25%	56.4	56.6		
	26%-100%	43.6	43.4		
	Amount of relief from pharmacologic analgesia			0.05 (1)	0.817
	0%-75%	48.4	49.5		
	80%-100%	51.6	50.5		
	Average ability to cope with pain			0.52 (1)	0.472
	Low (0-6 rating)	33.5	36.7		
	High (7-10 rating)	66.5	63.3		
Component 3. Structured Pain Rounds	Average pain			1.49 (1)	0.222
	Low (0-4 rating)	18.7	12.7		
	High (5-10 rating)	81.3	87.3		
	Time in severe pain			6.32 (1)	**0.012**
	0%-25%	59.1	42.9		
	26%-100%	40.9	57.1		
	Amount of relief from pharmacologic analgesia			2.76 (1)	0.097
	0%-75%	47.0	57.8		
	80%-100%	53.0	42.2		
	Average ability to cope with pain			6.10 (1)	**0.014**
	Low (0-6 rating)	32.6	47.9		
	High (7-10 rating)	67.4	52.1		
Component 4. Whiteboard Communication	Average pain			2.69 (1)	0.101
	Low (0-4 rating)	14.0	20.1		
	High (5-10 rating)	86.0	79.9		
	Time in severe pain			0.06 (1)	0.808
	0%-25%	55.6	56.8		
	26%-100%	44.4	43.2		
	Amount of relief from pharmacologic analgesia			2.43 (1)	0.119
	0%-75%	53.4	45.8		
	80%-100%	46.6	54.2		

Table 9. Continued

Component	Outcome	Yes	No	Chi-Square (df)[a]	*P* Value
	Average ability to cope with pain			0.29 (1)	0.593
	Low (0-6 rating)	33.3	35.8		
	High (7-10 rating)	66.7	64.2		
Component 5. Pharmacologic Analgesia	Average pain			3.78 (1)	0.052
	Low (0-4 rating)	18.3	0.0		
	High (5-10 rating)	81.7	100.0		
	Time in severe pain			0.07 (1)	0.788
	0%-25%	56.2	52.9		
	26%-100%	43.8	47.1		
	Amount of relief from pharmacologic analgesia			1.16 (1)	0.282
	0%-75%	48.8	62.5		
	80%-100%	51.2	37.5		
	Average ability to cope with pain			1.26 (1)	0.262
	Low (0-6 rating)	33.9	47.1		
	High (7-10 rating)	66.1	52.9		
Component 6. Nonpharmacologic Therapy Menu	Average pain			0.71 (1)	0.399
	Low (0-4 rating)	15.9	19.0		
	High (5-10 rating)	84.1	81.0		
	Time in severe pain			0.26 (1)	0.613
	0%-25%	58.0	55.6		
	26%-100%	42.0	44.4		
	Amount of relief from pharmacologic analgesia			0.24 (1)	0.626
	0%-75%	50.3	47.9		
	80%-100%	49.7	52.1		
	Average ability to cope with pain			3.21 (1)	0.073
	Low (0-6 rating)	29.7	37.9		
	High (7-10 rating)	70.3	62.1		

[a]Test statistics and *P* values from chi-square tests for association.
Notes: Data are reported as percentages. Bold denotes statistical significance.

ity of participants in all 3 groups reported higher ability to cope with pain (7-10 rating) vs low ability (0-6 rating), both postintervention groups had slightly more reports of higher ability to cope compared to the preintervention group. While the nonpharmacologic menu options were included as a bundle component because of their potential impact on coping with pain, many factors contribute to an individual's ability to cope with pain. Factors such as spiritual beliefs and prior experience with using distraction in dealing with pain may have impacted responses to this question by participants in all 3 groups. However, information regarding prior knowledge and/or utilization of nonpharmacologic adjunctive therapies was not measured in the preintervention or postintervention groups. Hence, we were unable to determine whether our study provided participants with a first encounter with nonpharmacologic pain management strategies.

Although the BITE Pain Therapy™ 6-component bundle failed to impact any of the 24-hour pain experience outcomes, one individual bundle component did have an impact. Interestingly, the only bundle component associated with significantly less time in severe pain and higher ability to cope with pain was structured pain rounds. The frequent nurse/patient interaction facilitated by structured pain rounds may result in better pain management. Mitchell et al synthesized the evidence of 16 studies examining the effect of hourly rounding on patient satisfaction with nursing care.[55] They concluded that despite little consistency in how hourly rounding is measured, moderate-strength evidence indicates that hourly rounding programs improved patients' perception of nursing responsiveness to requests for assistance. In addition, results from an hourly rounding best-practice implementation project on a 28-bed medical surgical unit showed a 5% increase in nurse communication and an 11% increase in pain management scores when the hourly rounding compliance rate increased to 64% from zero at baseline.[56] Hence, frequent rounding about pain that promotes nursing responsiveness to patient needs may have contributed to increasing the perception of less time in severe pain and a higher ability to cope with pain.

However, structured pain rounds did not have a relationship with participants' reports of less time in severe pain or lower average 24-hour pain scores. Despite reports by Jensen et al[53] regarding the validity of 24-hour pain score recall, challenges in accurately capturing patients' perceptions of postoperative pain using the faces scale exist. Anecdotally, many patients struggle with using the 0-10 numeric scale to communicate their level of pain, particularly when they are aware that a higher score might get them a stronger medication. Similarly, nurses may discount patients' reported pain scores that can lead to undertreatment or overtreatment of pain.[51] Others have suggested that using a numeric rating scale that integrates a functional assessment of pain-related impact on activities may be a more appropriate measure of patients' self-reported pain.[57] Clearly, opportunities exist in identifying effective strategies to comprehensively target pain management and in adopting reliable and valid multidimensional outcome measures to drive quality improvement.

Even though the findings from this study support that the BITE Pain Therapy™ bundled intervention improved participants' perception of pain care quality, the intervention adherence did not support sustainability of the unit-based project. Project sustainability requires continued use of intervention components with sufficient intensity to sustain achievement of program goals and outcomes.[58,59] Therefore, identifying pragmatic methods to both measure adherence and capture facilitators and barriers to intervention fidelity is critical. In this study, intervention adherence was measured using patient recall for a 24-hour period rather than real-time methods to capture bundle component adherence and patient-related responses to individual bundle components. Although multiple strategies were used to improve unit-based intervention adherence—weekly communication of adherence rates, communication huddles, and soliciting information about adherence facilitators and obstacles—several factors during the 30-month intervention period contributed to failed intervention fidelity: changes in unit nursing leadership, high nurse turnover, and nurses' perception of increased burden associated with delivering nonpharmacologic menu options. The findings of a qualitative study describing nurse leaders' perceptions of facilitators and obstacles to unit-based pain improvement projects are similar to what we uncovered.[60] Tavernier and colleagues[60] concluded that sustainable improvement related to pain management projects required overcoming the pervasive barriers of dynamic organizational change and lack of staff involvement.

LIMITATIONS

Major limitations of the study are the failure of intervention fidelity, a sample from surgical units from one facility, and a sampling plan that limited recruitment to one day each month to capture the primary endpoint of a unit-based intervention study. In addition, data were not collected on the specific nonpharmacologic menu options selected and whether the participant perceived a benefit.

IMPLICATIONS

The BITE Pain Therapy™ intervention is pragmatic and can be easily tailored to include nonpharmacologic therapies that are low cost, easily accessible, and acceptable to a variety of culturally diverse populations in different acute care settings. Since the inception of our project, the American Pain Society (APS) published guidelines for the management of postoperative patients[61] that includes recommendations for behavioral/cognitive therapies such as guided imagery and music therapy as adjuncts to multimodal pharmacologic pain management. In addition, the Joint Commission[10] revised pain assessment and management standards effective January 1, 2018, to include involving patients in developing pain management plans that include setting realistic expectations and measurable goals and providing nonpharmacologic options for inpatient pain treatment. All 6 bundle components in our patient-centered, multidisciplinary BITE Pain Therapy™ intervention address the APS guidelines and Joint Commission recommendations that focus on effective pain management. All of the BITE Pain Therapy™ bundle components are congruent with the standard of nursing care. Offering adjunctive complementary therapy options such as aromatherapy, distraction activities (ie, puzzles, games), and individual handheld massagers is feasible on medical surgical units. In addition, opportunities to provide pet therapy and music therapy may be available by using institutional volunteer services.

Our findings identified that postintervention participants with acute pain alone, irrespective of whether they received all bundle components or not, reported less time in severe pain and more relief from pharmacologic analgesia. This finding is consistent with the findings of the National Database of Nursing Quality Indicators study[62] and suggests that healthcare providers do a better job with acute pain in the inpatient setting. Therefore, interprofessional education about comprehensively assessing and effectively managing both acute and chronic pain in the hospitalized adult is needed.

Finally, additional research is warranted to replicate this study at other types of inpatient facilities and in different patient populations. Studies should be designed to test care delivery processes that deliver the intervention without increasing nurses' burden of work. In addition, studies should explore strategies to assist healthcare providers to identify which patients will benefit from the bundled pain management strategies and/or individual bundle components.

CONCLUSION

Findings from this study support that medical surgical patients participating in this study who received all 6 components of the BITE Pain Therapy™ intervention reported significantly higher levels of perceived pain care quality compared to those who did not receive all bundle components. Therefore, a bundled approach to pain management may be more beneficial than unstandardized strategies. Challenges exist in implementing the complete bundle to all patients in pain.

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