Implementation of the revised-FLACC Observational Pain Scale on a Pediatric Unit

by

Amanda M. Hansen

Under Supervision of

Shari Simone DNP, CPNP-AC, FAANP, FCCM, FAAN

Second Reader

Mary Ellen Connolly DNP, CRNP

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Abstract

Problem: Children with developmental delays, cognitive impairments, and intellectual disabilities are more likely to receive pediatric specialty care leading to frequent hospitalizations and surgeries. This population has atypical pain behaviors and cannot self-report pain; therefore, they are at risk for the under recognition and treatment of pain. In a large academic hospital, a pediatric inpatient unit has a high population of children meeting this criterion. The current standard pain assessment for patients unable to self-report is the FLACC scale; however, the revised-FLACC (r-FLACC) is tailored to assess pain in this population and offers the opportunity for parent or caregiver input.

Purpose: The purpose of this quality improvement project was to implement and evaluate the r-FLACC pain scale for assessing pain in pediatric patients with developmental delays, intellectual disabilities, and cognitive impairments.

Methods: The practice change took place over 15 weeks on a pediatric medical-surgical unit. Nursing utilized the r-FLACC pain scale to quantify eligible patients' pain every four hours with parental involvement. Data collection included nursing compliance with the r-FLACC, parent or caregiver opportunity to individualize the pain scale on admission, r-FLACC scores, and pain interventions. Parent and caregiver perception of the child's pain assessment using the r-FLACC was assessed upon discharge anonymously. FLACC scores concurrently recorded in the electronic medical record by nurses were extracted and compared to r-FLACC scores.

Results: During implementation approximately three (15%) patients a day qualified for use of the r-FLACC pain scale. There were 465 observations for which both the FLACC and r-FLACC were collected across 15 patients. The r-FLACC pain scores were similar and often higher than

concurrent FLACC scores. Discharge surveys revealed parents and caregivers were satisfied with the r-FLACC pain scale and their child's pain management and treatment.

Conclusions: The r-FLACC scale adequately captured this pediatric population's pain and caregivers were satisfied with their child's pain management. The r-FLACC pain scale provided an opportunity to better recognize and treat pain in this population. Next steps include integration of the r-FLACC pain scale in the electronic medical record to be used in all pediatric areas.

Implementation of the revised-FLACC Observational Pain Scale on a Pediatric Unit

Children ages 3-17 diagnosed with a developmental disability continue to increase with a current national rate of 17.8% (Zablotsky et al., 2019). Children with developmental delays, cognitive impairments, and intellectual disabilities are more likely to have other medical conditions requiring frequent specialty care often leading to hospitalizations and surgeries (Schieve et al., 2012). These children are a vulnerable population at high risk for under recognition and treatment of pain in both acute and chronic settings (Hauer & Houtrow, 2017). These children are at risk for receiving less analgesics post-operatively due to the inability to self-report pain (Hauer& Houtrow, 2017). Barriers to accurate pain assessment include the individualized variation of atypical pain behaviors often demonstrated by these children (Crosta et al., 2014).

A pediatric surgical inpatient unit with a high population of children with developmental disabilities (11%) have inconsistent pain assessment practices for this patient cohort (Figure 1). The standard pain assessment for patients unable to self-report is the Face, Legs, Activity, Cry, Consolability (FLACC) scale. The FLACC scale is not tailored for this specific population and does not offer the opportunity for parent input regarding how their child expresses pain. The revised-FLACC (r-FLACC) pain scale is an edited, validated tool with specific and observable pain behavior descriptors tailored to children with developmental, intellectual, and cognitive delays with the option for caretakers to individualize the scale. Approximately 250 admissions per year could be eligible and benefit from the r-FLACC implementation, averaging about 4-5 patients per week. The purpose of this quality improvement (QI) project is to implement and evaluate the r-FLACC pain scale for pediatric patients with developmental and cognitive delays in an inpatient unit to improve pain recognition and treatment.

Literature Review

An evidence review was performed to evaluate the best pain scale for children with cognitive impairment, developmental delays, and intellectual disabilities to be used in the acute clinical setting. The evidence was rated and reviewed as seen in Table 1 and synthesized and given a quality rating in Table 2.

The American Academy of Pediatrics released a clinical report offering guidance for the clinician working with this population and concluded no one pediatric observational pain scale could be recommended over another but noted advantages of some assessment tools over others (Hauer & Houtrow, 2017). For instance, the r-FLACC is often rated higher by nurses and physicians for higher overall clinical utility. Four pain scales were identified as observational scales for hospitalized children with cognitive impairment: the Non-Communicating Child's Pain Checklist-Postoperative Version (NCCPC-PV), the Individualized Numeric Rating Scale (INRS), the Pediatric Pain Profile (PPP), and the r-FLACC (Crosta et al., 2014).

In Crosta et al.'s (2014) systematic review, studies evaluating the psychometric properties and clinical utility of these scales in the acute care setting were reviewed. All four scales focus on examining the following: facial expression, body activity, vocalizations, consolability and sociability. Both the INRS and r-FLACC support the importance of individualizing a pain scale through parent involvement. Of the four scales, the r-FLACC was determined to be the most appropriate to implement in the acute care setting. The r-FLACC was reported to be easy to use, applicable and manageable to complete under time constraints.

Malviya et al., (2006) and Pederson et al. (2015) proved the r-FLACC to be reliable and valid. Through eighty observations, Malviya et al. (2006) found the r-FLACC to have interrater reliability (ICC: 0.76-0.0, κ = 0.44-0.57), criterion validity (ρ= 0.65- 0.87, P <0.001), and

construct validity ($P < 0.001$). Pederson et al. (2015) studied 27 children with cerebral palsy unable to self-report and found the r-FLACC to be reliable and valid with internal consistency ($\alpha = 0.9023, 0.9758$) and construct validity (difference= 2.23, $p = 0.0397$).

Hla et al. (2014) conducted a large cohort study investigating the differences in pediatric pain assessment amongst children, parents, nurses, and independent observers in the acute post-operative setting. The sample included 307 children of which one hundred were nonverbal. Conclusions included that there is a tendency for healthcare professionals and an independent observer to underestimate a child's pain, whereas parent and child pain scores were more strongly correlated. Therefore, it was also concluded that parental scoring for non-communicative or children with cognitive impairment could be a reliable proxy for pain scoring. This emphasizes the importance of parent involvement and supports the edits of the r-FLACC to include parental input.

Chen-Lim et al. (2013) performed a 24-month QI initiative comparing and implementing the r-FLACC and PPP for children with cognitive impairments. Overall, the r-FLACC was shown to be favorable from a parent and nurse perspective leading to pediatric pain policy change and gradual implementation. The barrier reported post-implementation was clear nurse understanding of when to use the FLACC as opposed to the r-FLACC.

Despite the level of evidence ranging from level IV to VII, the quality is predominately graded an A or a B with only one C. Overall, the r-FLACC has been seen to be a valid and reliable pain assessment tool for this specialty population. It has been used successfully by clinicians in the acute care and post-operative setting and demonstrated strong clinical utility. The recommended practice change is to implement the r-FLACC pain scale in the pediatric inpatient setting.

Theoretical Frameworks

The middle range theory chosen for this implementation is Kolcaba's Theory of Comfort (Figure 2). This theory was chosen since it is easily applicable to pain management and has strong concepts that hold true in pediatric nursing. Kolcaba's Theory of Comfort describes how nursing includes the intentional assessment of comfort needs, the design of varying interventions to address these needs (i.e., medication, repositioning, environment changes), and the reassessment of a patient's comfort after these interventions (Kolcaba & DiMarco, 2005). It also discusses the types of comfort ranging from relief, ease, and transcendence all in the following varieties of context: physical, psychospiritual, environmental, and sociocultural. The theory acknowledges intervening variables in pain and comfort assessment such as developmental age similarly to how the r-FLACC is designed with a specific target population in mind. The theory promotes proactive assessment and patient care. Utilizing the r-FLACC pain scale could proactively provide better patient outcomes, pain control, and family-centered care.

The Framework for Complex Innovations described by Helfrich et al. (2007) is applicable to this implementation plan (Figure 3). The Framework for Complex Innovations focuses on tailoring implementation plans to align within an organization through strong relationships and connections for optimal success. The implementation climate is appropriate since there is organizational support through targeted team members including the following: a project faculty advisor, a clinical site representative, an administrative sponsor, nursing management and leadership, pediatric pain team clinicians, general pediatric surgery clinicians, pediatric orthopedic surgery clinicians, and nursing change champions. The use of champions as part of the implementation plan aligns with this framework emphasizing the need for multiple organizational team members involvement to achieve benefits of change. The idea for

implementation was fostered and created on-site enabling the implementation to align with nursing and provider values. Lastly, qualitative and quantitative assessments will be used to measure structure, process, and outcome measures to determine implementation effectiveness.

Methods

This project took place on a 20-bed inpatient pediatric surgical unit in a large academic teaching hospital. The population on this unit often includes children who have developmental delays, cognitive impairments, and intellectual disabilities prohibiting pain self-report using either the Wong-Baker FACES scale or 0-10 numeric pain rating. This population by nature includes some of the most vulnerable patients and implementing this practice change advocated for their unique needs.

The practice change involved formal in-person education for all registered nurses within the first 2 weeks of implementation. Forty-two registered nurses received education on the r-FLACC and demonstrated usability implications and proficiency during in-person education sessions. Two unit clerks were also educated on the project to be aware of paper data collection that needed to be removed from the patients' charts upon discharge. Incorporating the r-FLACC into daily practice from weeks 3 to 15 was achieved through structure and process changes in pain assessment including the opportunity for parent or caregiver involvement upon admission using a self-made Nurse Admission Guide (Appendix A) and a hands-on r-FLACC pain scale (Appendix B). Patient screening was conducted 2-3 times per week through unit census chart audits performed by the project leader or champions. Data collection included r-FLACC scores, pain interventions, and parent or caregiver opportunity to individualize the pain scale on admission (Appendix C). Parent and caregiver perception of the child's pain assessment using the r-FLACC was assessed upon discharge anonymously (Appendix D). FLACC scores

concurrently recorded in the electronic medical record (EMR) by registered nurses were extracted weekly through chart audits by the project leader. All data extraction occurred on a secure desktop in a private location. Any paper data was stored in a secure, locked location on site. The data was de-identified once data collection was complete to protect confidentiality. The large academic hospital where the project took place granted Institutional Review Board (IRB) approval for this QI project. The project was given a non-human research determination by both the large academic hospital IRB and the school of nursing IRB.

Initially, 100% of all registered nurses who worked on the unit were educated on the project. However, due to staffing shortages and unprecedented times throughout implementation, travel and supplemental nurses staffed on the unit for short-term assignments needed to be educated and informed on shift. Various new staff members coming and going on the unit occasionally prevented and hindered data collection on some shifts. To counteract this outcome, in-person education was done one-on-one with these select individuals, but new staff members were onboarded and intermittent during the entire 15 weeks.

Utilizing the Nurse Admission Guide went well, and parents were almost always offered to edit the pain scale on admission. Within the first two to three weeks of initiation when comparing r-FLACC and FLACC scores, it was noted that the FLACC scores were markedly higher than the r-FLACC scores. In this instance, re-education to the staff was performed about scoring the pain scale and paper copies of the r-FLACC scale were created to be put side-by-side the tracking tool in the patient chart for easy reference during week 5 and 6. This raised compliance and awareness and allowed successful tracking and sensical scoring of the r-FLACC every 4 hours for eligible patients for the duration of implementation. The EMR ‘sticky note’ feature enabled reminders to be placed in eligible patient charts to increase r-FLACC scoring

consistency and momentum during week 9. A run chart was used to display patient eligibility on the unit during week 10 (Figure 4). Lastly, unfortunately, some scoring data was inevitably lost because the r-FLACC was scored on paper and not removed from patient charts upon discharge.

Capturing parent and caregiver satisfaction with the r-FLACC pain scale met more barriers than anticipated. Announcements were made to staff during implementation at various time points through email, 'huddle' announcements, and monthly staff meeting minutes to increase survey responses. The EMR 'sticky note' feature enabled useful reminders to be placed in patients charts and did increase the likelihood of parent and caregiver surveys being performed during week 9, but many parents and caregivers remained uncaptured. Most patients were missing a parent or caregiver at the bedside either upon admission or throughout majority of the patient's stay impeding the surveying opportunity. Two patients' parents were given the survey, but they failed to fill it out and return it. Three caregivers successfully completed the survey.

Results

Frequent census audits during implementation showed approximately three (15%) patients a day qualified for use of the r-FLACC pain scale (Figure 4) aligning similarly with pre-implementation data that estimated approximately 3-4 (15-20%) per week would qualify. Nursing compliance with scoring the r-FLACC pain scale and parent or caregiver opportunity to individualize the pain scale on admission was measured (Figure 5). Overall, registered nurse r-FLACC scoring compliance was 49%. Upon admission, 67% of eligible parents and caregivers were given the opportunity to individualize the r-FLACC pain scale. Three parent and caregiver surveys, 19%, were successfully completed. All completed surveys reported satisfaction with the r-FLACC pain scale and their child's pain management. The most common pain interventions

reported by registered nurses were as follows: medication (31), repositioning (25), rest and/or distraction (17), and heat or cold (1).

There were 465 observations for which both the FLACC and r-FLACC were collected across 15 patients. Originally, 16 patients were included in the study; however, r-FLACC data was only available to 15 patients due to nurse error when collecting paper scoring. A paired t-test was conducted to assess whether the differences between the FLACC and r-FLACC were statistically significant (Figure 6). The mean FLACC score was .2667 on a 0–10-point scale. The mean r-FLACC score was .3204 on a 0–10-point scale. The mean difference between FLACC and r-FLACC scores was approximately 0.05 points. FLACC and r-FLACC scores were highly correlated at .916 ($p < .001$). On average, nurses reported significantly higher pain scores using the r-FLACC than the FLACC ($t = -2.406$, $df = 464$, $p = .016$).

Discussion

The QI project proved that the r-FLACC pain scale was both similar and superior to the traditional FLACC pain scale for children with developmental delays, intellectual disabilities, and cognitive impairments. The r-FLACC did prove to better capture pain than the FLACC in eligible patients as evidence by the mean r-FLACC scores being higher than the mean FLACC scores. Nurses reported significantly higher pain scores using the r-FLACC than the FLACC as a pain assessment scale. Earlier publications have similar results and found the r-FLACC to be a helpful, quick, and reliable tool for this population in acute care settings. Other publications also supported the r-FLACC due to the emphasis on parent involvement and the opportunity to individualize the scale for each patient. Compliance for offering parents or caregivers the opportunity to edit the scale on admission was decent (67%) but could have been improved. Parents or caregivers were often not at the bedside or available.

Barriers arose throughout implementation that impacted registered nurse r-FLACC scoring and parent or caregiver opportunity compliance. Some barriers impacting nurse scoring compliance included the scale not being included in the EMR, high patient acuity, and the use of supplemental registered nurses due to a staffing shortage in the aftermath of the COVID-19 pandemic. Other barriers impacting parent's or caregiver's opportunity to edit the scale on admission or anonymously receiving a discharge survey included guardianship issues, absent caregivers or parents, language barriers, complex discharges, and incomplete surveys.

These barriers sequentially limited overall QI project results. The paper scores were kept securely in patient's individual blue charts at the bedside, but some papers were not taken out of the chart by bedside nurses or unit clerks at discharge and sent to medical records limiting the data collection. Providing 'just-in-time' education to unfamiliar supplemental nurses and unit clerks increased the risk for missing or incomplete data collection. Unit audits were performed two to three times per week to try and capture all eligible patients and track compliance, but while auditing the census at one given time there was always the risk of missing patients present on the same day depending on admission or discharge times. In this acute care setting, the census changed rapidly and continually 24/7. The r-FLACC pain scale not initially embedded in the EMR did provide an added benefit to the project despite its potential negative impact on scoring compliance or overall data. If the r-FLACC pain scale was embedded within the EMR than simultaneous FLACC data, current practice, would have not been performed or collected limiting the comparability of the r-FLACC and FLACC scores. Lastly, there were only a total of 15 patients with both FLACC and r-FLACC data making the sample size small. Fortunately, scoring was performed every four hours on each patient and led to many observations (465) creating a large data set for analysis.

Conclusion

Children with developmental delays, intellectual disabilities, and cognitive impairments are currently a growing population utilizing specialty services leading to complex hospitalizations and surgeries. Hospital stays for these children are intricate and require mindful post-operative monitoring, assessment, and care. This QI project supports the importance of utilizing observational pain scales to quantify pain when one is unable to self-report. As suggested in the literature, the r-FLACC pain scale is most appropriate to adequately capture pain for children with developmental delays, intellectual disabilities, and cognitive impairments. The QI project results reinforce this notion.

Although this QI project was only performed on one pediatric medical-surgical unit, the significant results show an area for an improvement in this population's post-operative pain assessment and management. For sustainability, the r-FLACC will be matriculated in the electronic medical record and be used accordingly in similar pediatric settings for use on eligible patients. Parents and caregivers were satisfied with their child's pain management while using the r-FLACC which fostered a positive healthcare environment offering high quality care. Future projects or studies could be performed to assess if utilizing the r-FLACC regularly could shorten this population's post-operative length of stay. Further research could also investigate utilizing the r-FLACC to measure this population's pain outside of the acute setting.

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Tables

Table 1

Evidence Review Table

Citation: Hauer, J. & Houtrow, A. J. (2017). Pain assessment and treatment in children with significant impairment of the central nervous system. *Pediatrics, 139*(6), e1-e27. Retrieved from https://pediatrics.aappublications.org/content/early/2017/05/18/peds.2017-1002					Level VII
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"This clinical report aims to address, with evidence-based guidance, the inherent challenges with the goal to improve comfort throughout life in this vulnerable group of children."	Report of expert committee	N/A	N/A	N/A	No clear recommendation can be made for the best pain assessment tool in children with CI. The r-FLACC offers the option for parental involvement which is not offered in other tools. Other tools can underreport pain in children with CI who often have atypical pain behaviors. Clinical utility of r-FLACC has been reported highly from nurses and physicians.
Citation: Crosta, Q. R., Ward, T. M., Walker, A. J., & Peters, L. M. (2014). A review of pain measures for hospitalized children with cognitive impairment. *Journal for Specialists in Pediatric Nursing, 19*, 109-118. Doi: 10.111/jspn.12069					Level V
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The aims of this review were to examine pain measures for	Systematic review of descriptive/ qualitative studies.	Potentially relevant articles retrieved and appraised (n=54).	N/A	N/A	Four pain scales for children hospitalized with CI: NCCPC-PV, PPP, r-FLACC, INRS.

hospitalized children with cognitive impairment who are unable to self-report and to describe the best available evidence for their clinical utility in acute care settings."		Excluded after appraisal (n=47). Studies included in review (n=7). Inclusion criteria: - English - Human subjects - "Examines psychometric properties and/or clinical utility of a pain tool specified for children with CI in an acute care setting." - 1994-2012 Exclusion criteria: - Studies conducted in homes or residential settings. - Pain assessments not validated in English.			All have established validity and reliability, but each had varying clinical utility. The r-FLACC shows feasibility in acute care setting- reported to be easy to use, have realistic time requirements, and flexibility with caregiver input.
Citation: Pedersen, L. K., Rahbek, O., Nikolajsen, L., & Moller-Madsenm B. (2015). The revised FLACC score: Reliability and validation for pain assessment in children with cerebral palsy. *Scandinavian Journal of Pain, 9*, 57-61. https://dx.doi.ord/10.1016/j.sjpain.2015.06.007					Level VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The aim of this study is to assess reliability and validity of the r-FLACC pain score for use in Danish children with CP."	A measurement study.	Convenient sample of children with CP who were unable to self-report and were being admitted for a planned orthopedic surgery. The surgical procedure varied in severity.	Two methods to assess post-operative pain were used. 1. Observational Visual Analogue Score (VAS-OBS)- parents/ caregivers estimated the	Sample size was large enough based off the recommendation that "a factor analysis requires 4-10 subjects per item in the score." (5	Internal consistency was excellent for the two raters: Cronbach alpha- 0.9023 and 0.9758. Intra-rater reliability was proved by a test-retest and excellent. ICC= 0.97530

		27 children with CP unable to self-report pain were included and informed consent was obtained. 3-15 years old, 11 girls, 16 boys.	pain of the child during a 2-minute period. 2. A 2-minute video recording was done so that the patient could simultaneously be scored with the r-FLACC. Two RNs independently reviewed the video to assign a r-FLACC score. 10 out of 27 children had pre-operative baseline video-recordings done and had another RN assess a r-FLACC score based on the video one year later to assess construct validity and inter-rater reliability, respectively. All 27 caregivers filled out a preoperative questionnaire related to each subgroup of the r-FLACC to identify unique pain behaviors. Each video included a close-up of the face, legs, and total body.	items in the r-FLACC so an ideal size would be 20-50). Data analysis included: t-test, factor analysis, Cronbach's alpha, ICC, Pearson's coefficients. ICC criteria: Poor: 0-0.39, Fair: 0.4-0.59, Good: 0.6-0.74, Excellent: 0.75- 1.0	Inter-rater reliability was good. ICC= 0.74576 Construct validity was supported with a rise in r-FLACC scores post-operatively compared to preoperatively (n=17, difference: 2.23, *p*= 0.0397).
Citation: ****Although older this is the original study to demonstrate validity and reliability of r-FLACC when it was created**** Malviya, S., Voepel-Lewis, T., Burke, C., Merkel, S., & Tait, A. R. (2006). The revised FLACC observational pain tool: Improved reliability and validity for pain assessment in children with cognitive impairment. *Pediatric Anesthesia, 16*, 258-265. Doi: 10.1111/j.1460-9692.2005.01773.x					Level VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results

"Available assessment tools lack consistent reliability as pain measures in children with cognitive impairment (CI). This study evaluated the validity and reliability of the revised and individualized Face Legs Activity Cry and Consol ability (FLACC) behavioral pain assessment tool in children with CI."	A measurement study.	Convenient sample of children aged 4-21 with CI scheduled for elective surgery. 52 children ranging from 4-19 years old. 21 parents added individualized behaviors to the r-FLACC, whereas the rest agreed the descriptors in the tool were sufficient. 12 children self-reported and used either the Simplified Faces Scale, 0-10 Numbers Scale, or a Simple Word Scale.	Preoperatively: The child was evaluated if he or she could self-report pain. The parents also created an individualized r-FLACC with specific pain behaviors when applicable. Postoperatively: Two nurses scored pain using the r-FLACC before and after pain medication administration, and children self-reported a pain score (if applicable). Observations were videotaped and later viewed (3-4 weeks later) by experienced nurses blinded to analgesic administration to score the patient's pain level.	Sample size was large enough to satisfy the calculations needed to investigate interrater, test-retest, criterion, and construct validity. Spearman's ρ and ICC were used to measure the strength of association of scores. For before and after analgesic administration data, Wilcoxon signed rank tests were used. Correlations ≥ 0.6: good to excellent. Ƙ values > 0.41: adequate agreement. *P* <0.05: statistically significant.	Interrater reliability was supported and considered excellent (ICC ranged from 0.76 to 0.90) and had adequate κ statistics (0.44–0.57). Correlations between r-FLACC, parent, and child scores showed criterion validity (ρ= 0.65– 0.87; *P* < 0.001). There was a decrease in r-FLACC scores after pain medication administration showing construct validity (6.1 ± 2.6 vs 1.9 ± 2.7; *P* < 0.001).
Citation: Hla, T. K., Hegarty, M., Russel, P., Drake-Brockman, T., Ramgolam, A., & Ungern-Sternberg, B. S. (2014). Perception of pediatric pain: A comparison of postoperative pain assessments between child, parent, nurse, and independent observer. *Pediatric Anesthesia, 24*, 1127-1131. Doi: 10.1111/pan.12484					Level VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results

"To investigate differences in the assessment of pediatric pain between children, parents, nurses, and independent observers in the acute postoperative setting."	Cohort study.	Opportunistic sample. 307 children admitted to a day-stay surgical unit between January 2012-February 2013 recruited in the post-operative period. 100 children of 307 were nonverbal/ non-communicative. Broad patient demographics.	Assessments of pediatric pain through observation from perspectives of nurses, parents, children/ patients, and an independent observer. After enrollment, an independent observer (either a resident medical officer or research student familiar with protocols) recorded their own assessment first of the child. Parents and nurses then were provided with either NRS (for older children) or Wong-Baker FACES scale (for younger children) to then assess pain. The independent recorded each assessment, but all remained blind to other answers/ assessments.	To determine differences in assessment of pediatric pain amongst observers in an acute setting. NRS and Wong-Baker FACES assessment tools are reliable and valid pain assessment tools. Inter-rater reliability analysis using κ statistic was used to determine agreement between different observers.	In the able to rate pain group: Children and parents tended to record higher pain scores than nurses and independent observers but was not statistically significant. Agreement through Cohen's κ test showed slight agreement between different scorers (cohen's κ between 0.1-0.2). Unable to rate pain group: Scores between parents, patients, independent observer, and nurse were all in agreement. The nurse and independent observer were in better agreement (κ= 0.353). Parent scores can be used as surrogate measure for this population.
Citation: Chen-Lim, M. L., Zarnowsky, C., Green, R., Shaffer, S., Holtzer, B., & Ely, E. (2013). Optimizing the assessment of pain in children who are cognitively impaired through the quality improvement process. *Journal of Pediatric Nursing*, 27, 750-759. http://dx.doi.org/10.1016/j.pedn.2012.03.023					Level VI
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
"A quality improvement (QI) project involving evidence-based review of pain assessment tools,	Quality improvement study.	Patients from the postsurgical/ trauma unit and an inpatient rehabilitation unit.	A 24-month QI process: Once a patient with cognitive impairment was identified a folder with the PPP and r-FLACC tools, data	Nurse preference towards r-FLACC pain scale (*n*= 93, 74%).	The r-FLACC was favorable from both a parent and nurse perspective leading to pediatric pain policy

feedback from the Family Advisory Council, trialing of selected tools within clinical settings including obtaining feedback from nurses, and parents caring for nonverbal children with developmental delay was reported."		Sites were chosen due to high number of children with cognitive impairment experiencing episodic or acute pain.	collection forms, and questionnaires were placed at bedside. Bedside nurses were educated prior to implementation. Bedside nurses reviewed pain assessments with parents. After review of the tools, a parent questionnaire was administered. Pain assessments collected by RNs every 4 hours. At the end of each shift an RN questionnaire was also filled out. 6 month post-implementation audits.	Parent response preference was a bit more divided. 54% prefer the PPP, 46% prefer the r-FLACC. Nurses rated the r-FLACC to be more accurate than the PPP (75.2%). For home use, parents preferred the r-FLACC over the PPP (*n*= 26, 59%).	change and gradual implementation.

Rating System for Hierarchy of Evidence

Level of Evidence	Type of Evidence
I (1)	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT and/or reports of expert committees.
III (3)	Evidence obtained from well-designed controlled trials without randomization.

IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative study
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities

Table 2

Synthesis Table

Evidence Based Practice Question (PICO): In hospitalized children with developmental delays, cognitive impairments, and intellectual disabilities unable to self-report his or her pain, is the r-FLACC pain scale compared to current practice (FLACC) more effective for pain recognition and treatment?			
Level of Evidence	**# of Studies**	**Summary of Findings**	**Overall Quality**
VII	**1**	Hauer & Houtrow (2017) address the vulnerability of children with CI, developmental delays, and CNS impairments. Overall, consensus shows that this population is at risk for chronic and acute pain. This clinical report offers guidance for clinicians in pain management, pain identification, and varying pain treatments for this population. As far as pain recognition, no one scale could be recommended over the other; however, the r-FLACC has been seen to have some advantages for children with CI and can be implemented in the acute care setting.	A- In this clinical report, it is clear expertise is evident. All recommendations come from sound and thorough research or studies.
V	**1**	Crosta et al. (2014) examine pain scales for hospitalized children with CI. Of the four pain scales found through a thorough review of the literature, the r-FLACC is found to be reliable, valid, and have high clinical usability. In the acute care setting, the r-FLACC is easy and quick to use while having the added benefit of promoting parent involvement and family-centered care.	B- A reasonable thorough and appropriate search was performed. Fairly definitive conclusions were drawn, and consistent recommendations were made; however, more specifics on each study included in the review could be added. The internal and external criteria within the review was evident and well-defined.
VI	**3**	Pedersen et al. (2015) measured the reliability and validity of the r-FLACC in Danish children with CP. The r-FLACC was found to be reliable and valid in this population.	B- An appropriate sample size was formed and sustained throughout to run statistics and test for reliability and validity of the r-FLACC. Recommendations were made consistently, and scientific evidence was appropriately referenced.

		Melviya et al. (2006) implemented the r-FLACC in children with CI and assessed the reliability and validity of the tool. The edits made to the original FLACC were based in scientific and clinical findings. The r-FLACC was found to be reliable and valid in this population. Chen-Lim et al. (2013) published a quality improvement project at the Children's Hospital of Philadelphia comparing nurse and parent perspectives with implementation of the r-FLACC and PPP for children with cognitive impairments on two pediatric units. The r-FLACC was found to be more favorable from both a nurse and parent perspective overall.	B- The sample size was large and sufficient to run tests and statistics to test for both reliability and validity with the r-FLACC assessment tool. Definitions and statistics performed were detailed and thorough. There was an appropriate amount of scientific evidence referenced. The edits made to the original FLACC were based in clinical findings. C- The sample size was small. Not many quantitative and qualitative statistics were performed. Recommendations were made consistently, and evidence was appropriately references.
IV	**1**	Hla et al. (2014) investigate the differences in pain assessment perceptions. With a large sample size, pain assessment data is collected from patients, nurses, parents, and independent observers. Two groups were identified within the sample: those who could self-report pain and those who were unable to. Findings include that a parental pain scores can correlate with a child's perception of his or her own pain and can be used for those who are unable to self-report. It was also concluded the nurses and independent observers did tend to produce lower pain scores than children/ patients.	A- This was a large study with a sufficient sample size. Although no formal control group was used, results were consistent, and participants were blinded from each other's results. Data was collected and presented thoughtfully, and results were consistent with the literature.

Rating Scale for Quality of Evidence (Newhouse)		
High (A)	Scientific	Consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence
	Summative Review	Well-defined, reproducible search strategies; consistent results with sufficient numbers of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions
	Experiential	Expertise is clearly evident
Good (B)	Scientific	Reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
	Summative Review	Reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.
	Experiential	Expertise seems to be credible.
Low Quality (C)	Scientific	Little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn
	Summative Review	Undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn
	Experiential	Expertise is not discernable or is dubious
Newhouse, R. (2006). Examining the source for evidence-based nursing practice. JONA.Volume 36, Number 7/8, pp 337-340		

Figures

Figure 1

Current Flow Map: Prior to Implementation

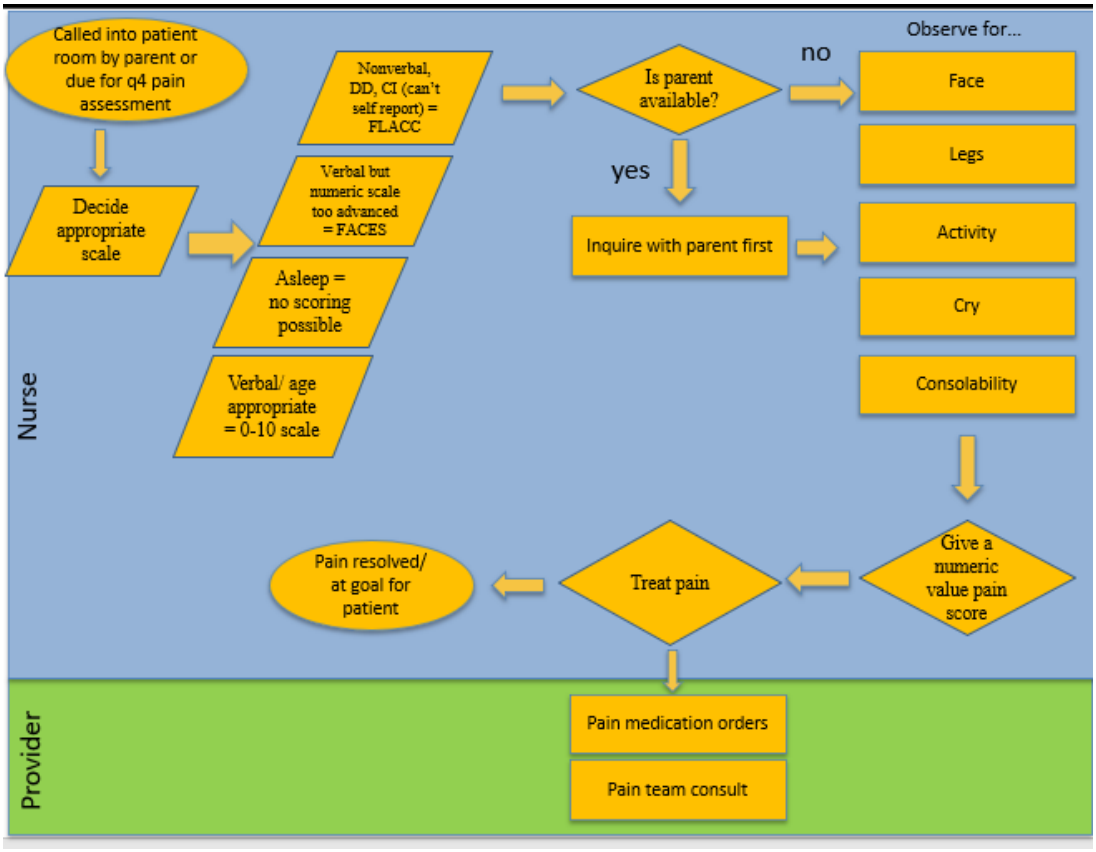


Figure 2

Comfort Theory Applied to Pediatric Nursing

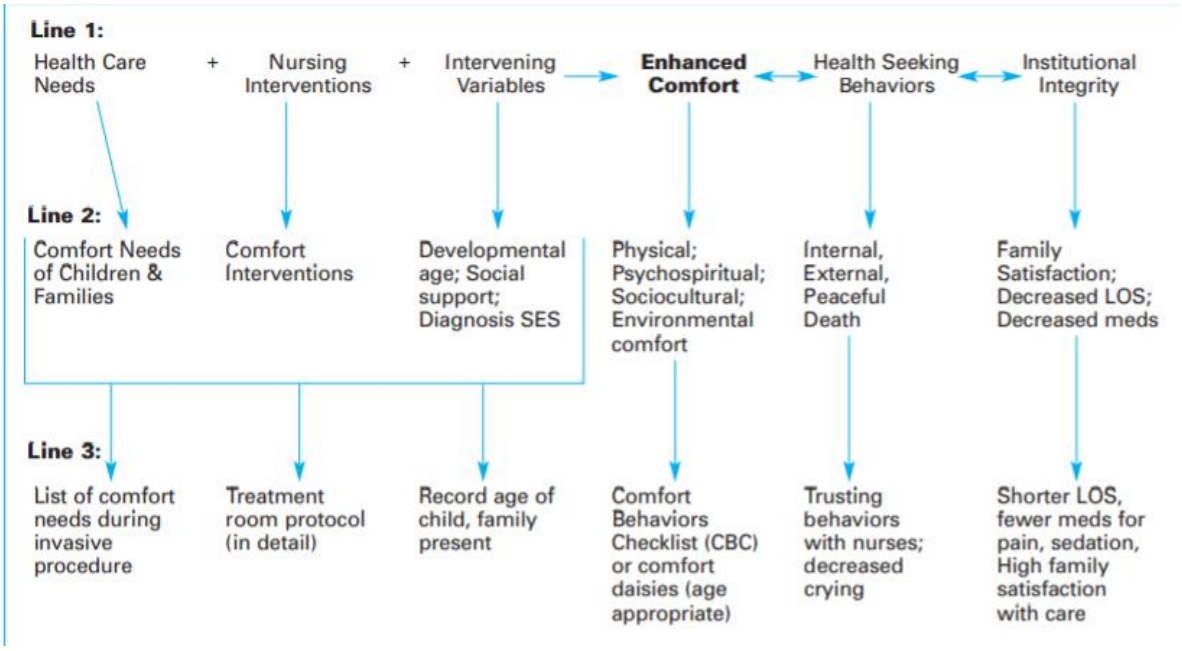
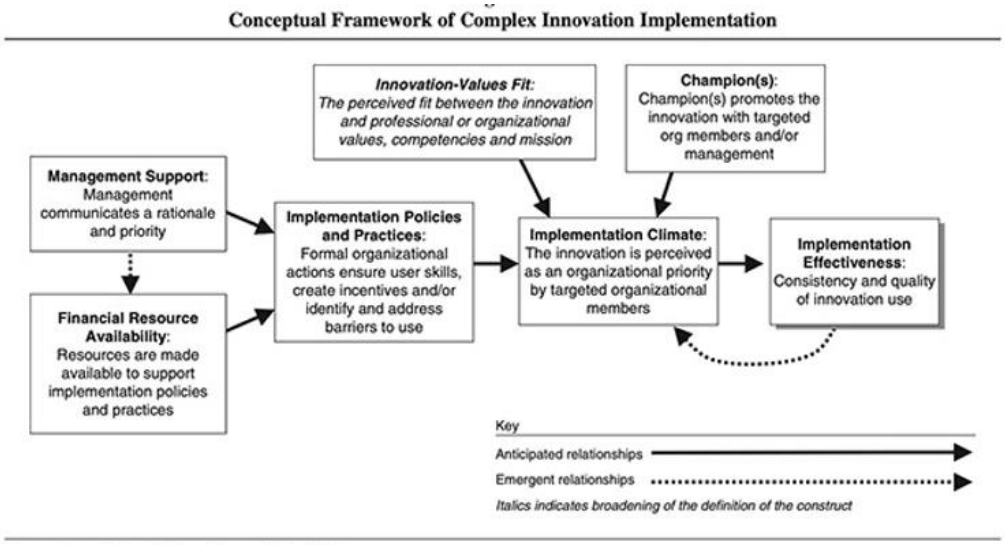


Figure 3

Conceptual Framework of Complex Innovation Implementation



Source: Adapted from Klein and Sorra (1996, 1056).

Figure 4

Patients Eligible for r-FLACC Pain Scale (N=16)

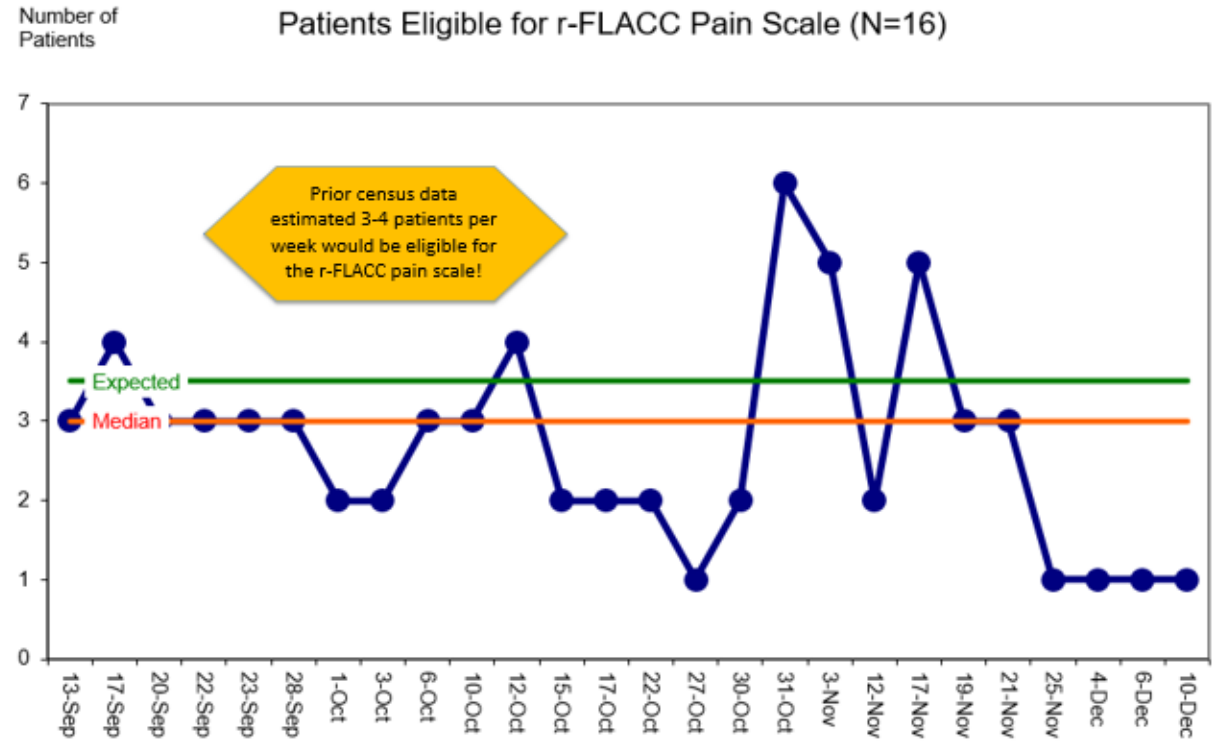
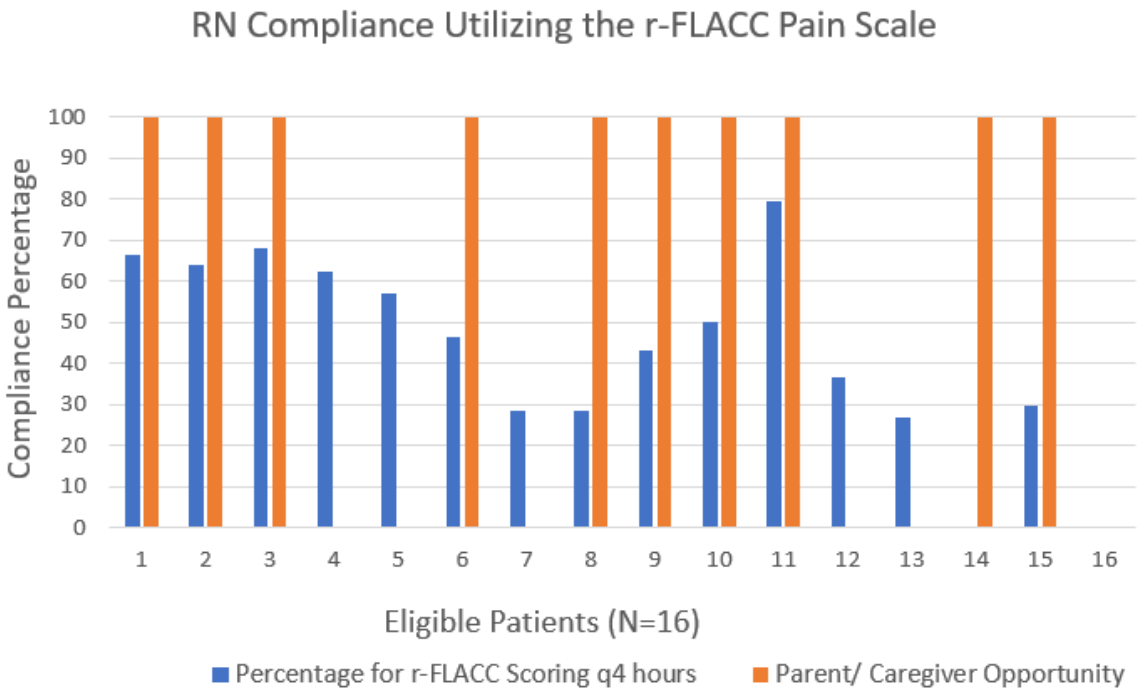


Figure 5

RN Compliance Utilizing the r-FLACC Pain Scale



Note: 2 patients excluded in compliance analysis due to missing data.

Figure 6

Paired t-Test: r-FLACC vs. FLACC

t-Test: Paired Two Sample for Means

	FLACC	*r-FLACC*
Mean	0.2667	0.3204
Variance	1.2563	1.4381
Observations	465.0000	465.0000
Pearson Correlation	0.9160	
Hypothesized Mean Difference	0.0000	
df	464.0000	
t Stat	-2.4069	
P(T<=t) one-tail	0.0082	
t Critical one-tail	1.6481	
P(T<=t) two-tail	0.0165	
t Critical two-tail	1.9651	

Appendix A

Nurse Admission Guide

If the child cannot self-report using the 0-10 numeric scale, would the child be able to use the following scale?

Yes= use it!

No= **

****Does he/ she have any of the following conditions or developmental delays:**

Cerebral palsy

Nonverbal

Autism

Other condition involving cognitive impairment

YES= Use the r-FLACC!

No= use the FLACC

Ask the caregiver about individual behaviors!

Examples of individual behavior in each category:

Face: pouty lip, biting lip

Leg: left leg with continued clonus

Activity: hits self, clenches fists, shivering

Cry: whining, says repetitive short phrases (ex: repeating 'all done')

Consolability: responds to head rubbing, favorite TV show

Appendix B

Hands-On r-FLACC Pain Scale

r-FLACC

Categories	0	1	2	INDIVIDUAL BEHAVIORS:
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, **sad, appears worried**	Frequent to constant quivering chin, clenched jaw, **distressed looking face, expression of fright/panic**	
Legs	Normal position or relaxed, **usual tone & motion to limbs**	Uneasy, restless, tense, **occasional tremors**	Kicking, or legs drawn up, **marked increase in spasticity, constant tremors, jerking**	
Activity	Lying quietly, normal position, moves easily, **regular, rhythmic respirations**	Squirming, shifting back and forth, tense, **tense/guarded movements, mildly agitated, shallow/splinting respirations, intermittent sighs**	Arched, rigid or jerking, **severe agitation, head banging, shivering, breath holding, gasping, severe splinting**	
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint, **occasional verbal outbursts, constant grunting**	Crying steadily, screams or sobs, frequent complaints, **repeated outbursts, constant grunting**	
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort, **pushing caregiver away, resisting care or comfort measures**	

Check if parent/ caregiver has none to add ☐

Appendix C

Tracking r-FLACC

De-Identified Patient ID: _________							
Pain Intervention (1= medication, 2= repositioning, 3= heat or cold, 4= rest/distraction)							
Parent/ Caregiver offered to edit scale on admission? (Yes=1, No=0): _________							
	Time of Day	00	04	08	12	16	20
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						
Day __	r-FLACC score:						
	Pain Intervention:						

Appendix D

Parent & Caregiver Satisfaction Survey

Check the box that best answers each question					
	Not at all 1	A little 2	Neutral 3	Somewhat 4	A lot 5
How useful and helpful was the tool in assessing your child's pain?					
How understandable were the descriptors of the tool?					
Do you think this tool adequately measured your child's pain?					
Were you satisfied with the patient's pain scoring and treatment?					