Process Evaluation of the Evidence-Based Practice Identification and Change Intervention to Improve Neonatal Pain Practices

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy

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Abstract

Pain management in hospitalized infants in the Neonatal Intensive Care Unit continues to be substandard despite the development and availability of evidence-based guidelines. The Evidence-based Practice Identification and Change (Lee et al., 2009) strategy is a multifaceted tailored intervention that has been used to promote evidence-based practice. However, the process of delivering the components of the intervention is not well understood and no valid measure for evaluating the fidelity of intervention implementation exists.

The overall objective was to develop and determine the face validity, content validity, construct validity, feasibility, and clinical utility of the Process Evaluation Checklist. Three prospective studies were conducted. In Study 1, the face and content validity of the Process Evaluation Checklist was determined. In Study 2, the construct validity of the Process Evaluation Checklist was examined by assessing the fidelity of implementing the Evidence-based Practice Identification and Change intervention in a clinical setting. In Study 3, the feasibility and clinical utility of the Process Evaluation Checklist was determined.

Overall, the face and content validity of the Process Evaluation Checklist was achieved. The intervention was implemented with high fidelity, supporting the construct validity of the
measure. A Research Practice Council, with assistance from an external facilitator and internal facilitators, implemented multifaceted knowledge translation strategies in the form of constant reminders to improve sucrose administration practices. Post intervention admission orders were significantly more likely to include sucrose, and odds of being administered sucrose were 13 times greater compared to baseline.

Beginning support was provided for the content and construct validity, feasibility, and clinical utility of the Process Evaluation Checklist for use with complex interventions. Using this measure to monitor intervention fidelity in different contexts and with different users over longer periods of time will provide additional support to the validity of the Process Evaluation Checklist.
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CHAPTER ONE

Introduction and Problem Statement

Infants hospitalized in Neonatal Intensive Care Units (NICU) are exposed to procedural pain from birth until discharge from hospital (Carbajal et al., 2008; Simons et al., 2003; Stevens et al., 2003). With increases in survival rates, especially in preterm and very low and extremely low birth weight infants (Jones, et al., 2005), hospitalized infants are exposed to frequent and ongoing diagnostic and therapeutic painful procedures (Carbajal et al., 2008; Johnston, Barrington, Taddio, Carbajal, & Filion, 2011; Johnston, Collinge, Henderson, & Anand, 1997; Simons et al., 2003). Simons et al. (2003) reported that infants underwent an average of 14.4 painful procedures per day within the first two weeks of admission to the NICU, while Carbajal et al. (2008) reported that infants experienced an average of 12 tissue damaging procedures per day. More recently, Johnston, Barrington et al. (2011) reported that infants from 14 Canadian NICUs had undergone, on average, 4 to 5 painful procedures per day. Stevens, Abbott et al. (2011) reported that infants in Canadian NICUs were exposed to a mean (M) of 7.2 (standard deviation [SD = 6.7]) painful procedures per day.

Although it appears that the frequency of painful procedures has declined, unrelieved acute pain in infants can lead to deleterious immediate and prolonged effects (Grunau & Tu, 2007; Hermann, Hohmeister, Demirakca, Zohsel, & Flor, 2006). Infants who are exposed to repeated painful procedures can experience alterations in pain processing and perception at the spinal and supraspinal regions (Anand & Scalzo, 2000; Bartocci, Bergqvist, Lagercrantz, & Anand, 2006; Slater et al., 2006). Exposure to repeated painful stimuli (e.g., heel lances) in early life has also been associated with peripheral tissue damage, and may lead to hyperalgesia and
hypersensitivity to subsequent painful stimuli (Fitzgerald, 2010; Taddio, Shah, Gilbert-MacLeod, & Katz, 2002). Furthermore, negative physiological, social, and cognitive outcomes can occur, especially in preterm infants who later develop heightened anxiety, depression, and hyperactivity (Grunau & Tu, 2007; Hermann et al., 2006). Repeated exposure to painful stimuli coupled with inadequate pain assessment and management while in the NICU could predispose infants to persistent or chronic pain (Stevens & Pillai Riddell, 2006). Exposure to frequent and repeated painful events is hypothesized to contribute to persistent pain problems, direct financial costs to the health care system, and indirect, emotional costs to parents (Lee, 2007; Stevens & Pillai Riddell, 2006). Therefore, it is essential to effectively manage pain in this population.

**Current Neonatal Pain Assessment and Management Practices**

Considerable evidence suggests that acute procedural pain remains poorly managed in infants (Carbajal et al., 2008; Johnston, Fernandes, & Campbell-Yeo, 2011). Simons et al. (2003) reported that analgesics to manage procedural pain were not administered to 39% of the study sample in the Netherlands. Johnston et al. (1997) found that analgesia or anesthesia was administered for only 6.8% of painful procedures. Stevens et al. (2003) indicated that 10% of infants at highest risk for neurologic impairment (NI) underwent the greatest number of painful procedures and received the least amount of opioids for procedural pain during the first few days of life. In a prospective assessment of neonatal pain practices that included real-time observation of health care professionals’ pain practices in infants at risk for NI, Stevens, McGrath et al. (2010) found that health care professionals were using a variety of pain assessment indicators to assess pain and implementing a wide variety of interventions for infants undergoing procedural pain; however, they did not document this information in the medical record consistently. Infants at moderate risk of NI had the highest number of pharmacological (i.e., topical
analgesics, opioids, sedatives) interventions administered compared to infants at high or low risk for NI (p < .05), while those at the highest risk for NI received the most behavioural (i.e., gentle care, talking/singing, clustered care, minimal handling, parental and additional health care provider involvement) interventions (Stevens, McGrath et al., 2010). Non-pharmacological interventions were more commonly used than pharmacological interventions, irrespective of the NI risk group. These findings suggest potential inconsistencies between pain practices that are documented in patient charts, which are often used as outcome indicators in published research, and actual health care professional behaviours when caring for infants undergoing painful events. Conversely, pharmacologic interventions were used more frequently than physical interventions in subgroup of Canadian NICUs (Stevens, Abbott et al., 2011).

Carbajal and colleagues (2008) reported that, of the 42,413 painful procedures performed on 430 infants, pharmacological interventions were administered to 2.1% of the infants, 18.2% were treated with non-pharmacological interventions, 0.4% with both types of interventions, and 79.2% received no preprocedural analgesia. Johnston, Barrington et al. (2011) reported that 46% of infants in NICUs who were exposed to tissue damaging procedures, and 57% who experienced non-tissue damaging procedures were not managed with analgesics. Opioids were administered for 14.5% of the tissue damaging procedures, while in 14.3%, sweet tasting solutions (i.e., sucrose or glucose) were used. Other non-pharmacologic interventions such the use of pacifiers were used infrequently (i.e., 16.3%) (Johnston, Barrington et al., 2011).

**Knowledge Translation: Bridging the Gap between Research and Practice**

Over the past decade, international pain guidelines, standards, and consensus statements have been developed to address the importance of assessing pain and providing the appropriate pharmacologic, physical, behavioural, and environmental interventions to manage pain in infants
(Anand, 2001; Batton, Barrington, & Wallman, 2006; Berry & Dahl, 2000; The American Academy of Pediatrics and Canadian Paediatric Society and the American Academy of Pediatrics, 2000; McGrath & Unruh, 2007). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (Berry & Dahl, 2000) and the Canadian Council on Health Service Accreditation (CCHSA) developed organizational standards for pain assessment and management in all patients in accredited health care institutions. The Neonatal-Pain Control Group summarized current evidence and recommendations for managing procedural pain, post surgical pain, sedation and analgesia for mechanical ventilation in infants, and implications for future research (Anand et al., 2006). Results from reviews of systematic reviews have also included evidence-based recommendations on pharmacologic and non-pharmacologic interventions to manage pain in infants (Yamada et al., 2008).

However, to date, there is little knowledge on the extent to which these guidelines, recommendations, and policies focusing on pharmacologic and nonpharmacologic pain strategies have been successfully translated into practice. Despite rigorous evidence on the effectiveness of pain assessment and management strategies, pain practices in infants remain a challenge; suggesting that there is a gap in translating evidence into clinical practice (Scott-Findlay & Estabrooks, 2006).

Johnston, Barrington et al. (2011) found no significant relationship between guideline availability and pain management practices in the NICU. However, the use of pain guidelines has the potential to bridge the gap between evidence-based research and health care professional practice through carefully planned and executed knowledge translation (KT) strategies. Knowledge translation may be understood as:
“A dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system.

This process takes place within a complex system of interactions between researchers and knowledge users which may vary in intensity, complexity and level of engagement depending on the nature of the research and the findings as well as the needs of the particular knowledge user (Canadian Institutes of Health Research [CIHR], 2011)

The traditional research to practice paradigm is often based on a direct, unidimensional, linear, rational approach to research utilization, where research is passively translated into practice (Nutley, Walter, & Davis, 2003). The process of translating knowledge or evidence into practice is not merely a mechanical or instrumental process, but rather, is interactive and complex. Passive dissemination of high quality, credible evidence-based pain guidelines are unlikely to result in behaviour changes when used alone; active approaches are more likely to be effective (Dopson, FitzGerald, Ferlie, Gabbay, & Lockock, 2002; Jamtvedt, Young, Kristoffersen, O’Brien, & Oxman, 2006; Rycroft-Malone et al., 2004).

Experiential or tacit forms of health care professionals’ clinical knowledge can influence the use of research evidence (Wood, Ferlie, & Fitzgerald, 1998). Therefore, there is a need to devise and implement innovative strategies to promote the uptake of knowledge/guidelines in the practice setting.

**Knowledge Translation Interventions Related to Pediatric Pain Practices**

The Evidence-Based Practice, Identification and Change (EPIC) strategy, also called Evidence-Based Practice for Improving Quality (EPIQ) is a multifaceted KT intervention, developed by Lee (2002) and Lee et al. (2009), to facilitate the translation of best pain practices for infants (Stevens et al., 2008). EPIC involves a group of interdisciplinary health care professionals who participate in identifying, developing, and implementing/facilitating tailored KT innovations based on current evidence using quality improvement methods to translate
evidence into clinical practice. Nested within the EPIC process is a combination of KT strategies including educational strategies, reminders, and audit and feedback. The goal of the EPIC intervention is to improve patient outcomes. The EPIC intervention has been used with some success in improving neonatal health care professionals’ practices in reducing nosocomial infections and bronchopulmonary dysplasia (BPD) in infants (Lee et al., 2009) and could be applied as a strategy to improve health care professionals’ pain practices. However, there is no clear, explicit indication of how the EPIC intervention was exactly delivered (Lee et al., 2009). As EPIC is complex and consists of interrelated components, which are tailored to the unit’s needs, challenges may exist in the implementation of EPIC within different contexts. Specifically, variability in the delivery in the EPIC components may be encountered during the tailoring of the intervention to the local contexts.

Process Evaluation/Fidelity of Complex Interventions

Implementation of guidelines that employ strategies to change health care professional behaviours are considered complex interventions (Medical Research Council., 2000). Often, details of the nature and implementation of the components of complex interventions are not reported which creates a “black box” limiting our understanding of the usefulness and effectiveness of these components (Hulscher, Laurant, & Grol, 2003). The complexity of these interventions may lead to variability in their implementation, which may influence achievement of desired/intended outcomes (Medical Research Council., 2000). In multisite studies, interventions may be delivered and received in different ways (Oakley, Strange, Bonell, Allen, & Stephenson, 2006). Methodological weaknesses reported in studies of complex strategies for practice guideline use/implementation have limited the external validity or generalizability of research findings (Grimshaw et al., 2004).
Process evaluations can serve to (a) provide prospective guidance to the implementation of the intervention, (b) examine the integrity or fidelity of intervention implementation, and (c) assist in interpreting results of an outcome evaluation when the results do or do not support effectiveness (Hulscher et al., 2003; Oakley et al., 2006; Rossi, Lipsy, & Freeman, 2004). Intervention fidelity refers to methods used to measure the degree of reliability and validity of intervention implementation to ensure that an intervention was implemented as planned (Bellg et al., 2004). As the components or active ingredients of interventions may change or transform during the implementation process, it is important to monitor the intervention fidelity (Rycroft-Malone, 2011).

In the Translating Research on Pain in Children Study (TROPIC; Stevens et al., 2008), the EPIC intervention was implemented in a prospective cohort comparative study of 16 of 32 units in eight participating Canadian pediatric hospitals. However, prior to its implementation, an evaluation of the delivery process and the usefulness of the components of the EPIC intervention was important to study and delineate, with the ultimate goal to guide replication on a broader scale and in different contexts (Bouffard, Taxman, & Silverman, 2003; Oakley et al., 2006; Sidani & Braden, 1998).

**Problem Statement**

Unrelieved pain in infants can lead to detrimental consequences in this vulnerable population. Despite efforts to improve pain assessment and management in infants through knowledge generation and the development of evidence-based practice guidelines and standards, health care professionals do not effectively translate or utilize research evidence to manage pain in infants in their day-to-day practice. As a result, there have not been acceptable, cost effective,
or significant improvements in pain assessment and management in infants (Lee, 2007; Simons et al., 2003; Stevens, 2002).

Translating research evidence into clinical practice is a complex process as it involves changing or modifying clinician behaviours. The strategies used in the EPIC intervention involve a complex process and the components are poorly articulated and substantiated in the literature. The complexity of the intervention poses challenges in the implementation and replication of its components and the evaluation of its impact on clinical outcomes in infants (Michie, Fixsen, Grimshaw, & Eccles, 2009). There is not a clear understanding of the process of delivering the components of the EPIC intervention to ensure the fidelity of the intervention implementation. Furthermore, there is no valid measure for evaluating the fidelity of implementing complex multifaceted KT interventions like the EPIC intervention.

**Purpose**

The purpose of this study was to develop, validate, and determine the feasibility and clinical utility of a process evaluation measure, specifically designed to parallel the steps of the EPIC intervention. The measure focuses on the assessment of the fidelity of the implementation of the EPIC intervention in the NICU context.
CHAPTER TWO

Review of the Literature

This chapter provides an overview of evidence to support the components of the EPIC intervention including evidence-based pain guidelines, and effective single and multifaceted evidence-based knowledge translation (KT) strategies. As the EPIC intervention is based on continuous quality improvement (CQI) methods, these methods as utilized in the NICU, are reviewed. The EPIC intervention is described, and empirical support of its effectiveness and potential to change health care professional pain practices is summarized. In addition, evidence is presented about health care professionals’ views regarding the barriers and facilitators for changing practices within the NICU. Finally, process evaluation and intervention fidelity measures are discussed.

Evidence-based Infant Pain Guidelines

Approximately 35 unidimensional, multidimensional and composite infant pain assessment measures have been developed and have undergone psychometric testing (Duhn & Medves, 2004; Hummel & van Dijk, 2006; Stevens, Pillai Riddell, Oberlander, & Gibbins, 2007). In a systematic review of 11 reviews conducted on acute pain interventions for hospitalized infants, five of the 11 highly rated reviews were focused on the evaluation of pharmacologic pain interventions and six reviews were on non-pharmacologic interventions (Yamada et al., 2008). Pharmacologic interventions that were supported for single painful procedures were premedication for intubation (Shah & Ohlsson, 2002), Dorsal Penile Nerve Block (DPNB) (Brady-Fryer, Wiebe, & Lander, 2004) and Eutectic Mixture of Local Anesthetics (EMLA®) cream for circumcision (Taddio, Ohlsson, Einarson, Stevens, & Koren, 1998; Taddio, Ohlsson, & Ohlsson, 1999), and oral sucrose for single painful procedures
Physical interventions that were effective for procedural pain were nonnutritive sucking or pacifiers (Pinelli, Symington, & Ciliska, 2002; Shiao, Chang, Lannon, & Yarandi, 1997), swaddling, holding, touching, positioning (Cignacco et al., 2007; Prasopkittikun & Tilokskulchai, 2003), and breast milk/breastfeeding (Shah, Aliwalas, & Shah, 2006). In addition, sensorial saturation and skin-to-skin care were effective nonpharmacologic interventions (Johnston, Fernandes, et al., 2011; Yamada et al., 2008). In a recent randomized controlled trial where sucrose versus water for heel lance in newborns was compared, there was a significant reduction in pain intensity using the Premature Infant Pain Profile (PIPP) (Stevens, Johnston, Petryshen, & Taddio, 1996) scores; however, there were no significant differences in the nociceptive brain activity and magnitude or latency of the spinal nociceptive reflex withdrawal between infants given sucrose versus sterile water two minutes prior to heel lance, which led the authors to question whether sucrose was analgesic (Slater et al., 2010). A number of methodological issues in the study by Slater et al. (2010) included (a) the small sample size, and therefore, the study might have been underpowered, (b) moderate attrition rates (i.e., 25% in EEG analysis; 42 % in the EMG analysis), (c) questionable methods used to measure and analyze EEG and EMG recordings (Heaton, Fernando, & Herd, 2011; Stevens, Craig, Johnston, Harrison, & Ohlsson, 2011; Vanhatalo, 2011), and (d) potentially insufficient doses of sucrose (i.e., 0.5 ml) administered to relieve pain in these full term infants (Linhares, Gaspardo, & Martinez, 2011). Therefore, methodological issues need to be addressed, and new evidence generated in light of the existing evidence.

**Single Knowledge Translation Strategies**

The Cochrane Effective Practice and Organization of Care Group (EPOC) is a collaborative review group within the Cochrane Collaboration. The focus of EPOC is to develop
systematic reviews to improve health care professional practices and the implementation of effective health services (Mowatt, Grimshaw, Davis, & Mazmanian, 2001). The EPOC group developed a data collection checklist for EPOC systematic reviews, which includes a classification of implementation strategies for translation of professional, financial, organizational, or regulatory interventions (Cochrane Effective Practice and Organisation of Care Review Group [EPOC], 2002). Implementation strategies include educational meetings, local consensus processes, educational outreach visits, local opinion leaders, patient mediated interventions, audit and feedback, reminders, marketing, and mass media (EPOC, 2002).

A systematic review of the literature on the effectiveness and efficiency of guideline dissemination and implementation strategies as defined by the EPOC taxonomy was completed on 235 studies consisting of 139 randomized controlled trials (RCT)s, 17 controlled clinical trials, 40 controlled before-after trials, and 39 interrupted time series (Grimshaw et al., 2004). Single KT strategies that have been widely used in guideline dissemination and that were reported in this review were reminders, educational materials, and audit and feedback. Overall, small to moderate improvements in patient care were reported. A median improvement of 14% was reported in 14 cluster randomized comparisons of reminders, 8% in four cluster randomized comparisons of the use of educational materials, 7% in five comparisons of studies evaluating the use of audit and feedback, a 6% improvement in 13 cluster randomized studies and four controlled before-after studies evaluating multifaceted interventions (Grimshaw et al., 2004).

**Reminders.** EPOC (2002) defined reminders as:

“Patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health care professional to recall information. This would usually be encountered through their general education; in the medical records or through interactions with peers, and so remind them to perform or avoid some action to aid individual patient care. Computer aided decision support and drugs dosage are included” (p. 9).
There are several forms of reminders that have been used in clinical practice. For example, administrative support reminders (van der Weijden & Grol, 2005) that include stickers on patient files have been used to remind or prompt health care professionals to implement or perform a specific pain practice. The use of reminders has been the most studied KT strategy to change health care professionals’ use of guidelines with small to moderate improvements in care across a variety of settings and health care professional behaviours (Buntinx, Winkens, Grol, & Knotnerus, 1993; Grimshaw et al., 2004; Prior, Guerin, & Grimmer-Somers, 2008). A systematic review of the use of on-screen point of care reminders to prompt health care professionals, for example to prescribe medications, demonstrated small to modest improvements in health care provider behaviours (Shojania et al., 2009).

**Educational interventions.** EPOC (2002) classified educational interventions into educational materials and educational outreach categories:

(a) “Distribution of educational materials includes published or printed recommendations for clinical care: clinical practice guidelines, audio-visual materials and electronic publications. Educational materials may be delivered to individuals or groups personally or through mass mailings” (p.9); and

(b) “Educational outreach visits (involve a trained individual who meets with health providers in their practice settings to provide information with the intent of changing the health provider’s practice. The information given may have included feedback on the performance of the provider(s). These educational sessions could take place as workshops or lectures” (p.9).

Although printed materials can be used to reach a large number of individuals, this KT strategy (including published articles and clinical practice guidelines) has been shown to result in small (i.e., 8%) changes in practice (Farmer et al., 2009; Grimshaw et al., 2004; Wensing & Grol, 2005). Educational interventions, specifically educational outreach, were the second most frequently studied intervention used to change health care professionals’ guideline use; they produced small to moderate improvements in care (Grimshaw et al., 2004; O’Brien et al., 2007;
Prior et al., 2008). Adult educational theories are based on the assumptions that interventions geared towards adults should be tailored to meet the needs and the learning styles of individuals (Grol, Wensing, Hulscher, & Eccles, 2005). Small scale interactive and didactic educational methods were more effective when used together (Forsetlund et al., 2009; Wensing & Grol, 2005). Educational meetings alone or combined with other KT strategies produced small effects on health care professional practices; however, they could contribute to positive patient outcomes (Forsetlund et al., 2009). Factors that could improve the effectiveness of educational interventions included assessing participants’ learning needs and addressing them in the intervention, encouraging active participation within the learning environment, utilization of an opinion leader, and increasing the duration and exposure to the intervention (Wensing & Grol, 2005). Educational outreach was often part of a multifaceted intervention (Grimshaw et al., 2004). When combined with educational materials, educational outreach was found to be an ineffective strategy (Grimshaw et al., 2004).

Grimshaw and colleagues (2004) found that the use of opinion leaders was inconsistent across studies included in their systematic review. The use of multidisciplinary committees in the delivery of educational interventions has also been a successful strategy to enhance research use in nurses and other health care professionals (Grimshaw et al., 2004; Thompson, Estabrooks, Scott-Findlay, Moore, & Wallin, 2007)

**Implementation strategies for pediatric pain guidelines.** Summaries for 17 studies that focused on educational strategies to promote implementation/use/application of pediatric pain guidelines are presented in Appendix A. Four studies were based on changing pain assessment and management practices for infants (Friedrichs, Young, Gallagher, Keller, & Kimura, 1995; Furdon, Eastman, Benjaman, & Horgan, 1998; Gallo, 2003; Geyer et al., 2002). In the 13
remaining studies, researchers focused on improving pain assessment and management practices in a variety of pediatric units such as post-operative care units, emergency departments and critical care units. Validated theories, frameworks, and models were used in six studies (Ellis et al., 2007; Howell, Foster, Hester, Vojir, & Miller, 1996; Johnston et al., 2007; Jordan-Marsh et al., 2004; Joyce, Keck, & Gerkensmeyer, 1999; Pederson, 1996) including the diffusion of innovation theory (Howell et al., 1996; Rogers, 2003), socioecologic theory (Smedley & Syme, 2000), the theory of planned behaviour (Ajzen, 1991), the Promoting Action on Research Implementation in Health Services (PARiHS) framework (Kitson, Harvey, & McCormack, 1998), and the Ottawa model of research use (Logan & Graham, 1998) to guide the design and evaluation of interventions.

All researchers focused on predominantly multifaceted educational strategies using educational outreach and educational materials to promote change in pain practices. Educational strategies included (a) educational materials (e.g., posters, reference guides, videos, and newsletters), (b) didactic approaches (e.g., formal in-service education classes), and (c) interactive methods (e.g., coaching, role modeling, use of focus groups). Task-based strategies referred to the didactic approaches to facilitating changes in practice (Harvey et al., 2002). Methods of facilitation used to change pain practices were primarily task-based in seven studies (Furdon et al., 1998; Gallo, 2003; Geyer et al., 2002; Joyce et al., 1999; Knoblauch & Wilson, 1999; Sheridan et al., 1997; Thompson, 2005). In two of the studies that focused on a task-based approach to changing health care professionals’ pain practice, researchers reported non-significant effects of the intervention (Joyce et al., 1999; Keck & Gerkensmeyer; Knoblauch & Wilson, 1999). In one of these studies, the time that elapsed before the first analgesic dose was
administered was longer post intervention implementation compared to preintervention (Knoblauch & Wilson, 1999).

In contrast, a holistic approach to KT included health care professionals as partners in the change process (Harvey et al., 2002). Facilitators enabled health care professionals to change their practice behaviours (Rycroft-Malone, 2004). A combination of task-based and holistic-based approaches were used in 10 studies (Duncan & Otto, 1995; Ellis et al., 2007; Friedrichs et al., 1995; Howell et al., 1996; Johnston et al., 2007; Jordan-Marsh et al., 2004; Meunier-Sham & Ryan, 2003; Pederson, 1996; Simons & MacDonald, 2006; Treadwell, Franck, & Vichinsky, 2002). All researchers reported positive effects of the interventions implemented.

Several researchers used interactive approaches to improve pain practices. In a cluster RCT, Johnston and colleagues (2007) used an interactive one-to-one coaching intervention in combination with audit and feedback. Nurse participants were provided with feedback from an audit of their pain practices and reflected on areas of improvement using a think aloud strategy. Coaches provided educational materials or sessions to facilitate practice improvements. Significant improvements were reported in the groups that received the coaching interventions in terms of nurses’ pediatric pain knowledge (p < .001), rates of documented pain assessments (p < .001), and use of nonpharmacologic interventions (p < .001). However, significant differences were found between sites that were not directly related to the effects of the coaching intervention.

Jordan-Marsh and colleagues (2004) used multifaceted educational initiatives to promote the adoption of the Poker Chip Tool (Hester, 1979) for pain assessment and the use of morphine as the analgesic of choice for postoperative pain. An interdisciplinary group of clinicians and administrative staff participated in this two year intervention. Nurses had access to and support
from the director of nursing research as well as from a visiting nurse researcher/consultant whose expertise was in pediatric pain. The director of nursing research, a nurse manager and a clinical nurse specialist were project leaders in this study, and staff nurses were recognized as collaborators in decision making processes throughout the intervention (Jordan-Marsh et al., 2004). The pain initiatives proposed by Jordan-Marsh et al. (2004) were in line with the hospital’s strategic plan and organizational commitment to pain management. Formal leaders who were committed to research based practice and shared the common goal of improving pain practices were members of an interdisciplinary team of directors of pediatrics, pharmacy and nursing research, a clinical nurse specialist, nurse manager, and pediatric anesthesiologist (Jordan-Marsh et al., 2004). These individuals organized the intervention strategies and engaged staff members to become informal leaders and role models. This two year intervention resulted in increases from baseline in pain intensity assessments (30% increase), and unit doses dispensed for acetaminophen with codeine (100% increase, p < .002) and morphine (455% increase, p = .0001). There was also a significant reduction in the distribution of meperidine (250% reduction, p = .0004). These changes were sustained for up to two years after the intervention.

Howell and colleagues (1996) included a process evaluation to describe staff nurses’ use of the pain assessment and management strategies in their practice. An educational intervention was administered to nurses over a six-month period. A Feasibility Rating Scale (FRS) was used to determine participants’ opinions about the formal training classes, the utility of pain management materials, efficacy of the pain program, perceived benefits of the program for patients, and how well the educational program had improved pain assessment and management skills. Scores on the FRS reflected a moderate level of perceived helpfulness of the strategies used (M = 3 out of a maximum score of 4). A focus group session led by an individual external
to the program, explored participants’ perceptions of the program and was conducted at the end of the study. Evaluation of the change process highlighted what strategies worked and what did not work. A core group of nursing staff described that they were moderately or well prepared for the change in pain practices. Pain assessment and management aids used to change practices were rated as moderately helpful and the program was perceived as being beneficial to the patients and compatible with existing policies. A staff nurse liaison, who acted as a change agent in the unit, was regarded as an integral instigator in promoting practice changes in the unit. Despite organizational changes that occurred during the study period, the use of pain management forms increased by 77% at the follow-up period.

**Audit and feedback.** EPOC (2002) defined audit and feedback as:

“Any summary of clinical performance of health care over a specified period of time”. The summary may also have included recommendations for clinical action. The information may have been obtained from medical records, computerized databases, or observations from patients” (p.9).

Feedback from colleagues or individuals in positions of authority is provided retrospectively to individuals, or groups regarding their practice that has been monitored over a specified period of time (van der Weijden & Grol, 2005). Variations exist in the content of the information obtained, how the information is gathered and the duration of data collection. In a systematic review of 118 RCTs evaluating the effects of audit and feedback alone or in combination with other strategies such as educational meetings and multifaceted interventions on health care professionals’ practices, results varied from a negative effect (16% absolute reduction in compliance) to small to moderate positive effects (70% increase in compliance) (Jamtvedt et al., 2006). When evaluated as a component of a multifaceted intervention, the contribution of audit and feedback as a KT strategy was small (Grimshaw et al., 2004; Jamtvedt
Similar to reminders, providing feedback in a timely manner or close to the time that health care professionals make decisions, could improve the use of feedback strategies (Hysong, 2009; Jamtvedt et al., 2006). Feedback that is focused on individual performances rather than aggregated data, and that is non-punitive, and goal oriented has been shown to be an effective approach to implement clinical practice guidelines and to maintain adherence to guidelines (Hysong, 2009; Kluger & DeNisi, 1998). Duncan and Pozehl (2001) reported that verbal and written feedback were effective methods used to disseminate results of an audit to nurses on their adherence to pain guidelines. Audit and feedback strategies are thought to be more effective when baseline practices are low and the feedback is delivered intensively (Jamtvedt et al., 2006). Based on these divergent findings, although audit and feedback could be effective in improving professional practice, mandatory use of this strategy was not warranted based on current evidence (Jamtvedt et al., 2006).

**Multifaceted Interventions**

Multifaceted interventions consist of two or more components or variations of a KT intervention(s) delivered in combination to change practice (Sidani & Braden, 1998; Wensing & Grol, 2005). For example, multifaceted educational interventions can include a combination of educational approaches such as use of materials and small and large scale sessions (Wensing & Grol, 2005). Wensing and Grol (2005) reported, in an overview of 19 systematic reviews of controlled trials focusing on multifaceted interventions that, although combined interventions were effective in approximately half of the systematic reviews, no one particular combination of interventions was superior due to the heterogeneity of the types of interventions used in the studies included in the reviews.
In a systematic review on the effectiveness of the dissemination of guidelines, Grimshaw et al. (2004) reported that educational materials were most frequently used in multifaceted interventions, followed by educational meetings, reminders, and audit and feedback; however, there was no relationship noted between the number of strategies comprising the intervention implemented and the degree of improvement in health provider practices. The authors compared multifaceted interventions to no intervention controls and to other intervention controls. A summary of these comparisons is in Table 1. Overall, multifaceted interventions were no more effective than single interventions and their effectiveness was not improved by including additional KT strategies (Grimshaw et al., 2004). Similarly, in a review of 14 studies on guideline dissemination in allied health professions, multifaceted KT strategies were no more effective than single strategies (Hakkennes & Dodd, 2008). Moreover, the use of additional KT strategies was not likely to improve effectiveness of guideline use (Hakkennes & Dodd, 2008). Conversely, Prior et al. (2008) reported on the effectiveness of strategies used to implement clinical guidelines from results of 33 systematic reviews. The most effective KT strategies included the use of multifaceted interventions such as interactive education sessions and clinical reminder systems. Ineffective single strategies included didactic education, printed educational materials, and clinical practice guidelines posted on websites (Prior et al., 2008). To date, the most effective KT components in multifaceted strategies have not been clearly described.
Table 1

Effects of Multifaceted Intervention Strategies to Promote Guideline Use (Grimshaw et al., 2004)

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Effects of strategy</th>
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</thead>
<tbody>
<tr>
<td>Educational materials + educational outreach vs. no intervention controls</td>
<td>Ineffective</td>
</tr>
<tr>
<td>Educational materials + educational meetings + educational outreach vs.</td>
<td>Modest to moderate effects</td>
</tr>
<tr>
<td>no intervention controls</td>
<td></td>
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<tr>
<td>Educational materials + educational meetings vs. no intervention controls</td>
<td>Small to modest effects</td>
</tr>
<tr>
<td>Educational materials + audit and feedback vs. no intervention controls</td>
<td>Modest effects</td>
</tr>
<tr>
<td>Educational materials + educational meetings + audit and feedback vs.</td>
<td>Small effects</td>
</tr>
<tr>
<td>no intervention controls</td>
<td></td>
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<tr>
<td>Educational materials + educational meetings + organizational interventions</td>
<td>Small effects</td>
</tr>
<tr>
<td>vs. no intervention controls</td>
<td></td>
</tr>
<tr>
<td>Educational materials + reminders vs. educational materials</td>
<td>Educational materials + reminders more</td>
</tr>
<tr>
<td>educational materials</td>
<td>effective than educational materials alone</td>
</tr>
<tr>
<td>Educational meetings + reminders vs. educational meetings</td>
<td>Educational meetings + reminders more</td>
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<td>educational meetings</td>
<td>effective than educational meetings alone</td>
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<td>Educational materials + educational meetings + educational materials +</td>
<td>Educational materials + educational</td>
</tr>
<tr>
<td>reminders vs. educational materials + educational meetings</td>
<td>meetings + reminders more effective than</td>
</tr>
<tr>
<td>educational meetings</td>
<td>educational materials + meetings alone</td>
</tr>
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</table>
**Summary.** The evidence to date remains unclear as to what types of KT strategies (i.e., single versus multifaceted interventions) are the most effective to promote the translation of evidence-based guidelines into practice. The use of reminders, educational interventions including educational materials, educational outreach strategies, meetings, and audit and feedback sessions alone, or in combination have demonstrated various degrees of effectiveness. Very few researchers reported whether their studies were guided by relevant theories or theoretical frameworks (Farmer et al., 2008). Wensing, Bosch, and Grol (2009) referred to the process of selecting the appropriate KT strategy as an “art”, and that implementing KT strategies should be tailored to the goals and barriers of the practice change (Wensing et al., 2009).

**Multifaceted Interventions Using Continuous Quality Improvement (CQI) Methods**

Continuous quality improvement (CQI) or improvement collaboratives are based on the principles of quality management and focus on changing health practice at the level of the organization (Plsek, 1999; Shortell, Bennett, & Byck, 1998). This multifaceted method applied to health care professionals to affect change is based on the model for improvement articulated in iterative and cyclical stages developed by Deming (1986) and adopted by Langley, Nolan, Nolan, Norman and Provost (1996). The science of improvement refers to the methods used to develop, test, and implement changes that could improve practice.

The knowledge assumed in quality improvement (QI) methodology includes an understanding of the interactions between people and processes within a system (e.g., NICU) (Berman, 1997). The improvement model includes three objectives (a) to develop the aim or change initiative, (b) to identify indicators of improvement, and (c) to determine changes that would result in improvement.
The Plan-Do-Study-Act (PDSA) cycle consists of four steps including (a) a planned activity, (b) implementation of the activity, (c) analysis of the data, and (d) an action based on the knowledge learned during the cycle (Langley et al., 1996). The cycle of improvement is based on measuring small scale tests of change over time. The underlying assumption of testing small cycles of change is that it allows for systematic reflection of change, and is considered to be superior to the “all-or-none” adoption of new innovations (Kilo, 1998). These cycles of change could be used to build knowledge to test and implement a practice change. Multiple cycles are required during the implementation process and social aspects of the change (i.e., interactions) need to be recognized.

The idea behind multiple or rapid cycles is that each cycle should lead closer to a permanent change in how things are done (Langley et al., 1996). The assumption is that increased frequency and number of cycles will sequentially build/develop knowledge, which will lead to increased improvements in practice (Langley et al., 1996). The complexity of tests of change are placed on a continuum or scale of formality, where the least formal and complex tests require less effort to introduce change whereas the more complex and formal changes require more resources (Langley et al., 1996).

A review of multifaceted CQI strategies in the NICU. A search of the Cochrane Database of Systematic Reviews revealed no systematic reviews of CQI strategies to change health care professional practices. In 2003, the Neonatal Intensive Care Quality Improvement Collaborative 2000 (NIC/Q 2000) with the Vermont Oxford Network formed a collaborative of 34 NICUs across the United States. Over a three year period, collaborative CQI initiatives were completed using a descriptive case series approach. Of the six targeted areas, four included the following morbidities (a) chronic lung disease (Burch et al., 2003; Sharek et al., 2003), (b)
nosocomial infection (Kilbride, Powers, et al., 2003; Kilbride, Wirtshafter, Powers, & Sheehan, 2003), (c) infant nutrition and necrotizing enterocolitis (Kuzma-O'Reilly et al., 2003), and (d) intraventricular hemorrhage and brain injury (Carteaux et al., 2003; McLendon et al., 2003). The CQI processes included literature reviews, analysis of local practices, benchmarking practices across hospitals, development of strategies using rapid cycles of change, and analysis and feedback of results of the practice change. Effects of the implementation of KT strategies on patient outcomes were mixed for intraventricular hemorrhage and brain injury (McLendon et al., 2003). Positive results were reported for nosocomial infection (Kilbride, Wirtshafter, et al., 2003) and nutrition practices (Kuzma-O’Reilly et al., 2003), and non-significant effects of implementation strategies were reported for chronic lung disease (Burch et al., 2003; Sharek et al., 2003).

As a follow-up to the NIC/Q2000, the Neonatal Intensive Care Quality Improvement Collaborative 2002 (NIC/Q 2002) included 46 NICUs in both the United States and Canada. Of the seven targeted areas, improvement strategies focused on bronchopulmonary dysplasia (BPD) (Payne, LaCorte, Karna et al., 2006; Payne, LaCorte, Sun et al., 2006), and pain and sedation (Dunbar et al., 2006; Sharek, Powers, Koehn, & Anand, 2006). The incidence of BPD was reduced (Payne, LaCorte, Karna et al., 2006; Payne, LaCorte, Sun et al., 2006). As quality improvement methods involve an understanding of the interactions between people and processes within an organization (Berman, 1997), all CQI initiatives in this review included a combination of both task focused and holistic methods to implement a variety of multifaceted KT strategies to promote practice changes. A summary of the CQI strategies in the NICU from collaboratives is in Appendix B.
**CQI and pain practices in the NICU: Descriptive studies.** Within the NIC/Q 2002 collaborative, Dunbar et al. (2006) implemented potentially better pain practices in 12 American NICUs using multidisciplinary QI teams. These teams implemented a variety of practice changes using PDSA cycles to evaluate the implementation strategies. To promote improvements in pain assessments in infants, the following strategies were used: (a) workshops on using the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) (Hummel, Puchalski, Creech, & Weiss, 2008), (b) leaving or having N-PASS cards at the bedside, (c) one-to-one bedside teaching, (d) a 30 minute video, (e) posters, (f) articles, (g) question and answer cases, (h) newsletters, (i) reminder stickers, and (j) structural changes in patient charts for pain assessment documentation. Strategies used to promote reduction in endotracheal suctioning included one-to-one or small group or educational in-services. Efforts to improve the use of sucrose for heel lances included: (a) allowing sucrose to be administered by nurses as needed, (b) providing staff education in the form of posters, emails, presentations at meetings, skill building workshop, (c) using champions or “super users” of sucrose to promote the practice change (including phlebotomists in the process), and (d) presenting regular feedback regarding sucrose use. Feedback provided to staff regarding the benefits of continuous opioid infusions for mechanically ventilated infants was used to obtain buy-in for this strategy. Efforts to improve postoperative pain assessment and management included bedside pain rounds. Finally, strategies used to assist weaning of opioids in infants included the addition of a protocol for opioid withdrawal, and a tracking system for infants at risk for iatrogenic opioid withdrawal.

Results of this descriptive series of case studies on improving pain practices in the NICU (Dunbar et al., 2006) showed improvements in (a) the management of endotracheal tube
suctioning, (b) pain assessment, (c) sucrose use during heel lance, d) post operative pain management, and (e) assessments and plans for weaning of opioids.

In an earlier study, Friedrichs et al. (1995) identified the need to improve pain assessment and management in the NICU based on practice issues raised by clinicians. The intervention strategy was developed by a Pain Task Force including a physician, nurse manager, staff nurse, and pharmacist. The intervention included a 2-hour educational program on pain physiology and pain management, the development of the NICU Infant State Assessment Tool, and additional multidisciplinary pain rounds with the goal of improving pain assessment and management in a single NICU. After three rapid cycles of change, an improvement in pain assessment and documentation was noted two years after introducing the practice change.

**CQI practices in the NICU: Prospective analytic studies.** Horbar et al. (2004) evaluated 114 NICUs where 57 units implemented a CQI initiative using literature reviews, interactive workshops, audit and feedback, and ongoing support for participants. Infants in the intervention group were more likely to receive surfactant in the delivery room (adjusted OR = 5.38, 95% CI [2.84, 10.20], were less likely to receive surfactant more than 2 hours after birth (adjusted OR = 0.35, 95% CI [0.24, 0.53], and were administered the first dose of surfactant earlier after delivery compared to the control group (adjusted hazard ratio =1.57, 95% [1.42-2.07]).

In a cluster RCT, Walsh and colleagues (2007) used a multimodal approach including potentially better practices to improve survival free bronchopulmonary dysplasia (BPD) to 36 weeks post-menstrual age in infants with birth weights under 1250 grams. Over a two year period, practice changes that were chosen based on collaboration with benchmarked centres as well as from systematic reviews of the literature resulted in no significant differences between
the intervention and control NICUs, with respect to the frequency of survival free BPD (Walsh et al., 2007).

**Summary.** CQI methods with PDSA cycles have been used effectively in NICU settings to promote practice changes. A variety of KT strategies were implemented to improve treatment and outcomes. Strategies that focused on improving pain practices in the NICU consisted of interactive educational strategies, reminders and audit and feedback, using different methods to deliver these strategies such as encompassing bedside rounds, posters, stickers, emails, presentations, newsletters, and unit champions (Dunbar et al., 2006; Friedrichs et al., 1995). The EPIC intervention incorporates CQI methods and includes the delivery of KT strategies to change health care professional behaviours (Lee et al., 2009).

**Evidence Based Practice Identification and Change (EPIC) Intervention**

In 2000, Lee and colleagues developed the Canadian Neonatal Network (CNN)™, a national neonatal database, and demonstrated that risk adjusted mortality rates using a validated measure, the SNAP: II (Richardson, Corcoran, Escobar, & Lee, 2001), neonatal morbidities (Sankaran, Chien, Walker, Seshia, & Ohlsson, 2002), and intraventricular hemorrhage rates (Synnes, Chien, Peliowski, Baboolal, & Lee, 2001) were related to differences in health care professional practices. Rooted in CQI methodology, Lee (2002) and Lee et al. (2009) developed the EPIC intervention to change health care professionals’ practices in the NICU setting. EPIC is an interactive, multifaceted, complex CQI intervention. In EPIC, evidence and systematic reviews of the literature are merged, potential practice changes using outcomes and practice data are identified, and a collaborative of credible, interdisciplinary health care professionals, who participate in developing and implementing KT strategies to improve patient care (Lee et al., 2009) are involved. Potential methods to improve existing pain practices are examined by (a)
planning to test a change in practice, (b) doing/implementing the test, (c) studying the results, providing feedback to participants, and (d) developing action plans based on what was learned through rapid cycles of change. EPIC differs from traditional CQI methods, as practice strategies are not adopted as “packages” of practice changes identified from benchmarked hospitals that report good outcomes (Lee et al., 2009). Instead, specific tailored strategies are developed for the individual participating centres based on data from these institutions and from current literature (Lee et al., 2009).

Evidence on the effectiveness of EPIC. The effectiveness of the EPIC intervention was tested in a cluster RCT, where six NICUs were randomly allocated to a nosocomial infection (NI) group or a bronchopulmonary dysplasia (BPD) group. Five NICUs served as a control group (Lee et al., 2009). The EPIC intervention consisted of two Phases. In Phase 1 Preparation Phase, which took place during the first year of the study, site investigators at each participating hospital were trained on critical appraisal skills, systematic reviews of the literature, and CQI methods, NI, and BPD. Site investigators from the NI and BPD groups identified research questions related to NI or BPD, conducted systematic reviews related to these topics, and reported their findings to their group. At each participating hospital, a multidisciplinary team consisting of the site investigator, nurse manager, educator, quality improvement specialist, infection control nurse or respiratory therapist, and a member of the executive team was formed. Further training during a two day workshop was given to this group. Barriers to change were identified during focus group sessions that were conducted with health care professionals and parents. Based on the evidence from systematic reviews, baseline practice audits, and qualitative reports from the focus groups, teams at each hospital generated a list of potential practice changes related NI and BPD. During Phase 2 Implementation and Change Phase of EPIC,
hospital teams implemented strategies to reduce NI and BPD rates over a two year period. A variety of KT strategies were implemented including the use of in-services, information packages, newsletters, order sheet prompts, posters, computer based resources, and feedback reports provided during rapid cycles, each lasting one to three months. By the end of the study, incidence rates for NI were significantly reduced by 32% in the NI group (OR for a one year incidence change = 0.82, 95% CI [0.72, 0.93], and by 45% reduction for NI in the BPD group (OR for one year incidence change = 0.77, 95% CI [0.66, 0.90]. There was also a significant reduction in BPD incidence rates by 15% in the BPD group (OR for a one year incidence change = 0.70, 95% CI [0.70, 0.91], and by 12% in the group of infants with BPD or who had died (OR for one year incidence change = 0.80, 95% CI [0.70, 0.92]. Insufficient monitoring and evaluation of the EPIC implementation process and a lack of resources could have contributed to inconsistencies in delivering the EPIC intervention across participating NICUs and subsequent variability in outcome achievement (Lee et al., 2009).

Assessing barriers and facilitators for changing practices within the NICU.

Implementation strategies that are informed by perceived barriers to care, available resources, and research evidence about the effectiveness and efficiency of different strategies contribute to the success of KT interventions (Feder, Eccles, Grol, Griffiths & Grimshaw, 1999). As part of Lee and colleague’s (2009) RCT evaluating the EPIC intervention in reducing incidence rates of nosocomial infection and chronic lung disease in Canadian NICUs, barriers and facilitators that influenced health care professionals’ practice changes in participating NICUs were identified (Stevens, Lee, Law, & Yamada, 2007). Individual interviews with 76 health care professionals and 14 focus groups consisting of 154 participants were completed at 13 participating Canadian NICUs. Questions focused on barriers and facilitators to changing practices in the NICU. From
these interviews and focus groups, five main categories of factors thought to be influencing practice changes in the NICU were generated including (a) human resources, (b) organizational structure, (c) communications, (d) rationale for change, and (e) the feedback process.

**Human resources.** Health care professionals identified staff turnover and the lack of support from the unit educators as barriers to changing practice. Inconsistent practices across neonatologists were also viewed as barriers to change. Health care professionals also indicated that support from unit leaders was essential for practice changes to occur (Stevens, Lee et al., 2007).

**Organizational structure and communications.** Barriers to change included the complexity of negotiations involved when approving new practices. A multidisciplinary approach to care included practice champions who were viewed as facilitators to changing practice. Health care professionals reported that frequent and consistent methods of communication were critical criteria for successful change to occur (Stevens, Lee et al., 2007).

**Rationale for change and the feedback process.** As a method to encourage buy-in, health care professionals stressed the importance of being informed about the rationale for the practice change and perceived benefits of the change for both health care professionals and patients. Providing updates or feedback on the process of the practice change and inclusion of health care professionals in the development, measurement, and evaluation of the change was also identified as an important strategy in promoting change (Stevens, Lee et al., 2007).

Information gained from qualitative interviews was used to identify important issues to consider when planning for practice changes in the NICU (Lee et al., 2009).

**The EPIC intervention to improve neonatal pain practices.** The two Phase EPIC intervention methodology by Lee et al. (2009) was adapted for use in the TROPIC Study
(Stevens et al., 2008) to promote improvements in health care professionals’ pain practices. The steps of the EPIC intervention are summarized in Table 2.

Research practice council members (RPC) consist of four to six health care professionals who are responsible for facilitating the pain practice change in their clinical unit. Once RPC members are trained and have identified their pain practice aim, they designed and implemented KT strategies to promote the practice change. KT strategies were delivered over three month cycles of change. During regular meetings, the KT strategies were discussed and revised based on any barriers to their implementation. For example, if the content of reminder posters was not clear to health care professionals, revisions to the poster were made. Tailoring of KT strategies to the needs of the unit is a unique quality and strength of the EPIC intervention. Interventions that are tailored to identify barriers are more likely to result in improvements in health care professionals’ practices compared to no intervention (Baker et al., 2010). To promote staff engagement in the pain practice change, an audit of pain practices is conducted at the end of each cycle, and results of the practice change are fed back to staff members.
Table 2

*EPIC Intervention Steps (Stevens et al., 2008)*

<table>
<thead>
<tr>
<th>Phase 1: Preparation phase</th>
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<tbody>
<tr>
<td>Establish the RPC (multidisciplinary group of four to six health care professionals)</td>
</tr>
<tr>
<td>Train RPC members on clinical and research evidence, evidence-based KT strategies, quality improvement methods</td>
</tr>
<tr>
<td>Review baseline pain practice data and identify potentially useful practice changes</td>
</tr>
<tr>
<td>Review existing clinical and research evidence to support the practice change</td>
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<tr>
<td>Decide on a practice change (s) to implement and develop an aim statement(s)</td>
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<tr>
<th>Phase 2: Implementation and change phase</th>
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<tbody>
<tr>
<td>Plan a test of practice change using evidence-based KT strategies (i.e., reminders, educational materials, educational outreach, audit and feedback)</td>
</tr>
<tr>
<td>Implement the practice change using PDSA cycles (two three-month cycles known as Cycle 1 and Cycle 2)</td>
</tr>
<tr>
<td>Evaluate the practice change using audit and feedback at end of each cycle</td>
</tr>
</tbody>
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*Note. KT= knowledge translation; PDSA = Plan-Do-Study-Act; RPC = Research Practice Council.*
Process Evaluation/Intervention Fidelity Measures

The evaluation of fidelity is rooted in the field of program evaluation, and has been used in psychological, social, and behavioural research (Gearing et al., 2011; Mowbray, Holter, Teague, & Bybee, 2003). Determining whether an intervention has been implemented as planned has been referred to as treatment integrity (Moncher & Prinz, 1991), treatment fidelity (Bellg et al., 2004; Moncher & Prinz, 1991), intervention fidelity (Santacroce, Maccarelli, & Grey, 2004), implementation fidelity (Carroll et al., 2007), and process evaluation (Hulscher, Laurant, & Grol, 2005; Linnen & Steckler, 2002). Variability exists in the way that fidelity is defined and measured across disciplines. Process evaluations have been conducted in a variety of social and behavioural sciences including program evaluation, mental health, psychology, health education, public health, and health promotion (Moncher & Prinz, 1991); however, they have not been widely utilized in implementation research (Flottorp, Havelsrud, & Oxman, 2003). In studies where process evaluations are conducted, there is a lack of clear definitions for the evaluation components (Linnen & Steckler, 2002).

Failure to detect significant intervention effects due to inadequate implementation of interventions compared to what was planned is referred to as Type 3 error (Basch & Gold, 1986; Hulscher et al., 2003; Sidani & Braden, 1998). Assessing the fidelity of implementing complex interventions addresses Type 3 error (Carroll et al., 2007). Assessment of fidelity provides evidence of variability in implementation of complex interventions, which could also contribute to limited effectiveness (Baranowski & Stables, 2000). For example, assessment of intervention fidelity can be used to monitor levels of adherence, or drift from the intervention process (Mowbray et al., 2003). An intervention that has not been delivered in its entirety and/or in a standardized way yields variability in outcome achievement, which reduces the power to detect
significant effects (Bellg, et al., 2004; Mowbray et al., 2003). Furthermore, without examining how the components of the intervention were implemented, in comparison to how they were planned, conclusions based on research findings might not be accurate (Bouffard et al., 2003; Mowbray et al., 2003). Finally, assessment of intervention fidelity allows for replication of the intervention, which supports its external validity (Mowbray et al., 2003). In the evaluation of complex, tailored interventions, the process of implementing and tailoring the intervention should be standardized, as the components of the intervention actually given, vary across participants (Hawe, Shiell, & Riley, 2004). The content should be tailored to the context in which the intervention will occur (Hawe et al., 2004).

Moncher and Prinz (1991) examined the fidelity literature in the areas of psychology, behavioural therapy, psychiatry, and family therapy from 1980 to 1988. From the 359 studies included in the review, there was no monitoring of intervention fidelity in 55%. Dusenbury, Brannigan, Falco, and Hansen (2003) evaluated studies and reviews on intervention fidelity in health education research over a 25-year period and developed key recommendations regarding intervention fidelity. First, they stressed the need for a universally acceptable definition of fidelity. Second, they recommended the development of measures and methodologies that focused on five elements of fidelity including (a) adherence, (b) dose, (c) quality of program delivery, (d) participant responsiveness, and (e) program differentiation. Third, the authors stated that there was a need to identify factors that may influence intervention implementation such as characteristics of the intervention providers. Finally, they recommended that funding agencies and journals should consider intervention fidelity as part of their review criteria (Dusenbury et al., 2003). Borrelli et al. (2005) conducted a review of 342 studies on intervention fidelity from 1990 to 2000 and included studies from public health, psychology, health
promotion, and behavioural medicine. Results were similar to those of Moncher and Pinz (1991) where 54% did not report strategies used to monitor intervention fidelity.

In a review of 12 fidelity measures for evidence-based practices developed for use in mental health, three of the 12 measures identified were reported to have acceptable psychometric properties, while for eight measures, no information about the psychometric properties was reported (Trabin, Minden, Workgroup, & Team, 2006). All measures in this report were developed for use in large systems and organizations of care. A wide range of psychometrically supported fidelity measures exist and are, for the most part, intervention-specific (Gearing et al., 2011; Mowbray et al., 2003).

A search of MEDLINE (OvidSP), PsycINFO (OvidSP), CINAHL (EBSCOhost) and SCOPUS, for the time period February 2001 to February 2011, using the search terms fidelity, and treatment or intervention or implementation, yielded 13 fidelity measures primarily aimed at mental health.

Two recent measures (Kieth, Hopp, Subramanian, Wiitala, & Lowery, 2011; Song, Happ, & Sandalowski, 2010) were related to psychoeducation and case management (Appendix C). These 13 measures did not comprehensively capture the key concepts of fidelity. Researchers have evaluated intervention fidelity using a variety of data collection methods (e.g., self report, observation, questionnaires, interviews, chart reviews, activity logs) and fidelity concepts (e.g., adherence, dose of the intervention) (Baquero et al., 2009; Kalafat, Illback, & Sanders, 2007; Lee et al., 2008; Naylor, Macdonald, Zebedee, Reed, & McKay, 2006; Price, McBride, Hyerle, & Kivlahan, 2007; Robert et al., 2007).

The National Institutes of Health (NIH) Behavioural Change Consortium (BCC) group formed the Treatment Fidelity Workgroup to develop intervention fidelity recommendations for
the assessment of health behaviour intervention implementation fidelity in research (Bellg et al., 2004; Borrelli et al., 2005). The CBB group identified five aspects of intervention fidelity including (a) intervention design, (b) training of providers, (c) delivery of the intervention, (d) intervention receipt, and (e) intervention enactment.

**Intervention design.** Documentation of key ingredients of the intervention includes (a) a description of the content of the intervention, (b) the dose (i.e., length, number and frequency of contacts) of the intervention and comparison groups, (c) a description of the types of providers or individuals required to successfully implement the intervention including their credentials and experience, and (d) a description of the theoretical framework or clinical guidelines that guided the intervention process (Bellg et al., 2004; Borrelli et al., 2005).

**Training of providers.** Information was included about whether the training sessions were standardized, and how skills were acquired and maintained over time (Bellg et al., 2004; Borrelli et al., 2005). For example, regular meetings could be organized with intervention providers to ensure that the intervention was being delivered as planned and to clarify any issues that might arise during the intervention implementation (Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005). In addition, booster sessions to re-enforce the implementation process could be used to prevent drift in provider skills (Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005).

**Delivery of the intervention.** To ensure that the strategies were implemented and adhered to as planned, procedure manuals and checklists could be used to monitor the delivery of the intervention (i.e., dose, duration, and reach) (Bellg et al., 2004; Borrelli et al., 2005). Regular meetings with providers also could be used to identify any issues with the delivery process.
Observing the delivery of intervention sessions provides additional evidence regarding the delivery of the intervention (Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005).

**Intervention receipt.** Documentation about whether participants who received the intervention understood the information provided (Bellg et al., 2004; Borrelli et al., 2005) is essential. Testing the participants knowledge, or direct observation of intervention sessions are examples of measuring receipt of the intervention (Resnick, Bellg et al., 2005).

**Intervention enactment.** Assessment of intervention enactment ensures that participants are using the behavioural/practice skills and cognitive strategies in their own setting. Evidence of treatment enactment has often been reported as the study outcomes (Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005).

Researchers who have applied the Bellg et al. (2004) and Borrelli et al. (2005) fidelity framework have operationalized and applied concepts within the framework that were specifically relevant to the intervention under evaluation (Bellg et al., 2004; Borrelli et al., 2005; Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005; Spillane et al., 2007). Fidelity measures are not easily applicable or adaptable to complex, tailored interventions such as the EPIC intervention. The evaluation of implementation fidelity for complex interventions such as EPIC must be customized to the intervention (Song et al., 2010). As there were no standardized measures that can be used to evaluate fidelity of the EPIC implementation, there was a need to develop and validate a new one.

**Summary.** The EPIC intervention is a complex KT strategy that has been used to effectively reduce nosocomial infection and chronic lung disease in neonates. This strategy could be further evaluated to improve pain practices in the NICU. As a key issue is potential inconsistencies in the delivery of the EPIC intervention components (Lee et al., 2009),
monitoring the fidelity of the EPIC implementation would identify the degree that the intervention components were implemented as planned. The review of the literature on fidelity measures indicated that existing measures were primarily intervention specific; there were no validated measures that could be used to monitor the implementation of the EPIC intervention. Therefore, there was a need to develop, and examine the validity, feasibility, and clinical utility of a process evaluation measure to assess the fidelity of implementing the EPIC intervention.
CHAPTER THREE

Conceptual Framework

In this chapter, the conceptual basis of this study is reviewed. Two conceptual frameworks were incorporated. First, the Promoting Action on Research Implementation in Health Services (PARiHS) framework (Kitson et al., 1998; Rycroft-Malone et al., 2004) guided the development of the EPIC intervention implementation KT strategy. Second, a fidelity framework (Bellg et al., 2004; Borrelli et al., 2005) guided the design of the PEC to evaluate the fidelity of the EPIC implementation. Research supporting each of these frameworks was reviewed and evaluated.

The PARiHS Framework

Conceptual frameworks provide “frame of reference, for organizing thinking, as a guide for what to focus on, and for interpretation of results” (Rycroft-Malone & Bucknall, 2010, p.28). Conceptual frameworks related to KT interventions can be used to (a) guide and develop sustainable and generalizable KT interventions, and (b) summarize, interpret, and explain factors influencing the implementation of and mechanisms underlying the effectiveness of complex interventions (Brazil, Ozer, Cloutier, Levine, & Stryer, 2005; Improved Clinical Effectiveness through Behavioural Research Group [ICEBeRG], 2006; Rycroft-Malone & Bucknall, 2010). Results from a systematic review of the use of theory in the translation of guidelines into practice up to 1998 indicated that behavioural change theories were used infrequently (i.e., 53 of 235 [22.5%] studies; Davies, Walker, & Grimshaw, 2010).

There are many variables that could influence research use at the level of the evidence, individual/group, and practice environment (Seers, 2007). The complex nature of evidence as a “transient moment in an indeterminate process of stabilization and destabilization” (Wood et al.,
along with practice behaviours within complex health care environments in which knowledge is translated, continues to pose many challenges for implementation research. Kitson et al. (1998) developed an interactive, multidimensional KT framework, the PARiHS framework which incorporates three key elements that are viewed as essential for translating research into practice. The interface of evidence, context, and facilitation is hypothesized to account for the complexity of behaviours that are involved in practice changes (Figure 1).

In the PARiHS framework, successful implementation (SI) of evidence into practice is a function of the sources of evidence (E) used to support the practice change, the context (C) in which the practice change occurs, and methods used to facilitate (F) the practice change (Kitson et al., 1998). Each of the PARiHS components is evaluated on a continuum ranging from high to low. Implementation of evidence into practice is considered to be successful and can be associated with positive outcomes when the research evidence, context in which the change occurs, and methods used to facilitate change are rated as “high” on the utilization continuum (Kitson et al., 1998; Rycroft-Malone et al., 2002). For example, the integration of the best pediatric pain evidence, in a highly supportive hospital unit/context, using effective strategies to facilitate knowledge translation can contribute to improved pain practices and clinical outcomes.

Elements of the PARiHS framework were conceived by a retrospective and theoretical analysis of four case studies (Kitson et al., 1998). Further refinement of the PARiHS framework was achieved through concept analyses of each of the key elements (Harvey et al., 2002; McCormack et al., 2002; Rycroft-Malone et al., 2004). A qualitative case study with health care professionals regarding the implementation of evidence into practice highlighted the importance of organizational fit and multi-professional collaboration with the PARiHS element of context (Rycroft-Malone et al., 2004).
**Evidence.** Evidence in the PARiHS framework is viewed as knowledge acquired from a variety of sources (Rycroft-Malone et al., 2004). Research evidence represents only one aspect of a health care professional’s source of knowledge within the practice environment (Denis, Hebert, Langley, Lozeau, & Trottier, 2002; Leckie, 1996). In addition to research evidence, other sources of information that health care professionals use in their practice include clinical experience, patient/parent preferences/experiences, and local data/information (Kitson et al., 1998).

**Research evidence.** High quality research evidence historically has been based on the paradigm of evidence-based medicine (EBM). EBM is “the explicit, judicious and conscientious use of current best evidence from health care research in decisions about care of individuals and populations” (Haynes, 2002, p.4). Rooted in clinical epidemiology, and within the paradigm of EBM, research evidence is rated on a hierarchy of graded evidence, where high quality meta-analyses and systematic reviews of rigorous RCTs are at the top of the hierarchy and expert opinion are ranked at the bottom (Haynes, 2004). The assumption behind EBM is that applying high quality evidence, (e.g., in the form of evidence-based guidelines) into clinical practice leads to high quality patient care (Haynes, 2004). Upshur, VanDenKerkhof and Goel (2001) emphasized the importance of including both quantitative and qualitative information in the taxonomy of evidence. Research evidence is also considered to be socially constructed by an individual’s level of experience and education (Rycroft-Malone et al., 2004). Research evidence is rated ‘high’ on the continuum when evidence (both quantitative and qualitative) is rigorous, relevant, valued, and generalizable (Rycroft-Malone et al., 2004; Rycroft-Malone, 2004).
Figure 1. Conceptual framework for EPIC intervention process (adapted from Kitson et al., 1998; Rycroft- Malone, 2004; Stevens et al., 2008).
**Clinical experience.** Health care professionals use clinical experience, which is also referred to as practice-based experiential/tacit knowledge and craft skills acquired through credible peers and by observation (Dopson et al., 2002; Estabrooks et al., 2005; Estabrooks, Scott-Findlay, Rutakumwa, Duan, & Rozanova, 2004; Kitson et al., 1998; Lecki, 1996). Practice-based evidence is considered ‘high’ on the evidence to practice continuum when experience is reflected upon, tested, valued, and regarded as relevant knowledge (Rycroft-Malone, 2004). For context specific practice issues, nurses tend to rely more on informal sources of knowledge/evidence through social interactions with peers, and intra-personal knowledge acquired from training as nurses (Estabrooks et al., 2005). Formal methods of obtaining knowledge can be discipline-based (e.g., conferences, seminars and workshops), institution-based (e.g., in-services, orientation) and unit-based (e.g., orientations, rounds, meetings) (Estabrooks et al., 2005; Estabrooks et al., 2004). Unit-based policy and procedure manuals, newsletters, communication books, and the internet are sources of practice knowledge for nurses. Off-unit sources include textbooks and journals as additional sources of knowledge; however, these sources have not been used as frequently by nurses due to their reported lack of time to access these resources (Estabrooks et al., 2005; Estabrooks et al., 2004).

Knowledge from clinical experience is considered ‘high’ on the evidence continuum when it is reflected upon, valued, and viewed as relevant through consensus (Rycroft-Malone, 2010). However, the translation of knowledge to practice may be negatively influenced when research evidence does not correspond with knowledge from clinical experience. For example, Denis et al. (2002) found that reusable filters for hemodialysis were implemented more successfully in sites where clinicians believed that there would be a clinical benefit in adopting this practice change.
**Patient experience.** Patients’ experiences regarding their care are also considered to be important contributors to the implementation of evidence into practice (Kavanagh & Watt-Watson, 2007; Rycroft-Malone et al., 2004). Patient experience is considered ‘high’ when this evidence is valued and seen as relevant (Rycroft-Malone, 2010). Patients who work with health care professionals as partners in the change process could contribute to successful KT activities (Kavanagh & Watt-Watson, 2007; Rycroft-Malone, 2004).

**Local data/information.** Knowledge that is obtained from the local practice context, such as audit and health care professional performance data (Rycroft-Malone et al., 2004), also influences evidence application to practice. Local data/information is considered ‘high’ on the evidence to practice continuum when these data are valued and viewed as important evidence, and are rigorously evaluated and interpreted (Rycroft-Malone, 2010). Audits of performance can be viewed as an important source of evidence as the data collected can be analyzed and used to inform practice changes (Rycroft-Malone et al., 2004).

**Context.** Kitson et al. (1998) and Estabrooks, Floyd, Scott-Findlay, O’Leary and Gushta (2003) emphasize the importance of assessing the environmental context in which evidence-based practice occurs. The complexity of clinical environments and the constantly changing “force fields” both internal and external to a practice environment shape the adoption of evidence into practice (McCormack et al., 2002). The practice environment or environmental context of an organization is socially constructed and could have a direct influence on the behaviours of health care professionals and the way knowledge is perceived (Nutley et al., 2003). Factors that influence the practice environment range from professional boundaries within a practice setting to government and health policy factors external to a practice organization (Dopson et al., 2002). Within PARiHS, context refers to the environment or setting where an evidence-based practice
change occurs (Kitson et al., 1998; McCormack et al., 2002). Four sub-elements of the environmental context are receptive context, culture, leadership, and evaluation of systems (Rycroft-Malone, 2004).

**Receptive context.** Characteristics of a receptive context include the availability of professional/social networks to implement a practice change/intervention, appropriate human, financial, and equipment resources, and initiatives that are in line with the organizations’ strategic plans/goals (Kitson et al., 2008; Rycroft-Malone, 2010).

**Culture.** Culture has been defined as “the way things are done around here” (Drennan, 1992). Culture refers to “a way of thinking about or viewing an organization, comprised of basic assumptions, values, artifacts and creations” (McCormack et al., 2002, p.97). Multiple cultures with their own values, assumptions, and beliefs can exist within a practice setting (McCormack et al., 2002). Although individuals become attuned to the culture of the organization, they also have their own cultural assumptions and become socialized to their own unit subculture (e.g., NICU) and occupational culture (e.g., nursing) (Brown & Duguid, 2001). Based on their professional training, practice behaviours become engrained through education, exchange with peers, and within their own practice unit. Nurses, for example, perceive and define themselves based on the work they do (Rycroft-Malone et al., 2004). Culture is considered ‘high’ on the continuum when there is a high regard for individuals, a supportive learning environment, facilitative management styles, teamwork, collaborative partnerships, and decentralized decision-making (McCormack et al., 2002; Rycroft-Malone, 2010; Rycroft-Malone et al., 2004).

**Leadership.** Effective or ‘high’ leadership involves the use of transformational leaders who assume a decentralized role where they influence, enable, and empower individuals to share
a common vision through the development of clear roles, and the promotion of effective teamwork and decision making (McCormack et al., 2002).

**Evaluation.** Evaluating the effectiveness of the KT strategies should rely on multiple sources of information (McCormack et al., 2002). Evaluation and feedback at the individual, team, and system levels using ‘hard data’ (e.g., performance audits), or ‘soft data’ (e.g., feedback from health care professionals about the intervention) will enable health care professionals to be more receptive to implementing pain practice changes (McCormack et al., 2002).

**Facilitation.** Facilitation has its roots in psychology, counseling, and problem-based learning (Harvey et al., 2002). The process of facilitation refers to enabling or making easier, the implementation of evidence into practice, taking into consideration the evidence that will be used to change practice, and the specific unit/context in which the practice change will occur (Harvey et al., 2002). The process of facilitation is situated on a continuum where the purpose or role of the facilitator ranges from taking on specific tasks to help others achieve goals through low intensity, episodic contact (task oriented), to enabling (holistic oriented) individuals or groups to achieve the goals themselves by individuals in high intensity roles (Harvey et al., 2002). Facilitators responsible for helping to change behaviours of others are usually appointed to their role, and can be internal or external to an organization depending on the underlying purpose of facilitation (Harvey, et al., 2002; Rycroft-Malone et al., 2002).

Skills required by facilitators vary depending on the context and goals of the behavioural change. Task oriented facilitators provide practical help and support to individuals and groups by applying technical or project management skills, whereas facilitators who empower individuals and groups to achieve goals by helping them to analyze, reflect, and change their practice behaviours are viewed as enablers (Harvey et al., 2002; Kitson et al., 2008).
Although facilitation appears to focus on enabling individuals or groups to change practice behaviours, skilled facilitators should be able to move along the continuum using a combination of task oriented and enabling skills depending on the requirements of the practice change (Harvey et al., 2002). Therefore, facilitation could be considered ‘high’ on the knowledge to practice continuum when appropriate supports are in place to facilitate change, and when the use of task and enabling skills are based on the specific needs of the proposed change (Harvey et al., 2002).

**Research Support for the PARiHS Framework**

In a comprehensive review of literature on the PARiHS framework (Helfrich et al., 2010), 17 empirical articles were identified as having applied elements and sub-elements of this framework to research studies and literature reviews. These studies were retrospective or cross-sectional in design. In 13 studies, the PARiHS framework was used as an organizing framework to guide research and evaluation. In three studies, the framework was used to guide research utilization, and in one study, PARiHS elements were used to develop a measurement tool. The authors provided key recommendations for future applications of the PARiHS framework. First, PARiHS elements and sub-elements should be used to guide implementation research using prospective study designs (Helfrich et al., 2010). Second, there is a need to explain how intervention components are linked to the elements and sub-elements of the PARiHS framework. Finally, the conceptualization of some of the PARiHS elements and sub-elements require further clarification (Helfrich et al., 2010).

Additional strengths and challenges of the PARiHS framework have been identified. The elements and sub-elements of this framework represent factors to consider when translating evidence into practice, and can be applied to a variety of clinical settings, patient populations,
and health care professionals (Rycroft-Malone, 2010). One of the challenges of applying the PARiHS framework relates to how the elements and sub-elements work together across the levels of an organization (Rycroft-Malone, 2010). More specifically, the question remains as to whether evidence, context, and facilitation are weighted equally in the implementation process (Rycroft-Malone, 2010) and, if not, what the ideal balance should be.

The focus of this study was to evaluate the process of implementing the EPIC intervention in a particular context (i.e., NICU) using various types of evidence to ultimately change pain practices with infants. Within the proposed study, the EPIC intervention is based on strong pain intervention effectiveness evidence. However, there is little knowledge of the process of implementing the intervention, the context in which the practice change occurs, or the effectiveness of the facilitators of the EPIC intervention. The EPIC intervention was guided by the PARiHS framework to promote KT. The facilitation component of the EPIC intervention required an assessment of fidelity of the intervention implementation that was guided by an intervention fidelity framework. Therefore, the assessment of the fidelity of the EPIC intervention implementation was aligned with the facilitation component of the EPIC intervention.

**PARiHS Framework and the EPIC Intervention**

The steps involved in the EPIC intervention are summarized within (a) Phase 1, Preparation Phase, and (b) Phase 2, Identification and Change Phase (Table 2). The process of integrating the key components of the PARiHS framework within the Phases of the EPIC intervention and the process for their evaluation are outlined as follows:
Phase 1: Preparation phase.

Evidence. Three types of ‘high’ sources of evidence related to pain assessment and management practices were used. First, a baseline chart review of the NICU’s current pain practices (pain assessments, nature and frequency of all painful procedures, application/provision of pharmacologic, physical or psychological interventions) was conducted. Information obtained from this audit was used to describe practice variations in the NICU and to inform potentially best pain practice changes that would be the focus of Phase 2. Rycroft-Malone et al. (2004) emphasized that collection of evidence in the form of local audit data was one source of evidence that can be used to inform practice changes.

Second, the Research Practice Council (RPC) (consisting of three to four health care professionals who were champions of on the EPIC intervention process) were trained to critically review systematic reviews of the literature on neonatal pain management, CQI methods, and effective KT strategies (i.e., reminders, educational interventions and audit and feedback).

Although the evidence used in the EPIC intervention is weighted more heavily on research evidence, a third source of evidence available to RPC members was their clinical experience/expertise; RPC members prioritized these sources of evidence and decided on their final practice changes through consensus among members.

Phase 2: Identification and change phase.

Context. The elements of context and facilitation from the PARiHS framework were the focus of Phase 2. Context was defined as the hospital unit where the identification and implementation of practice change were to occur. Hospital units that have participated in the EPIC intervention studies have required support from their management teams to participate in the implementation process (Lee et al., 2009; Stevens, Lee et al., 2007). The PARiHS context
sub-elements of leadership and evaluation were relevant to the EPIC intervention implementation. RPC members were eligible to participate if they exhibited a shared vision to improve pain practices, and held positions in the unit that could influence practice changes. The EPIC intervention included an evaluation component where regular audits of practice were conducted to determine the extent of the pain practice change (Stevens, Lee et al., 2007). Results of the evaluation were fed back to the RPC members and unit staff. Characteristics of the unit culture where the pain practice change occurred were not directly measured in the EPIC intervention implementation process. However, monitoring the barriers and facilitators to implementing the KT strategies was used to account for factors that could have contributed to the progress and the direction of the practice change.

**Facilitation.** Most of the emphasis in this study was based on the PARiHS element of facilitation. As internal facilitators, RPC members implemented the KT strategies to promote pain practice changes. Facilitators with expertise in pain management, leadership, and knowledge of the practice culture can contribute to successful implementation of pain evidence into practice (Kavanagh & Watt-Watson., 2007).

Although the EPIC intervention implementation process has been articulated and supported by the PARiHS framework, there is little evidence regarding the extent to which the steps of the EPIC intervention have been carried out as designed (Lee et al., 2009). This supports the need for assessing intervention fidelity of the EPIC intervention implementation. An evidence-based intervention fidelity framework was used to guide the development of a process evaluation measure to assess the fidelity of implementing the EPIC intervention.
**Intervention Fidelity Framework**

The intervention fidelity framework that guided the development of the PEC was based on relevant concepts of the fidelity framework developed by Bellg et al. (2004), and Borrelli et al. (2005). This framework was chosen as it was consistent with the monitoring of health behavioural change interventions, which was the focus of the EPIC intervention.

**Research Support for the Intervention Fidelity Framework**

Components of the fidelity framework by Bellg et al. (2004) and Borrelli et al. (2005) have been applied in studies focusing on behavioural change in patients (Resnick, Bellg et al., 2005; Resnick, Inguito et al., 2005; Spillane et al., 2007). Two reviews of studies that applied the fidelity components indicated variability in their use. In a review of 342 studies evaluating the fidelity of behavioural change interventions, and 29 studies targeting the implementation fidelity of studies on second hand smoking reduction, about half of the studies (i.e., 69% and 52% respectively) in the reviews described the provider credentials (Borrelli et al., 2005; Johnson-Kozlow et al., 2008). Evidence of provider training (including how providers were trained, how skills were acquired, and how skills were maintained over time) was reported in less than 30% of the studies reported in the review by Borrelli et al. and in less than 50% of the studies in the review by Johnson-Kozlow et al. (2008). Moreover, considerable variability in adherence to the intervention was reported; particularly in terms of the degree to which the content and dose of the intervention were delivered (Borrelli et al., 2005; Johnson-Kozlow et al., 2008). Participant comprehension of the intervention was described in approximately half of the studies reviewed (Borrelli et al., 2005; Johnson-Kozlow et al., 2008). Finally, evidence of participants’ enactment of the behavioral intervention recommendations was noted in 73%-93% of the studies evaluating intervention fidelity (Borrelli et al., 2005; Johnson-Kozlow et al., 2008).
Except for enactment, all other fidelity components were reported in approximately less or equal to half of the studies in these reviews. These results underscore the need to improve monitoring and documentation of intervention fidelity.

**Fidelity Framework and the Fidelity of the EPIC Intervention Implementation**

Relevant components of the fidelity framework developed by Bellg et al. (2004), and Borrelli et al. (2005) were used to guide the development and validation of the measure for monitoring the fidelity of the EPIC intervention implementation. At the same time, monitoring the fidelity of two Phases of the EPIC intervention was used to support the construct validity of the process evaluation measure. Intervention design was operationalized as the types of providers (i.e., RPC members) who were responsible for implementing the EPIC intervention including their credentials and experience. Training of the intervention providers included those individuals who facilitated the intervention implementation (i.e., external and internal facilitators including the RPC members). Delivery of the EPIC intervention was aligned with Phase 2 of the EPIC intervention where different KT strategies were used to promote practice change. Intervention receipt referred to the degree of usefulness of KT strategies implemented from the perspective of the RPC members and input from health care professionals where possible. This information was thought to assist RPC members to revise or tailor the KT strategies to the needs of the unit. Intervention enactment referred to the success of the pain practice changes. Table 3 summarizes the steps of the EPIC intervention that were monitored and documented on the fidelity measure.
Table 3  
*Fidelity Framework to Evaluate the EPIC Intervention Implementation*

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<tr>
<th>EPIC intervention steps</th>
<th>Fidelity framework</th>
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<tr>
<td><strong>Section 1: Phase 1 preparation phase</strong> <em>(April - June 2008)</em></td>
<td></td>
</tr>
<tr>
<td>Establish the RPC</td>
<td>(a) Step 1: Identifying the RPC members and credentials</td>
</tr>
<tr>
<td>Train RPC members clinical and research evidence, evidence-based KT strategies, quality improvement methods</td>
<td>(b) Step 2: Training of intervention providers: Describing the content of the training of the RPC members responsible for delivering the EPIC intervention on the inpatient unit, and evaluating the usefulness of the training</td>
</tr>
<tr>
<td>Review baseline pain practice data and identify potentially useful practice changes</td>
<td></td>
</tr>
<tr>
<td>Review existing clinical and research evidence to support the practice change</td>
<td>Describing the process of selecting the pain practice targeted for change as carried out by the RPC members</td>
</tr>
<tr>
<td>RPC members decide on a practice change to implement and develop a pain practice aim statement</td>
<td>RPC members</td>
</tr>
</tbody>
</table>
Section 2 Phase 2: Implementation and change phase  
(July 2008 - March 2009)

Plan a test of change using KT strategies (reminders, educational materials, educational outreach, audit and feedback).

Implement the practice change using PDSA cycles (two three-month cycles known as Cycle 1 and Cycle 2).

Evaluate the change using audit and feedback at end of each cycle.

(c) Step 3: Delivery of the intervention: Describing the KT strategies delivered/implemented by the RPC members in terms of the dose, reach, duration, barriers, facilitators and as received by the unit staff (in terms of their usefulness) during the EPIC implementation.

(d) Step 4: Assessing the intervention enactment of the pain practice change by examining the relationship between the KT strategies delivered and the pain practice outcomes operationalized as the proportion of patients on whom the selected pain practice change was implemented (i.e., who had sucrose ordered and administered for acute procedural pain within the first 24 hours of admission to the NICU).

(e) RPC member and health care professionals’ perspectives/insights on the EPIC intervention implementation.

Note. Fidelity framework was based on the work by Bellg et al. (2004) and Borrelli et al. (2005); EPIC = Evidence-based Practice Identification and Change (Lee et al., 2009); KT = knowledge translation; NICU = Neonatal Intensive Care Unit; QI = quality improvement; RPC = Research Practice Council.
Summary

The EPIC intervention is conceptualized as a KT strategy to change practice outcomes on infant pain in the NICU. This intervention is a facilitation strategy that was guided by the PARiHS framework in terms of using evidence to identify a practice change, considering the context in which the practice change occurred, and implementing and promoting the practice using internal and external facilitators. To evaluate and monitor the implementation of the EPIC intervention, an intervention fidelity measure was developed and validated. This measure was guided by an intervention fidelity framework developed by Bellg et al. (2004) and Borrelli et al. (2005).
CHAPTER FOUR

Methods

In this chapter, details about the research questions, operational definitions of validity and of key variables, research design, and data collection procedures are described. Study instruments are reviewed. Finally, data management and analysis, and ethical considerations are discussed.

Overall Purpose

The overall purpose of this study was to develop and validate the Process Evaluation Checklist (PEC) for monitoring the fidelity of implementing the Evidence-based Practice Identification and Change (EPIC) intervention (Lee et al., 2009).

Specific Objectives

The objectives of each study were to:

Study 1. To determine the (a) face validity and (b) content validity of the PEC;

Study 2. (a) To examine the construct validity of the PEC by assessing the fidelity of implementing each step of the EPIC intervention (Table 3 a to d); and (b) To determine RPC member and health care professionals’ perspectives/insights on the EPIC intervention (Table 3 e).

Study 3. To determine the feasibility and clinical utility of the PEC in assessing the EPIC intervention implementation.

Operational Definitions

Face validity. Face validity indicates if a measure includes appropriate items that appear to measure what it is proposing to measure (Streiner & Norman, 2008). The comprehensiveness and clarity of the items that capture the components or steps of the EPIC intervention are assessed.
Content validity. Content validity is a separate but initial step towards evaluating construct validity. Content validity is defined as “the degree to which the elements of an assessment instrument are relevant to and representative of the target construct for a particular assessment purpose” (Haynes, Richard, & Kubany, 1995, p.238). To assess content validity, items in the PEC were examined to ensure that the appropriate information was included and the content was reflective of all the components or the steps in the EPIC intervention (Haynes et al., 1995; Lynn, 1986; Soeken, 2005; Streiner & Norman, 2008). Content validity was determined by calculating a content validity index (CVI) for items (I-CVI), and scale/subscales (S-CVI) comprising the Process Evaluation Checklist (PEC).

Construct validity. Construct validity involves testing the relationships among items constituting a measure and between the concepts reflected by the measure and theoretically related constructs (Streiner & Norman, 2008). Construct validity of the PEC was inferred by determining the degree of fidelity of implementing all phases of the EPIC intervention using the PEC. This process of monitoring the components of fidelity in the EPIC intervention implementation is similar to running a factor analysis that supports the factorial structure of a measure, which is the first aspect of construct validity (Streiner & Norman, 2008). The audit to determine the progress of the practice change (i.e., use of sucrose) in relation to the KT strategies implemented as captured by the PEC provided evidence of the second aspect of construct validity of the PEC (i.e., in relation with other concepts).

Painful procedures. Painful procedures included both skin-breaking (e.g. heel lance) and non-skin-breaking (e.g. suctioning) procedures that were performed within the first 24 hours of the infant’s admission to the NICU (Porter, Wolf, Gold, Lotsoff, & Miller, 1997; Porter, Wolf, & Miller, 1999).
**Pain practices.** Pain practices were operationalized as the processes of pain assessment and pain management. Pain assessment practices incorporated the use of validated pain assessment measures. Pain management practices included the use of specific pharmacological and non-pharmacological (i.e., physical, and psychological) interventions supported by current evidence (e.g., use of sucrose to reduce procedural pain).

**Pain practice outcomes.** The pain practice outcomes were related to pain management and were assessed as (a) the proportion of patients for whom sucrose was ordered on admission and within the first 24 hours of admission, and (b) the proportion of patients who were administered sucrose for procedural pain within the first 24 hours of admission.

**Knowledge translation (KT) strategies.** KT strategies were operationalized as reminders, educational interventions, and audit and feedback (EPOC, 2002). Educational interventions were divided into educational materials and educational outreach. Educational materials included information about the pain practice change using a variety of methods for delivery (e.g., posters, handouts). Educational outreach included educational sessions. KT strategies were assessed as either single components such as the use of reminders, or multiple components, referred to as multifaceted, where strategies were used in combination (e.g., the use of reminders and audit and feedback).

**Intervention fidelity.** Intervention fidelity was the degree that the intervention was delivered as designed or planned (i.e., completeness, compliance) (Sidani & Braden, 1998). Overall, fidelity was operationalized as the proportion of the activities and components of the intervention that were actually implemented out of the total number of those planned (Kraag et al., 2007). Components from the intervention fidelity framework developed by Bellg et al.
(2004) and Borrelli et al. (2005) considered relevant to the EPIC intervention process were applied to the PEC. These fidelity components included:

**Intervention design.** Identification of the intervention providers (i.e., Research Practice Council [RPC] members) included information about their credentials and experience (Bellg et al., 2004; Borrelli et al., 2005).

**Training of providers.** Training of RPC members included asking them about the usefulness of their training sessions. By the end of the training session, RPC members described the process of selecting the pain practice targeted for change (Borrelli et al., 2005).

**Delivery of the intervention.** Processes used to report the level of adherence to the EPIC intervention included information about the dose, duration and reach of the KT strategies delivered (Bellg et al., 2004; Borrelli et al., 2005).

**Intervention receipt.** Receipt was operationalized as RPC members’ comprehension and perceived usefulness of the KT strategies implemented. This information was documented in the PEC as the usefulness scores for the KT strategies implemented, and barriers and facilitators of the implementation of these strategies (Bellg, et al., 2004; Borrelli, et al., 2005).

**Usefulness of KT strategies.** Usefulness was operationalized as how helpful the KT strategies (e.g., posters, stickers) were in promoting the pain practice change as perceived by the RPC members. Usefulness was assessed on a 5-point Likert scale where 1 represented a rating of “not at all useful” to 5 which represented a rating of “extremely useful”.

**Intervention enactment.** Intervention enactment entailed determining whether health care professionals were actually implementing targeted pain practices (i.e., documentation of sucrose ordering and administration) in their day-to-day practice setting (Resnick, Bellg et al.,
This information was collected from the chart audits conducted during the study. Methods used to disseminate results (e.g., posters, newsletters) were documented on the PEC.

**Feasibility of the PEC.** Feasibility was the ease of implementing the PEC in day-to-day practice and factors that could influence its use. Feasibility was operationalized by assessing the clarity of the instructions for using the measure, the structure, format, length and method of scoring, the ease of interpreting the information from the PEC and incorporating the PEC into the practice setting (Stevens & Gibbins, 2002).

**Clinical utility of the PEC.** Clinical utility was the extent to which the PEC could assist health care professionals to identify the most useful KT strategies to guide and plan the implementation of pain practice change (Stevens & Gibbins, 2002; Voepel-Lewis et al., 2008).

**Overview of Study Design, Setting, and Study Samples**

The research design, setting and samples are summarized in Table 4 for Studies 1, 2, and 3.
Table 4

*Overview of Study Design, Setting and Study Samples*

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Study 2</th>
<th>Study 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Prospective descriptive design to determine face and content validity of the PEC</td>
<td>Concurrent, embedded mixed methods case study design to examine the construct validity of the PEC by assessing the fidelity of implementing each step of the EPIC intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quantitative and qualitative data collected simultaneously and the quantitative methodology predominated (Cresswell, 2009; Cresswell &amp; Plano Clark, 2011). Qualitative descriptive design used to plan and conduct the focus groups (Neergaard, Olesen, Andersen, &amp; Sondergaard, 2009; Sandelowski 2000)</td>
</tr>
<tr>
<td>Setting</td>
<td>Questionnaire administered</td>
<td>EPIC conducted in a 32 bed, outborn single Level 3 NICU in a university affiliated pediatric tertiary care centre, serving metropolitan Toronto and Central and Northern Ontario. 723 patients were admitted in 2008 to this NICU for diagnostic/therapeutic procedures (e.g., heel lances, intravenous access), including surgery (NICU Manager, personal communication, January 12, 2009)</td>
</tr>
<tr>
<td>Sample</td>
<td>Face validity: Co-Investigators</td>
<td>Health care professional staff and eight trainees</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>from the TROPIC study</td>
<td>approached to participate</td>
<td>from one tertiary level NICU (N=192). Trainees included four departmental fellows, two neonatal-perinatal fellows who rotated between two other hospitals, and two medical residents. (Table 5).</td>
</tr>
<tr>
<td>(Stevens et al., 2008)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note.* CNN = Canadian Neonatal Network; NICU = Neonatal Intensive Care Unit; PEC = Process Evaluation Checklist; RPC = Research Practice Council; TROPIC = Translating Research on Pain in Children (Stevens et al., 2008).
Table 5

*Study 2 Unit Profile (N = 192 NICU Staff) at Time 1*

<table>
<thead>
<tr>
<th>Position</th>
<th>Full time</th>
<th>Part time</th>
<th>Casual</th>
<th>Total No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff physicians</td>
<td>8</td>
<td>3</td>
<td>11</td>
<td>11 (5.7%)</td>
</tr>
<tr>
<td>Staff nurses</td>
<td>108</td>
<td>23</td>
<td>15</td>
<td>146 (76.0%)</td>
</tr>
<tr>
<td>Managers</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>Charge nurse/ Clinical support nurse</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>10 (5.2%)</td>
</tr>
<tr>
<td>Educators</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>CNS/NP</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>10 (5.2%)</td>
</tr>
<tr>
<td>Respiratory therapists</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>Social workers</td>
<td>2</td>
<td></td>
<td>2</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>Dieticians</td>
<td>2</td>
<td></td>
<td>2</td>
<td>2 (1.0%)</td>
</tr>
<tr>
<td>Quality team leader</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Transitional care coordinator</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>RT educator</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Total</td>
<td>141</td>
<td>33</td>
<td>18</td>
<td>192</td>
</tr>
</tbody>
</table>

*Note.* CNS/NP = Clinical Nurse Specialist/Nurse Practitioner; RT = Respiratory Therapist; No = number.
Sample Recruitment Procedures

**Study 1: Face and content validity of the PEC.** Two different groups of experts were invited to participate in Study 1. One group was involved in determining the face validity and another group was involved in determining the content validity of the PEC. Participants were purposefully sampled; that is, a small number of participants were consciously selected on the basis of the inclusion criteria (Russell, Gregory, Ploeg, & DiCenzo, 2005). The 26 investigators in the TROPIC study (Stevens et. al., 2008) were invited to participate in determining the face validity of the PEC. This multidisciplinary group of professionals was considered eligible because they were familiar with the two phases of the EPIC intervention. These experts were clinicians and researchers in nursing, medicine, and pharmacy from eight hospital sites across Canada.

To establish content validity of the PEC, selection of content experts followed the methods described by Grant and Davis (1997). Specifically, 19 health care professional members of the Canadian Neonatal Network (CNN) including neonatologists, nurses, and researchers from NICU settings across Canada were invited to participate in validating the content of the PEC. These health care professionals, representing different disciplines, were considered eligible as they had expertise and/or familiarity with implementing the original EPIC intervention in a clinical practice setting (i.e., Neonatal Intensive Care Unit) according to the Director of the CNN (Dr. Shoo Lee, personal communication, April 14, 2008). After Research Ethics Board (REB) approval from the hospital and university was obtained, the researcher met with the Director and the Central Coordinator of the CNN who identified the 19 CNN members. These individuals included the site investigators and research coordinators or nurses from the participating CNN sites. The Steering Committee of the CNN provided permission for the CNN
coordinator to approach the CNN members to ask them to complete the questionnaire about the content validity of the PEC. The CNN Central Coordinator then contacted the CNN experts by email and invited them to participate in completing the PEC content validity survey.

**Study 2: Construct validity of the PEC.** The sample consisted of two groups of individuals; the RPC members and the health care professionals employed in the NICU where the EPIC was delivered. The RPC members were responsible for delivering the EPIC intervention to the NICU health care professional staff. Once approval from the Research Ethics Board (REB) and the NICU research feasibility committee was obtained, the researcher met with the unit medical directors, manager, and clinical leaders to obtain support and to introduce the study. A summary of the study was disseminated to the unit staff via email, the unit newsletter, and a study poster (Appendix D).

**RPC members.** Purposive sampling was used to identify and select the RPC members. Eligibility criteria to participate as a member of the RPC included a multidisciplinary group of unit based health care professionals who (a) worked full time in the NICU, (b) had a shared vision to improve pain practices, (c) demonstrated strong facilitator qualities including appropriate skills and attributes such as knowledge about hospital pain guidelines, policies and procedures, and (d) were in a position to influence practice change in the NICU. Health care professional trainees or students were excluded.

**NICU health care professional staff.** Purposive sampling was used to recruit a sample of health care professionals to participate in a focus group session scheduled one month after implementation of the EPIC intervention. Health care professionals were eligible to participate if (a) they had worked at least 0.5 of a full time equivalent (FTE) in the participating NICU, and (b)
had been present during the nine-month period over which time the EPIC intervention was
implemented.

To recruit health care professionals in the NICU, the researcher informed the unit
manager and clinical leader in the NICU of the purpose and logistics (i.e., time) of the focus
group sessions at an interprofessional leadership meeting. A poster situated on the unit’s
research board was used to inform the staff about the focus group session. The unit manager and
clinical leader agreed upon a date from a number of date options for the focus group and
identified a variety of potential health care professionals who were available and who could be
approached on the day of the interview. A neutral health care professional who was not directly
involved in the study (i.e., clinical leader) approached these individuals to determine whether
they would be interested in hearing about the study. If the health care professionals were
interested in hearing more about the study, the researcher explained the study and purpose of the
focus group session.

**Patient chart review.** A baseline audit of pain practices in the NICU was conducted by
the researcher and research consultant prior to the Phase 1 Preparation Phase of the EPIC
intervention (December 2007) (Time 1). Retrospective clinical practice data were collected on
socio-demographic characteristic of infants, information about the type and frequency of acute
painful procedures performed on infants as documented by health care professionals, pain
assessments completed, and pharmacologic, and non-pharmacologic (i.e., physical and
psychological) interventions used to manage procedural pain in infants over a 24-hour period.
Clinical practice data were collected during the first 24 hours of admission as the highest number
of painful procedures generally occurs during the first day of admission (Simons et al. 2003).
Chart data were included for infants who met the following inclusion criteria (a) had been
discharged from the NICU at the time of the audit, and (b) had received a painful procedure within the first 24 hours of admission.

**Study 3: Feasibility and clinical utility of the PEC.** Two separate samples were recruited to participate in evaluating the feasibility and clinical utility of the PEC (Table 4).

**Content validity of the questions from the PEC feasibility and clinical utility questionnaire.** Prior to assessing the feasibility and clinical utility of the PEC, content validity for the assessment measure was determined. Purposive sampling was used to identify individuals who would assist in determining the content validity of the questions used in the PEC Feasibility and Clinical Utility Measure. Investigators and research team members from the TROPIC study (Stevens et al., 2008) core site and two other sites were invited to be participants, as these individuals had been involved in more detailed training regarding the use of the PEC compared to individuals from the other participating sites.

**Feasibility and clinical utility of the PEC.** Purposive sampling was used to identify participants who would evaluate the feasibility and clinical utility of the PEC. All research nurses/coordinators who were employed with the TROPIC study (Stevens et al., 2008) were eligible and were invited to participate, if they had used the PEC during the study period.

**Sample Size**

**Study 1: Face and content validity of the PEC.** To determine face validity of the PEC, a purposive sample of the 26 co-investigators from the TROPIC study (Stevens, et al., 2008) was targeted as all were familiar with the EPIC intervention process. The number of experts recommended to establish content validity ranges from a minimum of three to a maximum of 10 (Lynn, 1986). As the method of delivery of this questionnaire was by email, we expected the minimum acceptable response rate to be 36%; the average participants’ response rates for email
surveys range from 31 - 46 %, with a mean of 36.83% (Sheehan, 2001). Therefore, all 26 investigators were recruited to attain the recommended number of experts, assuming a 36% response rate.

Study 2: Construct validity of the PEC.

**RPC members.** The number of RPC members (N = 4) from one NICU was based on the EPIC procedure manual developed for the TROPIC study (Stevens et al., 2008) and eligibility for membership (see sample recruitment procedures). Three of the four RPC members attended the regular meetings 50% of the time over the course of the study, which also supported the rationale (from a practical perspective related to logistics) for choosing four members to be responsible for facilitating the practice changes.

**Pain assessment and management practices.** The retrospective chart review of pain practices included patient information about the type and frequency of painful procedures, proportion of infants who had their pain assessed, pharmacologic, and non-pharmacologic (i.e., physical and psychological) interventions to which infants were exposed during the first 24 hours of hospitalization in the NICU. Approximately 90% of patient beds were occupied during a given week and rates of discharge varied based on the acuity of the infant (Nurse Manager, personal communication, December 14, 2007). Given that there were 32 beds in the NICU, and an estimated 80% met the eligibility criteria for chart review, 30 independent patient charts were reviewed over a month long period at (a) baseline (Time 1) prior to implementation of the EPIC intervention, (b) after the first three month cycle of change to measure the progress of the pain practice outcome (sucrose analgesia use), and (c) at the end of the EPIC intervention (Time 2) to assess whether the pain practice outcome had changed over the course of the study. All available charts that met the eligibility criteria were consecutively reviewed over a one-month period. For
studies evaluating preliminary efficacy of an intervention within the same unit across time, a
sample size of 20 to 25 is considered adequate (Hertzog, 2008).

**RPC and health care professional focus group.** All RPC members (N = 4) were eligible
to participate in the focus group session. For the focus group with the NICU health care
professionals, a sample size of six to nine individuals was sought to obtain a representation of
various disciplines in the NICU while allowing for meaningful participation in the discussion by
all participants. The sample size for focus group participants deemed adequate varies from four
to 20 individuals (McLafferty, 2004).

**Study 3: Feasibility and clinical utility of the PEC.** As with Study 1, the number of
experts recommended to establish content validity ranges from three to 10 individuals (Lynn,
1986). To establish the feasibility and clinical utility of the PEC, a purposive sample of all
research nurses/coordinators who had used the PEC in the study conducted by the TROPIC study
(Stevens et al., 2008) and who had met the inclusion criteria for participation were targeted. As
the method of questionnaire delivery was by email, we expected the response rate to be similar to
Study 1 (i.e., 36%).

**Data Collection Procedures and Study Instruments**

**Process Evaluation Checklist (PEC).** A checklist includes a list of planned activities
and is used to determine whether the activities were implemented as planned. A checklist
“provides guidance for the collection of relevant evidence used to determine the merit, worth or
significance of an evaluand” (Martz, 2010, p. 215). Based on the guidelines by Armstrong and
colleagues (2005), and Stein and colleagues (2007), the PEC was developed by the researcher to
monitor fidelity of implementing the EPIC intervention. Item generation was completed by the
researcher, the principal investigator of the TROPIC study (Stevens et al., 2008) and a nurse
practitioner who was familiar with the EPIC intervention process and activities. The PEC consisted of two sections. Section 1 included items capturing Phase 1 activities of the EPIC intervention and Section 2 represented items for the four types of KT strategies (i.e., reminders, educational materials, educational outreach, and audit and feedback) used in Phase 2 of the EPIC Intervention. The steps and activities involved in Phase 1 and 2 of the EPIC intervention process were then translated into individual statements by the researcher and nurse practitioner and confirmed by the principal investigator of the TROPIC study (Stevens et al., 2008). For example, in Section 1 of the PEC, the first step in the EPIC process was to identify the RPC members. The corresponding item for this first step was: What is the professional status of the RPC team members? The steps in the EPIC intervention process and the corresponding items developed for the PEC are summarized in Table 6.

Section 1 of the PEC corresponds to Phase 1 of the EPIC intervention. The EPIC intervention steps are related to the concepts of evidence and facilitation within the PARiHS framework. There were 17 items included in Section 1. Information about RPC members’ profession, and how they were recruited was included. RPC members were asked about the perceived usefulness of the EPIC intervention training session which included a review of baseline practice data, research evidence to support pain practice changes, effective KT strategies, quality improvement methods, and facilitators and barriers to attending the training sessions. A 5-point Likert scale was used (1 = not useful and 5 = extremely useful) to evaluate each item. The selection of five response options was appropriate as reliability generally does not improve beyond five levels, and individuals are not able to discriminate response options beyond this number of categories (Strenier & Norman, 2008). For two items, RPC members were asked about their pain practice aim that was the focus of improvement for Cycles 1 and 2.
RPC members were asked to describe the sources of evidence they used to assist in identifying their pain practice change and about the effectiveness of the practice changes strategies to improve pain practices in the unit.

Section 2 of the PEC corresponded to Phase 2 of the EPIC intervention. Phase 2 focused primarily on the concept of facilitation in the PARiHS framework. In Section 2 of the PEC, there were four subscales developed on four types of evidence-based KT strategies: educational outreach, educational materials, reminders, and audit and feedback. Information was collected on the date the strategy was used, the type of KT strategy implemented, the specific medium used (e.g., posters), the reach (i.e. targeted audience), location of the materials used, duration of the KT strategy implementation, and the dose (i.e., number of times the strategy was used). Educational outreach included items about the location of the strategy (e.g., class room) and the content that was presented (e.g., objectives of the strategy, role of participants). RPC members rated the usefulness of each KT strategy delivered. The ratings were averaged to a mean usefulness score. Open ended questions were used to collect information about factors that facilitated and/or hindered the implementation of the KT strategy. These questions could be used to capture some information related to the context of the unit. For example, if a reminder poster was rated as not useful, the barrier might be related to the lack of time reported by staff to read the poster.
### Table 6

*EPIC Intervention and Items related to EPIC in the PEC*

<table>
<thead>
<tr>
<th>EPIC intervention</th>
<th>Process evaluation checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1: Preparation phase</strong></td>
<td><strong>Section 1: Phase 1 preparation phase</strong></td>
</tr>
<tr>
<td>1) Establish the RPC</td>
<td>Identify the RPC members and credentials (i.e., professional background)</td>
</tr>
<tr>
<td>2) Train the RPC members on the EPIC process</td>
<td>Training of the RPC members and usefulness of the training sessions: Review of baseline practice data, pain evidence (systematic reviews), effective KT strategies to implement pain practice changes, quality improvement processes including rapid cycle methodology.</td>
</tr>
<tr>
<td>Review baseline practice data and identify potentially useful practice changes</td>
<td>Usefulness of training session and factors facilitating and hindering attendance at the training session</td>
</tr>
<tr>
<td>Review existing clinical and research evidence to support the practice change</td>
<td>Identify potentially useful pain practice changes, how they were chosen, and develop an aim statement</td>
</tr>
<tr>
<td>RPC members decide on a practice change to implement and develop a pain practice aim statement</td>
<td></td>
</tr>
</tbody>
</table>
### Phase 2: Implementation and Change Phase

3) Plan a test of change using KT strategies (reminders, educational materials, educational outreach, audit and feedback)  
Implement the practice change using PDSA cycles (two three-month cycles known as Cycle 1 and Cycle 2)  
4) Evaluate the change using audit and feedback at end of each cycle of change

| KT strategies delivered/implemented (i.e., dose, duration, reach) |
| Educational interventions: educational outreach and educational materials, reminders, audit and feedback |
| Receipt/Usefulness of KT strategies |
| Enactment of practice change |
| PEC completed for audit and feedback on KT strategy used to reflect enactment of sucrose administration practices |

*Note. KT = knowledge translation; PEC = Process Evaluation Checklist; QI = quality improvement; RPC = Research Practice Council.*
Study 1(a). Face validity of the PEC. A preliminary version of the PEC was sent electronically to the 26 TROPIC study (Stevens et al., 2008) co-investigators. The co-investigators were asked to provide feedback and suggestions regarding the instructions and the content of the items in the PEC within a one-week period. Specifically, they were asked to evaluate whether the items of the PEC captured the steps of the EPIC intervention and whether any items should be added, clarified, or removed. According to the REB, providing their suggestions and feedback was voluntary and implied consent to participate.

Study 1 (b). Content validity of the PEC. Experts participating in the content validity of the PEC were sent a package containing a cover letter and a questionnaire. The cover letter provided an explanation about the purpose of the PEC measure and the reason why the CNN members were invited to participate. Instructions about how to rate the items’ importance/relevance were provided on each page of the questionnaire. A sample of the questionnaire is presented in Appendix E. Operational definitions for fidelity, feasibility, and usefulness of the KT strategies were included in the instructions.

The questionnaire included the items, instructions, and response scales used in the PEC to be rated for content validity. Participants were asked to rate each item on the PEC according to how important its content was in representing the steps of the EPIC intervention. A 4-point Likert scale with anchors that ranged from 1 (not important) to 4 (very important) was used (Lynn, 1986). The experts were also asked to rate whether items on the PEC represented the content in the scale/subscales of interest, and to provide feedback on the clarity and comprehensiveness of the items in reflecting the steps of the EPIC intervention, areas of omission and where improvements or revision could be made. The cover letters and questionnaires were delivered electronically to participants by the CNN coordinator and were
returned to a neutral individual (an administrative assistant at the researcher’s site). Returning the completed questionnaire implied consent to participate. Participants were informed that all information collected was confidential and results were reported in aggregate form to maintain confidentiality.

**Study 2: Construct validity of the PEC.** In Study 2, the construct validity of the PEC was evaluated by assessing the fidelity of implementing the EPIC intervention. A sample of the final version of the PEC is described in Appendix F.

**Measurement Instruments**

Instruments used in Studies 1 to 3 are summarized in Table 7

Table 7

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Interview guide

PEC feasibility and clinical utility measure 3 K

*Note. CPPR = Canadian Paediatric Pain Research; PEC = Process Evaluation Checklist; RPC = Research Practice Council.*

**Canadian pediatric pain research (CPPR) database.** The web-based data entry system, the Canadian Pediatric Pain Research (CPPR) database was developed for the TROPIC study (Stevens, et al., 2008) and was used in Study 2 to collect data about the NICU unit profile,
painful procedures (i.e., type and frequency of painful procedures) and pain practices (i.e. pain assessments; pharmacological, physical, and psychological interventions) at baseline and at the end of the EPIC intervention implementation (Appendix G). Face validity of the variables in the database was established by the TROPIC study co-investigators through a consensus process with pain experts and the data entry process was pilot tested by the research nurses from this study. These data were collected to determine the enactment of pain practices during Study 2, and to establish the construct validity of the PEC.

**Rapid cycle data collection form.** Selected local data on the RPC members’ targeted pain practice changes were one of the sources of evidence used to inform the RPC members about the progress of their practice change outcomes (i.e. documentation of sucrose orders and of sucrose administration) (Appendix H). These data were collected using the rapid cycle data collection form developed for Study 2. The form was developed by the researcher, reviewed by the quality and risk management team at the study site, and pilot tested with the RPC members to ensure that the data collected reflected important aspects of the targeted practice change.

**Unit activity log.** The unit activity log was used to collect information about pain assessment and management activities that had occurred in the NICU during Study 2. (Appendix I). This log was completed by the researcher at the end of each month.

**RPC and health care professionals interview guides.** The RPC member and health care professional interview guides were developed for use in Study 2. A semi-structured interview guide (Appendix J) was generated by the researcher for the RPC member focus group interview using concepts from the EPIC intervention process and the PARiHS framework. To gain a perspective on the EPIC process, the RPC members were asked about their role as facilitators in promoting the practice change and the effectiveness of the KT strategies used
during the course of the study including barriers and facilitators to implementing these strategies. Questions and probes for health care professional participants were related to the KT strategies used to promote this practice change. The interview guide was reviewed by the researcher’s PhD committee members, and pre-tested with the nurse practitioner consultant and a post-doctoral nursing fellow who were familiar with the EPIC intervention. The wording of the instructions for the focus group and questions pertaining to the RPC’s role and the effectiveness of KT strategies were revised based on the feedback from the pretest.

**PEC feasibility and clinical utility measure.** The PEC feasibility and clinical utility measure, based on some of the concepts by Voepel-Lewis et al. (2008), was developed by the researcher and used in Study 3 (Appendix K). This measure included eight items rated on a 5-point scale, where higher scores indicated higher feasibility and clinical utility of the PEC. Seven questions were related to the feasibility of the PEC measure and one item covered the clinical utility of the PEC. Items related to the feasibility of the PEC included questions about (a) the clarity of the instructions on how to complete the sections of the PEC, (b) structure, (c) format of the PEC forms, (d) length of the PEC forms, (e) the method of scoring, (f) interpretation of the information obtained from the PEC, and (g) whether the PEC could be incorporated into the practice setting. The item related to the clinical utility of the PEC assessed the extent to which the information obtained from the PEC could be used to guide and plan practice change interventions. A comment section was added at the end of the questionnaire to obtain any additional feedback from the respondents.

**EPIC Intervention Process**

**EPIC Phase 1.** There were two steps in EPIC Phase 1 that were captured/assessed in the PEC (Table 6) including:
Step 1: Identifying RPC members and credentials. An important step in examining intervention fidelity includes documentation about the characteristics of individuals (i.e., providers) who would be responsible for implementing the intervention (Borrelli et al., 2005). The first step in Phase 1 of the EPIC was focused on identifying the RPC members to assume responsibility for implementing the EPIC in the NICU (Table 6). Based on the RPC eligibility criteria, key committee chairs, managers, educators and coordinators in the NICU recommended individuals who might participate as members of the RPC. The researcher received permission to introduce the study at relevant meetings where the researcher explained that the RPC members would be required to attend a three hour training session to learn about the EPIC process, participate in bi-weekly meetings with the researcher to discuss the progress of the practice change, and obtain additional coaching as required. These regular meetings between the researcher and the RPC members were planned to keep the RPC members on track with the study timelines, thus preventing provider drift from the study (Bellg et al., 2004). Approximately one hour per week was to be devoted to promoting the pain practice change using a variety of KT strategies. Finally, the RPC members were asked to participate in a focus group session at the end of the EPIC intervention to discuss the implementation of the EPIC process. Details about the RPC member credentials and how they were identified were documented on the PEC (Appendix F).

Step 2: Training of RPC members. Provider training and ensuring that provider skills were maintained was another component of intervention fidelity that was evaluated (Borrelli et al., 2005). After explaining the study, the researcher obtained consent from four individuals who were interested in participating as RPC members (Appendix L). Information was collected regarding their profession and years of neonate-specific health care professional experience at
their institution (Appendix M). The researcher trained the RPC members in the two phases of the EPIC intervention. The interactive training sessions included a procedure manual and covered the rationale underlying each step of the EPIC intervention process, the procedure to carry out each step, and evidence on effective KT strategies and quality improvement methods. Specifically, training sessions included materials on current systematic reviews of evidence related to pain assessment and management in infants, evidence based KT strategies that could be used during Phase 2 of the EPIC intervention, and a presentation on quality improvement methods and use of plan-do-study-act (PDSA) cycles. Finally, the researcher presented the RPC members with the results of the baseline pain practice audit conducted on their unit and described where the unit was doing well and where improvements could be made. Based on the data provided, the RPC members discussed potential pain practice changes for their unit. The RPC members generated a list of potential changes and identified their practice change by the end of the training sessions. Process evaluation of the EPIC intervention was introduced at the training session as well as the role of the researcher who was to complete the PEC with the RPC members during biweekly meetings.

Section 1 of the PEC was developed to be consistent with the steps of Phase 1 Preparation of the EPIC intervention. The RPC members completed section 1 of the PEC at the end of Phase 1 of the EPIC during a meeting with the researcher. At this time, the RPC members were asked to rate the usefulness of the training sessions on a 5-point Likert scale ranging from 1 (not at all useful) to 5 (extremely useful) and commented on facilitators or barriers to the training sessions (Appendix F).

**EPIC Phase 2.** There were two steps in EPIC Phase 2 that were captured/assessed in the PEC including:
**Step 3: KT strategies delivered/implemented, and received during EPIC.** The researcher met with RPC members during biweekly 30 to 60 minute meetings to assist them with planning the pain practice change using a variety of KT strategies including educational outreach, educational materials, reminders, and audit and feedback. KT strategies were implemented over two consecutive three-month cycles that followed PDSA cycle methodology (Langley et al., 1996). During the biweekly meetings, the researcher and the RPC members completed the PEC tool for the appropriate KT strategies delivered including information about the dose, location, duration, and reach of the strategies. These meetings were also used to discuss barriers, set backs or facilitators and successes of the KT strategies delivered, and this information was documented on the PEC. Discussions between the researcher and the RPC members facilitated the tailoring of the strategies for the following week or cycle. The RPC members rated the usefulness of each KT strategy, which represented the degree of receipt of the strategies (Appendix F). Finally, the RPC members decided by consensus, whether these strategies would be repeated or expanded for the next three-month cycle.

**Step 4: Enactment of the practice change.** To determine if health care professionals were moving towards achieving their practice aim, audits were conducted using a rapid cycle data collection form both during and at the end of Cycles 1 and 2 (Appendix H). At the end of Cycle 1, the researcher conducted an audit on the progress of the pain practice change. Results from the audit were fed back to the RPC members and the unit staff using a variety of methods such as a newsletter. RPC members rated the degree of usefulness of the audit and feedback strategy using the pertinent section of the PEC. At the end of Cycle 2, which marked the end of Phase 2 the EPIC intervention, data collection on pain practices and pain practice outcomes was repeated using the CPPR database. During the course of the two cycles, the researcher recorded
on a unit activity log, any unit or hospital related activities or co-interventions that could potentially influence the direction of the pain practice change (Appendix I).

**Focus groups with RPC members and health care professionals.** Two focus group sessions were conducted to gain a collective view and a range of perspectives about aspects of fidelity of implementing the EPIC intervention from the RPC members and health care professionals in the participating NICU (Powell & Single, 1996). The qualitative data from the focus group sessions were used to describe aspects the EPIC intervention implementation that could not be quantified (Cresswell, 2009; Cresswell & Plano Clark, 2011).

The RPC members and a sample of health care professionals in the NICU who participated in the EPIC intervention were invited to a focus group session at the end of Cycle 2 using the inclusion criteria and recruitment strategies described in the section on sample recruitment procedures for Study 2. Prior to the focus group session, consent to participate in and to audiotape the focus group discussion was obtained (Appendix L). Focus group sessions were facilitated by a post-doctoral fellow with the TROPIC study (Stevens et al., 2008) who had an in-depth understanding of the EPIC intervention and experience conducting focus group interviews. Information was collected from participants related to profession, and years of NICU experience in the hospital (Appendix M). The interviewer documented additional information noted in the focus group session in the form of field notes. At the beginning of the focus group session, the interviewer described the study, the purpose of the focus group, set the ground rules for discussion (e.g., requested that each person speak one at a time), and discussed procedures for confidentiality and privacy related to the data collected and how the data would be used (Fitch & Lewis, 2003). Each focus group session was audiotaped to provide accurate data for transcription. Focus group sessions were intended to last from 30 to 60 minutes and were
scheduled based on the availability of participants. Lunch and light refreshments were provided for participants as a token of appreciation for their involvement in the focus group sessions.

**Study 3. Feasibility and clinical utility of the PEC.** The PEC Feasibility and Clinical Utility Questionnaire was developed and validated for content validity prior to use to evaluate the feasibility and clinical utility of the PEC.

First, three co-investigators and two core team members were identified by the Principal Investigator of the TROPIC study (Stevens et al., 2008) as having familiarity with the PEC, and were approached by the Project Manager of the study to determine whether they were interested in completing the questionnaire regarding the content validity of the PEC Feasibility and Clinical Utility Questionnaire. If the individuals indicated an interest in participating, the researcher contacted them by phone to explain what was expected of them if they agreed to participate. To ensure anonymity, a research administrative assistant emailed the questionnaire to these individuals with two follow-up email reminders. Returning the completed questionnaire implied consent to participate.

Once the content validity of the PEC Feasibility and Clinical Utility Measure was completed, the Project Manager of the TROPIC study (Stevens et al., 2008) informed all research nurses about the questionnaire and invited the researcher to a meeting to discuss the purpose of the study questionnaire (Appendix K). Following this meeting, a message was sent electronically by a research assistant to the 11 research nurses/coordinators who had been using the PEC in this study (Stevens et al., 2008). These individuals were asked to rate the feasibility and clinical utility of the PEC and to submit their responses using the secure on-line ClassApps site (to ensure anonymity) of the TROPIC study (Stevens et al., 2008) within two weeks. A research assistant emailed a reminder to the research nurses at the end of the first week.
According to the REB, providing their suggestions and feedback was voluntary and implied consent to participate.

**Data Management**

To ensure confidentiality and anonymity in accordance with institutional and privacy policies, all data collection forms were identified by a study code number only, stored separately from any identifiable data in the researcher’s office at the participating hospital, and followed the two-lock policy as mandated by privacy policies at the participating hospital. Computer files and databases related to the study were accessible by password only. The computer was located in the researcher’s locked office located at the participating hospital. Data were saved on a secured password protected and encrypted hospital network drive.

Content validity data for the PEC, chart audit data regarding the progress of the practice change were double entered into an Excel database. To maintain participant anonymity, the PEC feasibility and clinical utility questionnaire data were entered into an on-line ClassApps application developed for the TROPIC study (Stevens et al., 2008). The KT strategies used during the EPIC intervention implementation was also double entered into the ClassApps application as the database was password protected.

Baseline demographic and clinical data were entered into the CPPR database using data security processes (i.e., confidentiality, transfer of data, and access to data). Data entered into the CPPR database were reviewed for accuracy by a database manager from the TROPIC study (Stevens et al., 2008). Qualitative data from focus group interviews were transcribed verbatim by a trained transcriptionist who had signed a privacy agreement. To ensure that the transcribed data were accurate, the researcher reviewed the focus group transcriptions along with the audiotapes of each focus group and, where necessary, corrections to the text were made. There
were few corrections for clinical terminology made to each focus group transcript. Following completion of the research study, the data will be kept as long as required by the participating institution’s “Records Retention and Destruction” policy (e.g., seven years) and destroyed according to this same policy.

**Data Analysis**

Research objectives for Studies 1 to 3, data source, and a plan for analysis are summarized in Table 8.
Table 8

*Plan for Analysis*

<table>
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<th>Data source</th>
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<th>Qualitative analysis</th>
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<tr>
<td>(i) Usefulness of training sessions</td>
<td>(i, ii) Section 1 of the PEC + RPC member focus group</td>
<td>(i, ii) Descriptive statistics (M, SD, Mdn, IQR, min, max for usefulness scores)</td>
<td>Qualitative content analysis (RPC member focus group)</td>
</tr>
<tr>
<td>(ii) Identification of pain practice targeted for change</td>
<td>(i, ii) Section 1 of the PEC + RPC member focus group</td>
<td>(i, ii) Descriptive statistics (M, SD, Mdn, IQR, min, max for usefulness scores)</td>
<td>Qualitative content analysis (RPC member focus group)</td>
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</table>
(i) KT strategies most frequently delivered (including dose, reach, duration, barriers, facilitators of the KT strategies implemented)  
(ii) usefulness of the KT strategies received  

Enactment of practice change:  
(i) Relationship between KT strategies used, and pain practice changes.  
(ii) RPC and health care professional perspectives on EPIC process  

Study 3  
(i) Content validity of the PEC feasibility and clinical utility questionnaire  
(ii) Feasibility and clinical utility of the PEC  

| (i) KT strategies most frequently delivered (including dose, reach, duration, barriers, facilitators of the KT strategies implemented) | (i, ii) Section 2 of PEC | (i) Descriptive statistics (frequencies and proportions reported during Cycles 1 and 2) | (i) Qualitative description of barriers and facilitators of KT strategies documented in the PEC |
| (ii) usefulness of the KT strategies received | (i,ii) Focus group with RPC members and health care professionals | (ii) Descriptive statistics (M, SD for usefulness scores) | (i, ii) Qualitative content analysis of focus group data |

Enactment of practice change:  
(i) Relationship between KT strategies used, and pain practice changes.  
(ii) RPC and health care professional perspectives on EPIC process  

| (i) KT strategies most frequently delivered (including dose, reach, duration, barriers, facilitators of the KT strategies implemented) | (i, ii) Section 2 of PEC and CPPR database, rapid cycle data collection form | (i) Independent samples t-tests, chi-square tests | (ii) Qualitative content analysis of focus group data |
| (ii) usefulness of the KT strategies received | (i) Focus group with RPC members and health care professionals | (ii) Simple logistic regression modeling for ordering and giving sucrose onto time was conducted |

| (i) KT strategies most frequently delivered (including dose, reach, duration, barriers, facilitators of the KT strategies implemented) | (i, ii) Section 2 of PEC and CPPR database, rapid cycle data collection form | (i) Independent samples t-tests, chi-square tests | (ii) Qualitative content analysis of focus group data |
| (ii) usefulness of the KT strategies received | (i) Focus group with RPC members and health care professionals | (ii) Simple logistic regression modeling for ordering and giving sucrose onto time was conducted |

**Note.** CPPR = Canadian Pediatric Pain Research; CVI = content validity index; EPIC = Evidence-based Practice Identification and Change (Lee et al., 2009); KT = knowledge translation; M = mean; SD = standard deviation; Mdn = median; min= minimum; max = maximum; PEC = Process Evaluation Checklist; RPC = Research Practice Council.
Study 1: Face and content validity of the PEC.

Content validity index. The content validity index (CVI) was used to establish the content validity of the items and scale/subscales of the PEC (Armstrong et al., 2005). The CVI represents the level of experts’ agreement on the individual items and the total scale/subscale (Polit, Beck, & Owen, 2007). Item CVI (I-CVI) was computed as the proportion of experts who rated an item as a 3 (i.e., quite important) or 4 (i.e., very important) on the 4-point rating scale, out of the total number of experts who provided ratings for the item. Scale/subscale CVI (S-CVI) was the proportion of items within the scale/subscale that were assigned a rating of 3 or 4 on the 4-point scale by at least 80% of the expert raters (Lynn, 1986; Polit et al., 2007). If all experts rated all items as either a 3 or 4, the S-CVI was given a value of 1.00. The average ratings for items using the S-CVIs (S-CVI/Ave) were also reported Polit and Beck (2006). It was decided apriori that items with an I-CVI of 0.7 or greater would be retained; 0.5-0.7 would be revised; less than 0.5 would be removed unless there was theoretical support for keeping the item. These CVI interpretations were consistent with recommendations by Lynn (1986) and Polit et al. (2007).

Study 2: Construct validity of the PEC.

Quantitative data analysis. Quantitative data were analyzed using SPSS version 15.0 and SAS version 9.2 (SAS institute, Inc., Cary, NC). Descriptive statistics (means, standard deviations, medians, and inter-quartile ranges) were calculated for continuous data. Categorical data were analyzed and reported as frequency counts and proportions. Independent t-tests were conducted to compare means between groups, at baseline (Time 1) and at the end of the EPIC intervention implementation (Time 2). Chi-square and Fisher Exact tests for association were used to compare proportions across the two time periods. Logistic regression was used to model
the probability of the selected practice change based on time. The significance (p values) of statistical tests were two-tailed where a p < .05 was considered statistically significant.

**Qualitative data analysis.** Rather than reporting similarities or differences by health care professional designation, a whole group analysis was conducted for each focus group where the group was the unit of analysis (Ritchie, Spencer, & O’Connor, 2003). The aim of the analysis was not to condense but broadly describe a phenomenon, where concepts and categories represented the outcome of the analysis (Elo & Kyngas, 2008).

Qualitative content analysis was the method used to analyze the focus group data. A conventional content analysis approach was used (Hsieh & Shannon, 2005; Mayring, 2000). In this inductive approach, codes and categories emerged directly from the data, and where possible, the language and words used by participants, also known as in-vivo concepts, formed the codes (Mayring, 2000; Sandelowski, 2000; Spencer, Ritchie, & O’Connor, 2003).

Data from both focus groups were initially read completely to gain an overall perception of the information reported by participants. The RPC member and health care professional focus group data were analyzed together. Meaning units, or sentences and words in the transcripts that had related content were developed and reduced to codes (Graneheim & Lundman, 2004). Codes were compared and sorted into categories and sub-categories. Existing codes were revised, similar paraphrases were bundled and summarized and new emerging codes were developed for data that could not be coded into initial categories (Hsieh & Shannon, 2005; Ritchie, et al., 2003). The latent content or main interpretation of the categories was then described using excerpts/quotations from participants (Graneheim & Lundman, 2004). A coding framework was developed for categorizing the focus group data (Appendix N).
Qualitative content analysis of the focus group data was used to explicate or support the findings documented in the PEC. Categories identified from the qualitative focus group with the RPC members and health care professionals confirmed, and provided additional perspectives about the EPIC process.

The researcher and a second coder, a post-doctoral fellow with the TROPIC study (Stevens et al., 2008) independently analyzed the focus group data. Once the overarching categories and sub-categories were determined, the researcher met with the second coder, discussed the codes, and resolved any discrepancies through discussion. Most discrepancies were related to the wording of the overarching categories and subcategories.

Methods used to demonstrate rigor and validity in qualitative description of the focus group data were based on strategies described by Whittemore, Chase, and Mandle (2001) and included:

Credibility and authenticity. Providing an accurate account or perspective of the facts related to an event supports the credibility, authenticity, or descriptive and interpretive validity in qualitative descriptive designs (Sandelowski, 2000; Whittemore et al., 2001). To achieve credibility and authenticity of the data collected, purposive sampling was used where a variety of health disciplines from the NICU who were exposed to the EPIC intervention process and pain practice change, were invited to participate in the health care professional focus group sessions. Data from the focus groups were transcribed verbatim by trained transcriptionists who were provided with instructions on how to transcribe the audiotaped interviews and ensure privacy of the data (i.e., data were de-identified), and any discrepancies in the transcribed data were checked by the researcher using the audiotapes from the focus groups. Identifying categories
and subcategories as part of a standardized qualitative content analysis process also provided support for the credibility and authenticity of the focus group data (Neergaard et al., 2009).

**Criticality and integrity.** To ensure that the interpretation of the focus group data reflected a comprehensive account of the events reported (Sandelowski, 2000), the researcher and a second coder, a post-doctoral fellow in nursing who conducted the focus groups and who was familiar with the EPIC intervention process, coded the transcripts from the two focus groups independently. Discrepancies in coding and development of categories were addressed through discussion between coders. The researcher also met with a participant from each of the focus groups and asked the individual to verify the interpretations from interview data, a method referred to as member checking (Whittemore et al., 2001). A record and details regarding codes and categories identified from the focus group data formed the audit trail of the coding process (Whittemore et al., 2001) for the focus group data. Quotes from focus group sessions were used to illustrate the interpretations of the data and highlighted the differences between categories (Graneheim & Lundman, 2004).

**Study 3. Feasibility and clinical utility of the PEC.** To establish content validity of the questions developed for the PEC Feasibility and Clinical Utility questionnaire, the same analysis used in Study 1 (i.e., calculation of a Content validity index (CVI) was used. Descriptive analysis (e.g., means, standard deviations) was conducted to report the actual scores from participants who completed the questionnaire.

**Missing Data**

For Study 1, each item was assessed for missing data. If missing data on each item was greater than 15%, then the mean value for that item (based on the ratings of those who completed it) was used in the imputation (McKnight, McKnight, Sidani, & Figuerdo, 2007). The CPPR
database included built-in logic checks for accuracy and to prevent missing data. Logic checks were conducted for the end of Cycle 1 rapid cycle data that were entered into an Excel database.

**Ethical Considerations**

Ethical approval was obtained from the REB at the hospital where the studies were conducted and at the affiliated university. Once REB approval was obtained, the proposal was submitted to the NICU research committee to determine study feasibility in the NICU as concurrent studies were being implemented in this setting. As this study included quality improvement methods and tailoring of the KT strategies by the RPC members, Cycle 1 and 2 within cycle audit data collection forms and all KT strategies implemented were submitted to and approved by the hospital’s Quality and Risk Management Department for Quality Improvement Projects to ensure all proper procedures and safeguards were in place and adhered to.

As this study explored the facilitation of pain practice guidelines developed in the NICU, consent was not required from the health care professionals in the NICU because these activities represented usual practice. Patients’ medical charts were retrospectively audited once patients had been discharged from the NICU; therefore, consent from parents was not required. Consents were obtained from the RPC members who implemented the EPIC intervention and who participated in the focus group interview at the end of the study intervention. Consents were also obtained from the health care professionals who participated in a focus group session following the completion of the EPIC intervention implementation. The RPC members and health care professionals who participated in the focus group sessions were informed that their participation was voluntary, and that they could refuse to participate or withdraw from the study at any time. The only costs to the participants were related to their time required to participate in the focus group and in the intervention. The RPC members received a $200 gift certificate at the
completion of the one year study to compensate for their participation as RPC members during the two Phases of the EPIC intervention.
In this Chapter, the results from the three studies are presented. Figure 2 provides a schema for Studies 1-3.

**Study 1: Face and Content Validity of the PEC**

The purpose of Study 1 was to determine the face and content validity of the PEC. Data collection occurred in August 2007 for face validity and May to June, 2008 for content validity.

**Study 1(a): Face validity of the PEC.** Nine of the 26 (34.6%) co-investigators from the TROPIC study (Stevens et al., 2008) provided feedback about the face validity of the items included in the PEC. Respondents included 7 nurse clinicians/researchers, 1 physician, and 1 psychologist.

Comments from respondents focused primarily on the structure/layout of the PEC items and the need to clarify or expand on the concepts included in the PEC. Further changes were made to the PEC based on recommendations from the respondents. Specifically, definitions were provided for each category of KT strategy (i.e., reminders, educational interventions, audit and feedback). Items that were confusing were re-worded, clarified, refined, and arranged in a suitable sequence. One comment was to consider providing a Likert scale so respondents could check off their responses. Therefore, a 5-point Likert scale was added to allow respondents to choose a response related to the usefulness of the KT strategies implemented.
Figure 2. Study schema for Studies 1-3

Note. EPIC = Evidence-based Practice Identification and Change (Lee et al., 2009); PEC = Process Evaluation Checklist.
Study 1(b): Content validity of the PEC. Eight of 19 (42.1%) questionnaires were completed by experts from the CNN and returned following two reminders. Responses from the questionnaires were the basis for the content validity ratings for the PEC. Participants included one nurse clinician, two Advanced Practice Nurses (APN) s, and three physicians. Two respondents did not identify their profession. This final sample size is consistent with Lynn’s (1986) recommendations of recruiting a minimum of three to a maximum of 10 experts to determine content validity.

Content validity index (CVI) for items and subscales. A content validity index (CVI) was determined for each item and subscale of the PEC. The CVI values are summarized in Table 9. All but six out of the 66 items in the PEC were rated by at least seven of eight experts.

PEC section 1. I-CVIs (i.e., number of experts rating each item either a 3 or 4) ranged from 0.6 to 1.0. The S-CVI (i.e., proportion of items rated 3 or 4 by at least 80% of the experts) was 0.8. The S-CVI/Average (i.e., mean rating score for all items) was 0.9. Two items with an I-CVI of 0.6 were discarded including one item requesting information about the number of participants on the RPC and another item to capture “other comments”. Their content was redundant with other items on the PEC. A third item assessing the effectiveness of the pain practice KT strategies that were identified by RPC members as a focus of improvement was rated 0.6; however, this item was retained as it provided information, from the RPC’s perspective, about how effective the KT strategies were in improving the targeted pain practice (Yamada, Stevens, Sidani, Watt-Watson, & de Silva, 2010).
Table 9

Content Validity Index Ratings (Yamada et al., 2010)

<table>
<thead>
<tr>
<th></th>
<th>No. items</th>
<th>I-CVI range</th>
<th>S-CVI</th>
<th>S-CVI Ave</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1: Phase 1</td>
<td>17</td>
<td>0.6-1.0</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Section 2: Phase 2 KT strategies selected</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subscales</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reminders</td>
<td>10</td>
<td>0.7-1.0</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Educational materials</td>
<td>13</td>
<td>0.8-1.0</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Educational outreach</td>
<td>15</td>
<td>0.9-1.0</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Audit and feedback</td>
<td>11</td>
<td>0.6-1.0</td>
<td>0.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Note. CVI = content validity index; I-CVI = item-CVI; S-CVI = scale/subscale CVI; S-CVI/Ave = scale/subscale CVI average; KT = knowledge translation; Maximum CVI is 1.0; No. = number.

PEC Section 2. The I-CVIs for the items pertaining to the subscale on reminders ranged from 0.7 to 1.0. The S-CVI was 0.9 and the S-CVI Ave was 0.9. The I-CVI for items in the subscale representing educational materials ranged from 0.8 to 1.0. The S-CVI was 1.0 and S-CVI average was 0.9. All items in the subscale for educational outreach had I-CVIs over 0.8. The S-CVI was 1.0 and S-CVI average was 0.9. All items in these first three subscales were retained. I-CVIs for the subscale for audit and feedback ranged from 0.6 to 1.0. The S-CVI was 0.3 and S-CVI average was 0.7. The eight items that had I-CVIs of 0.6 focused on the usefulness of specific methods used to deliver the KT strategy (e.g., use of posters). No rationale was provided by raters as to why these specific items were rated lower than similar items used in the three other types of KT strategies (i.e., reminders, educational materials, educational outreach).
When items describing the method used to deliver audit and feedback strategies were compared to an overall item asking about the usefulness of audit and feedback as a KT strategy, the S-CVI and S-CVI average were 1.0. As these six items were similar to those developed for reminders, educational materials and educational outreach, they were retained to maintain consistency across the PEC subscales. The pattern of missing data on ratings for the individual items was random, in that only one or two raters had missing data on different items (Yamada et al., 2010).

Summary of Study 1. The face validity of the PEC was established from input received by expert respondents. The items and scale/subscales of the PEC generated acceptable item and scale/subscale CVIs based on the feedback received from expert participants. Therefore, the findings support the content validity of the PEC.

Study 2: Construct Validity of the PEC

Data collection occurred from December 2007 (i.e., Time 1 data collection) to April 2009 (i.e., focus group). The quantitative and qualitative results of the construct validation process of the PEC are consistent with the relevant components of the intervention fidelity framework developed by Bellg et al. (2004) and Borrelli et al. (2005).

Step 1: Identifying RPC members and credentials. Phase 1 of the EPIC intervention was conducted over a three-month period from April to June 2008. The RPC consisted of one neonatologist, two APNs and an APN Educator. Their clinical experience in the current NICU ranged from 12-24 years.

All RPC members volunteered to participate in the study, and all were members of the NICU pain committee. One RPC member reported that she was motivated to improve practices to reduce patients’ pain experiences, had knowledge of the NICU culture and was well connected.
with the NICU nursing staff. As members of the pain committee, the RPC members felt that they had developed an interest and expertise in neonatal pain assessment and management.

**Step 2: Training of RPC members.** All RPC members attended interactive training sessions conducted by the researcher during the Phase 1 of the EPIC intervention. According to RPC members, attendance at the training sessions was made possible due to the “diligence of scheduler” (i.e., researcher). RPC members noted that scheduling conflicts and workload hindered their availability to attend some of the proposed training dates. Therefore, to accommodate all RPC members, training sessions were organized in one to two hour sessions on three occasions in June 2008 for a total training duration of 3.5 hours. Comments from RPC members about factors that facilitated their attendance at the training sessions related to their interest in being involved in the EPIC intervention process.

The RPC members’ ratings of the usefulness of the training session content are summarized in Table 10. Overall, the review of effective KT strategies, QI methodology and results of baseline practice data were rated very useful (i.e., Mdn score = 4.50-5.00 on 5-point Likert scale), whereas the review of evidence was judged as useful (i.e., Mdn score = 3.50). Prior to Cycle 2, the researcher reviewed the QI process with the RPC members. This meeting served as a booster and planning session for Cycle 2.
Table 10

RPC Usefulness Scores Related to EPIC Intervention Training

<table>
<thead>
<tr>
<th>Training session content covered</th>
<th>M (SD)</th>
<th>Mdn (IQR)</th>
<th>Min, Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of literature on pain assessment</td>
<td>3.75 (0.96)</td>
<td>3.50 (1.75)</td>
<td>3.00, 5.00</td>
</tr>
<tr>
<td>Review of evidence on pharmacologic pain management</td>
<td>3.75 (0.96)</td>
<td>3.50 (1.75)</td>
<td>3.00, 5.00</td>
</tr>
<tr>
<td>Review of evidence on non pharmacologic pain management</td>
<td>3.75 (0.96)</td>
<td>3.50 (1.75)</td>
<td>3.00, 5.00</td>
</tr>
<tr>
<td>Review of effective KT strategies</td>
<td>4.25 (0.96)</td>
<td>4.50 (1.75)</td>
<td>3.00, 5.00</td>
</tr>
<tr>
<td>QI process including rapid cycle methodology</td>
<td>4.50 (0.58)</td>
<td>4.50 (1.00)</td>
<td>4.00, 5.00</td>
</tr>
<tr>
<td>Review of baseline practice data</td>
<td>4.75 (0.50)</td>
<td>5.00 (0.75)</td>
<td>4.00, 5.00</td>
</tr>
</tbody>
</table>

Note. Usefulness scores (scored out of 5 on Likert scale, where 1 = not useful; 2 = somewhat useful; 3 = useful; 4 = very useful, and 5 = extremely useful); IQR = interquartile range; M = mean; SD = standard deviation; Mdn = median; Min = minimum; Max = maximum; KT = knowledge translation; QI = quality improvement.

At the end of their training sessions, RPC members identified a pain practice change based on several sources of evidence including information about their unit’s baseline pain practices. Baseline data were gathered in a retrospective pain practice audit, conducted seven months prior to the RPC member training (i.e., December, 2007). Demographic and clinical characteristics of the 30 infants are presented in Table 11. The data on painful procedures and pain management contributed to the outcomes of the EPIC intervention. To maintain privacy and confidentiality of personal health information, it was not possible to collect the exact date of birth for the infants in the study. On admission to the NICU, infants in this study ranged from 0
to 90 days of age and their gestational age at birth ranged from 24 to 42 weeks and birth weight ranged from 650 grams to 4.50 kilograms (Nurse Practitioner, Personal Communication, December 10, 2010). A review of infant diagnoses revealed that all infants were eligible to receive sucrose.

Table 11

*Time 1 Demographic and Clinical Characteristics of Study Infants (N = 30)*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>14 (46.8)</td>
</tr>
<tr>
<td>Medical</td>
<td>20 (66.8)</td>
</tr>
<tr>
<td>Surgical</td>
<td>10 (33.3)</td>
</tr>
</tbody>
</table>

*Note.* No. = number; Medical refers to infants admitted with a primary medical diagnosis (e.g., prematurity, respiratory distress; Surgical refers to infants admitted with a primary surgical diagnosis (e.g., gastroschisis, duodenal atresia).

*Time 1 painful procedures.* All 30 patients had at least one or more painful procedures documented in their charts within the first 24 hours of admission to the NICU. A total of 547 painful procedures were documented for the 30 infants during this time period (M = 8.90, SD = 3.58 per infant, Mdn = 9.00, IQR = 6.00). The type and frequency of the 10 most commonly documented painful procedures (n = 406) performed on the 30 infants in the first 24 hours of admission for Time 1 represented 74.2% of all painful procedures (Table 12). The most frequently performed painful procedure was endotracheal suctioning accounting for 109/547 (19.9%) of all painful procedures.
Table 12

*Time 1 Top 10 Frequency of Painful Procedures (N =30 infants)*

<table>
<thead>
<tr>
<th>Painful procedure</th>
<th>Frequency of performance across all infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suctioning: endotracheal</td>
<td>109</td>
</tr>
<tr>
<td>Tape removal from skin</td>
<td>68</td>
</tr>
<tr>
<td>Capillary sampling</td>
<td>58</td>
</tr>
<tr>
<td>Venepuncture/ phlebotomy</td>
<td>29</td>
</tr>
<tr>
<td>Peripheral intravenous attempt or insertion</td>
<td>29</td>
</tr>
<tr>
<td>Moving/repositioning&lt;sup&gt;a&lt;/sup&gt;</td>
<td>28</td>
</tr>
<tr>
<td>Suctioning: oral or nasal</td>
<td>26</td>
</tr>
<tr>
<td>Scraping/ swabs: nasopharyngeal swabs</td>
<td>25</td>
</tr>
<tr>
<td>Nasogastric tube attempt or insertion</td>
<td>20</td>
</tr>
<tr>
<td>Intravenous insertion</td>
<td>14</td>
</tr>
<tr>
<td>Total frequency for top 10 painful procedures</td>
<td>406</td>
</tr>
</tbody>
</table>

*Note.*<sup>a</sup>Moving/repositioning an infant who has an underlying painful condition (e.g., post-operative incisional pain, fractures (Nurse Practitioner, personal communication, December 7, 2010).

*Time 1 pharmacologic and physical interventions.* Twenty-two of the 30 (73.3%) infants had a pain management intervention documented within the first 24 hours of admission to the NICU. Sixteen of the 30 (53.3%) infants had an analgesic documented in their chart, 11/30 (36.7%) had a physical intervention, and 5/30 (16.7%) had evidence of receiving both pharmacologic and physical interventions. Of the analgesics administered, opioids were documented in 12/30 (40.0%) charts. Non-opioids (i.e., acetaminophen) were documented for 1/30 (3.3%) infants. Sucrose was administered to 3/30 (10.0%) infants. The frequency of pharmacological interventions administered is summarized in Table 13.

Eleven of the 30 (36.7%) infants had at least one physical intervention documented in their chart (Table 14). The most frequently reported physical intervention was
positioning/bundling/containing for 7/30 (23.3%) infants, whereas rocking, and breastfeeding were documented for 1/30 (3.3%) infant. None of the infants had a psychological intervention (e.g., distraction) documented.

Table 13

*Time 1 Pharmacologic Interventions (n = 16)*

<table>
<thead>
<tr>
<th>Pharmacologic Interventions</th>
<th>No. infants</th>
<th>Time 1 frequency of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl bolus</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Fentanyl infusion</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Morphine bolus</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Morphine infusion</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Sucrose</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Non-Opioids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

*Note.* No. = number.
Table 14

*Time 1 Physical Interventions (n =11)*

<table>
<thead>
<tr>
<th>Physical interventions</th>
<th>No. infants</th>
<th>Time 1 frequency of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort positioning/ bundling/ containing/ swaddling</td>
<td>7</td>
<td>29</td>
</tr>
<tr>
<td>Non-nutritive sucking (e.g. pacifiers)</td>
<td>5</td>
<td>22</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other- rocked by mother</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note.* No. = number.

For 9 of the 30 (30.0%) infants who had undergone a painful procedure, there was documentation of a pain management strategy administered specifically for the procedure. Of these infants, 8 (88.9%) had a pharmacologic, 3 (33.3%) had a physical and 2 (22.2%) had a combination of strategies.

*Time 1 pain assessment.* A total of 29/30 (96.7%) of the infants had at least one pain assessment documented in their charts in the first 24 hours of admission with a mean (M) of 4.76 times (standard deviation [SD] = 1.83). The Premature Infant Pain Profile (PIPP: Stevens et al., 1996), a highly reliable and valid composite measure for acute pain in infants (Stevens, Johnston, Taddio, Gibbins, & Yamada, 2010) consisting of seven items was used. The PIPP includes physiological (heart rate, oxygen saturation), behavioural (brow bulge, eye squeeze, nasolabial furrow) and contextual (gestational age, behavioural state) indicators of pain. Each indicator is scored on a 4-point scale that represents changes in the indicators from baseline. The range of possible ratings is 0 representing no pain to a maximum score of 21 indicating the highest pain. The mean (SD) pain score at baseline was 5.09 (2.22).
Given that only 3/30 (10.0 %) of infants were administered sucrose within the first 24 hours of admission, documentation of ordering and of administering sucrose were the top two proposed pain practice changes identified by all RPC members by consensus. The RPC members reported on the PEC that their practice change was based on a systematic review of the literature (Stevens, Yamada, & Ohlsson, 2004; 2010), results of the baseline pain practice audit, and their own expert opinion. As sucrose required an order by a physician or nurse practitioner, the first pain practice aim statement for Phase 2 of EPIC Cycle 1 was to improve documentation of sucrose ordering to 50%. In Cycle 2, the practice aim was to improve documentation of sucrose administration for at least one painful procedure to 75%.

**Step 3: Frequency of KT strategies delivered during EPIC.** Phase 2 of EPIC was delivered over a nine-month period from July 1, 2008 to March 15, 2009 and was extended by 1.5 months to accommodate the end of the Cycle 1 audit and two weeks of the holiday season. Meetings between the RPC members and the researcher captured their adherence to the delivery of the EPIC intervention.

There were 14 biweekly RPC meetings with the researcher between July 2008 and March 2009. Two meetings were cancelled due to scheduling conflicts. Fifty percent of the meetings were attended by at least three out of the four RPC members; only one third of the meetings were attended by two out of the four. One RPC member was out of the country for approximately half of the first cycle. Another RPC member changed roles from educator to staff nurse near the beginning of the second Cycle; however this individual remained on the RPC as an active participant. The researcher communicated by email, phone, or through face-to-face meetings with individual RPC members who were not able to attend the biweekly meetings following the meetings.
To ensure that the KT strategies were delivered as planned, frequency, reach, and duration of KT strategies delivered by the RPC during Cycle 1 and Cycle 2 were documented using the PEC (Table 15). Items in the PEC that referred to the usefulness of the KT strategies represented the fidelity component referred to as intervention receipt. Details about the types of KT strategies used, their dose and usefulness are described in Table 16.

Table 15

*Cycle 1 and 2 Frequency, Reach and Duration of KT Strategies Delivered*

<table>
<thead>
<tr>
<th>KT strategies</th>
<th>No. of unique KT strategies used</th>
<th>Reach (Range of staff targeted)</th>
<th>Duration of strategy (Range in days; min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cycle 1</td>
<td>Cycle 2</td>
<td>Cycle 1</td>
</tr>
<tr>
<td>R</td>
<td>1</td>
<td>3</td>
<td>203</td>
</tr>
<tr>
<td>EO</td>
<td>4</td>
<td>1</td>
<td>7 - 150</td>
</tr>
<tr>
<td>EM</td>
<td>3</td>
<td>0</td>
<td>203</td>
</tr>
<tr>
<td>AF</td>
<td>2</td>
<td>3</td>
<td>4 - 21</td>
</tr>
</tbody>
</table>

*Note.* KT = knowledge translation; min = minute; N/A = no new educational materials were implemented; No. = number; R = reminders; EO = educational outreach; EM = educational materials; AF = audit and feedback.
Table 16

*Cycle 1 and 2 Type, Dose and Usefulness Scores of KT Strategies Delivered*

<table>
<thead>
<tr>
<th>Type of KT strategy</th>
<th>Cycle 1 dose</th>
<th>M (SD) usefulness</th>
<th>Cycle 2 dose</th>
<th>M (SD) usefulness</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reminders</strong></td>
<td>1</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Sticker on admission order</td>
<td>1</td>
<td>4.75 (0.50)</td>
<td>1</td>
<td>4.75 (0.50)</td>
</tr>
<tr>
<td>Reminder sticker on MAR</td>
<td>1</td>
<td>4.00 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poster</td>
<td>1</td>
<td>4.00 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen saver</td>
<td>1</td>
<td>3.50 (1.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Educational outreach</strong></td>
<td>14</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Resident/fellow orientation(^a)</td>
<td>7</td>
<td>3.33 (0.58)</td>
<td>4</td>
<td>3.33 (0.58)</td>
</tr>
<tr>
<td>Senior staff meeting</td>
<td>1</td>
<td>4.25 (0.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing education days(^b)</td>
<td>5</td>
<td>4.25 (0.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:1 bedside teaching</td>
<td>1</td>
<td>4.25 (0.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roving in-services</td>
<td>4</td>
<td>4.00 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Educational materials</strong></td>
<td>3</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Posters for HCP</td>
<td>1</td>
<td>4.50 (1.00)</td>
<td>1</td>
<td>4.50 (1.00)</td>
</tr>
<tr>
<td>Poster for parents</td>
<td>1</td>
<td>4.50 (1.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poster for HCP revised</td>
<td>1</td>
<td>4.50 (1.00)</td>
<td>1</td>
<td>4.50 (1.00)</td>
</tr>
<tr>
<td><strong>Audit and Feedback</strong></td>
<td>4</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td>1</td>
<td>3.00 (2.00)</td>
<td>1</td>
<td>3.00 (0)</td>
</tr>
<tr>
<td>Verbal report to RPC(^c)</td>
<td>3</td>
<td>4.25 (0.50)</td>
<td>2</td>
<td>4.00 (0)</td>
</tr>
<tr>
<td>Leadership meeting</td>
<td>1</td>
<td>2.00 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain committee meeting</td>
<td>2</td>
<td>4.00 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit newsletter</td>
<td>1</td>
<td>3.00 (1.63)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total: 22 dose 21 dose

Note. \(^a\)Resident and \(^b\)Nursing education, and \(^c\)verbal reports to RPC in Cycle 1 were continued between Cycle 1 and 2 and were included in Cycle 1 dose; HCP = health care professional; KT = knowledge translation; MAR = medication administration record; M = mean; SD = standard deviation; RPC = research practice council; Usefulness score based on 5-point Likert scale (1 = not useful; 2 = somewhat useful; 3 = useful; 4 = very useful; 5 = extremely useful).
During Cycle 2, the RPC members focused primarily on the second practice change with the specific aim of improving documentation of sucrose administration to 75% within the first 24 hours of admission to the NICU. RPC members continued to provide KT strategies from Cycle 1 that were carried over into Cycle 2 (Table 17).

Table 17

*KT Activities Continued from Cycle 1*

<table>
<thead>
<tr>
<th>KT strategies</th>
<th>Dose of KT strategies and duration (days; min)</th>
<th>Reach (No. staff targeted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational outreach for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residents and fellows</td>
<td>4 x 5-10 min/session</td>
<td>22/22</td>
</tr>
<tr>
<td>Educational materials-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posters-health care professionals</td>
<td>1 x 105 days</td>
<td>203 (all staff)</td>
</tr>
<tr>
<td>Poster-parents</td>
<td>1 x 105 days</td>
<td>30 (parents) + 203 (all staff)</td>
</tr>
<tr>
<td>Sticker on admission order</td>
<td>1 x 105 days</td>
<td>203 (all staff)</td>
</tr>
</tbody>
</table>

*Note.* KT = knowledge translation; min = minutes; No. = number.
KT strategies were introduced at different time points determined by the RPC members during Cycle 1 and Cycle 2. Ten unique KT strategies were introduced during Cycle 1 and documented using the PEC (Table 15). Improving staff awareness and knowledge about sucrose use was addressed by implementing educational outreach sessions (n = 4) which were the most frequently delivered KT strategy, followed by educational materials (n = 3), audit and feedback strategies (n = 2), and reminders (n = 1). In Cycle 2, the practice aim was to improve sucrose documentation of administration. RPC members delivered three additional reminders, and three audit and feedback strategies, plus one new educational outreach session. The duration and reach of KT strategies varied depending on the type implemented. For example, reminder stickers were present in patient charts for 62 days during Cycle 1. Educational outreach sessions lasted from five to 20 minutes. Posters targeted all health care professionals in the unit, whereas some educational sessions were aimed at specific staff (e.g., 53 staff during Cycle 2). No new educational materials were delivered in Cycle 2 (Table 16).

**KT strategies most frequently delivered during Cycle 1.**

*Delivery of educational outreach sessions.* During Cycle 1, educational sessions, the most frequently implemented KT strategy (i.e., four unique types of educational sessions), was delivered to both medical and nursing groups by the RPC. RPC members discussed the documentation of sucrose orders in patient charts (Table 16). The first type of educational session included small to moderate group unit mandatory orientation sessions for residents and fellows. These five to ten minute sessions included information about sucrose use and were delivered by two RPC members (i.e., nurse practitioner and neonatologist) over seven occasions. A second type of educational session included one 20 minute meeting with seven senior medical staff who were key decision makers regarding NICU medication directives. This session focused...
on research evidence to support the unit’s sucrose clinical practice guideline. A third type of educational outreach strategy included 20 minute large group sessions incorporated into five mandatory nursing education days organized by the RPC member clinical educator. Finally, five minute bedside teaching sessions were implemented on one occasion to 20 staff nurses.

Receipt/usefulness of educational outreach sessions. Presentations by RPC members at nursing education days and one-to-one bedside teaching sessions were rated by the RPC members as very useful (M score = 4.25) methods for learning about sucrose administration practices (Table 16). The presentation at the senior medical staff meeting was rated as very useful (M = 4.25) compared to the resident and fellow orientation sessions, which were rated as useful (M = 3.33) methods to promote sucrose ordering. Residents and fellows were presented with information about ordering sucrose in mostly small group sessions delivered by RPC members who were well known in the unit. However, RPC members commented that one barrier to this type of strategy was the lack of time available to discuss sucrose in detail compared to a senior staff meeting. Residents and fellows were faced with an overload of new information during their orientation to the NICU.

Most useful KT strategy. Reminder stickers, the most useful KT strategy identified during Cycle 1 were rated by the RPC members as a very useful (M score = 4.75) (Table 16). Reminder stickers were introduced at the end of the first month (July 2008) during Cycle 1. Stickers were placed directly on admission order sheets for two months during Cycle 1. The purpose of the sticker was to remind all staff, especially the advanced practice nurses (APN) and physicians to order sucrose on the infant’s NICU admission orders. RPC members reported that the sticker provided a consistent message for health care professionals. According to the RPC, the colourful sticker was an effective visual reminder. However, some staff interpreted the
sticker as an order to give sucrose. Two staff nurses, who were working with one of the RPC members on sucrose KT strategies and other pain initiatives in the NICU, assisted with replenishing the stickers on admission orders during the study; however, RPC members commented on the PEC that a potential barrier to this reminder strategy was that stickers were not consistently replenished on admission order sheets (Table 18).

Least useful KT strategy. An audit and feedback KT strategy delivered by email near the end of Cycle 1 was rated the least useful method to disseminate results of the practice audit (Table 16). One RPC member emailed the results of the audit to 21 health care professionals who had prescriptive authority for ordering sucrose in the NICU. RPC members rated this strategy as useful (M score = 3.00). Another RPC member felt that it was important that the email be sent from an individual who was known to the recipients as the message would more likely be read by the recipients. However, the RPC members as a group stated that the effectiveness of communicating information was dependent on individuals having time to read the email message, which was identified on the PEC as a potential barrier to using this type of KT strategy.
Table 18

Tracking of Reminder Stickers

<table>
<thead>
<tr>
<th>Date</th>
<th>N</th>
<th>Reminder sticker on admission order No. (%)</th>
<th>N</th>
<th>Reminder sticker on the MAR No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 2008</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>July 2008</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Aug 2008</td>
<td>32</td>
<td>23 (72.0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>End of Cycle 1</td>
<td>30</td>
<td>10 (33.0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Jan 2009</td>
<td>12</td>
<td>7 (58.3)</td>
<td>12</td>
<td>8 (66.7)</td>
</tr>
<tr>
<td>Feb 2009</td>
<td>24</td>
<td>17 (70.8)</td>
<td>24</td>
<td>6 (25.0)</td>
</tr>
<tr>
<td>End of Cycle 2</td>
<td>30</td>
<td>6 (20.0)</td>
<td>30</td>
<td>11 (36.6)</td>
</tr>
</tbody>
</table>

Note. MAR = medication administration record; N/A = not applicable at time of audit; No. = number; Dec = December; Jan = January; Feb = February; Aug = August.

**KT strategies most frequently delivered during Cycle 2.** Reminders and audit and feedback strategies were the most frequently delivered KT strategies in Cycle 2. Three new reminder strategies and three new audit and feedback strategies were introduced during Cycle 2.

**Delivery of reminder strategies.** The first reminder was a sticker that was used to remind staff to document sucrose administration on the medication administration record (MAR) (Table 16). Stickers were placed on charts for the entire three-month duration of Cycle 2. The second reminder was a poster delivered near the end of Cycle 2 that was aimed at all health care professionals and was displayed for one week in all patient rooms, the staff lounge, staff washrooms, and the residents’ and fellows’ room. The third new reminder was a screen saver that was displayed two weeks before the end of Cycle 2 on 20 computer stations in the unit.
Receipt/usefulness of reminder strategies. During Cycle 2, stickers placed on the medication administration record (MAR) were rated by RPC members as a very useful (M score= 4.00) KT strategy (Table 16). Staff nurses informed RPC members that the message on the sticker provided enough information to alert nurses that sucrose was a pain initiative in the NICU. At times, however, stickers were placed incorrectly on the MAR and some nurses had signed their name beside the reminder sticker and not in the correct location on the MAR. RPC members noticed that stickers were not consistently replenished on consecutive MAR sheets, which might have hindered the use of this strategy; this issue was similar to the issue encountered with the reminder stickers used in Cycle 1.

Reminder posters were rated by RPC members as a very useful (M = 4.00) strategy (Table 16). RPC members commented on the PEC that the colourful posters were effective visual direct prompts, which contributed to their usefulness as a KT strategy. Health care professionals in the unit informed the RPC members that the posters were bright, well positioned in the unit, and served as visual reminders. One RPC member commented on the PEC that the posters were, “in the corner of your eye”. A potential barrier to poster reminders was that often, health care professionals did not have time to read them. Another RPC member commented on the PEC that the posters were often “lost in so much information on the walls”.

The use of screen savers on desktop computers as reminders were scored as less useful (M = 3.50) than the stickers and posters. RPC members commented that health care professionals over time might eventually become desensitized with the message and often, the message was not consistently present on the screen.

Delivery of audit and feedback strategies. Three new audit and feedback strategies were introduced in Cycle 2 (Table 16). Results from Cycle 1 and 2 audits were presented by an RPC
member at a unit leadership meeting mid way through Cycle 2. The meeting was attended by the unit manager, quality improvement leader, educator, respiratory technicians, and advanced practice nurses. A second method used to disseminate progress of the practice change was the unit newsletter, also delivered mid way through Cycle 2, where a message and graph of the progress of sucrose ordering and use was disseminated. Finally, reports for Cycle 1 and 2 audits were presented by the researcher during two NICU pain committee meetings.

Receipt of Cycle 2 audit and feedback strategies. Feedback sessions using a visual display of results from the audit was regarded by RPC members as a very useful (M score = 4.00) method to inform the pain committee about the progress of sucrose use, as these individuals had an interest in promoting pain practices in the NICU (Table 16). The unit newsletter, which was accessible to all staff, was rated of lower level of usefulness (M = 3.00) by RPC members. RPC members reported that a variety of information was usually included in the unit newsletter; therefore, the feedback report might have been too detailed or mixed with other news and would require time to read. A less effective, or somewhat useful (M = 2.00) feedback strategy was a presentation of the audit results at a unit leadership meeting. Although the information presented at the meeting was similar to the feedback presented at the pain committee meeting, RPC members commented on the PEC that the information presented was viewed as “nice to know versus need to know information”, as this audience included health care professionals who were not directly involved in administering sucrose at the bedside.

Most useful KT strategies. The most useful KT strategies continued to be the reminder stickers, posters, and feedback to the pain committee, all of which were rated as very useful (M = 4.00) (Table 16). Roving in-service education sessions, an educational outreach strategy, were delivered near the end of Cycle 2 and were also rated as a very useful (M = 4.00) KT strategy in
Cycle 2. Roving in-services consisted of five minute educational sessions conducted at the bedside by three RPC members. These sessions covered 51 nurses and two physicians over four sessions. The presentation included five slides shown at the bedside on documentation of sucrose administration, and information on dosing guidelines. RPC members noted on the PEC that the visibility of RPC members in the unit during these roving in-service sessions facilitated the promotion of sucrose use. The existence of other research and clinical projects in the unit, and the busyness of the unit precluded more nurses from participating in these sessions and were viewed as potential barriers to the implementation of roving in-services. RPC members felt that there was a need to enlist individuals with dedicated time to conduct more roving in-services.

**Least useful KT strategy.** The least useful KT strategy continued to be the feedback session presented at the unit leadership meeting (M = 2.00).

**Step 4: Enactment of the practice change.** Data on enactment of ordering of sucrose and documentation of administration by health care professionals were collected from the audit of pain practices and pain practice outcomes at the end of Cycle 1 and 2 of the EPIC intervention, and were compared to the implementation of the KT strategies during these cycles. The PEC was used to document the types of methods used to feedback the results of the audit as described in Table 16.

**Pain practice outcomes: Cycle 1 chart audits.** Results from the chart audits conducted within and at the end of Cycle 1 and 2 are summarized in Table 19. Cycle 1 occurred between July and September 2008. The aim of Cycle 1 was to improve documentation of sucrose ordering to 50% from baseline (Time 1). Documentation of sucrose ordering was not collected at baseline (Time 1). Therefore, as an audit and feedback strategy, RPC members conducted their own two audits to determine rates of sucrose ordering during Cycle 1. Within two months
of starting Cycle 1, sucrose ordering within the first 24 hours of admission increased from a baseline rate of 25% (July 2008) to 42.3%, representing an absolute increase of 17.3%. By the end of Cycle 1, 73.3% infants had sucrose ordered within the first 24 hours of admission to the NICU which represented an absolute increase of 48.3% from baseline. As the RPC predicted an increase in sucrose ordering to 50%, they exceeded their expectations for Cycle 1.

Although the main focus during Cycle 1 was to promote sucrose ordering, sucrose documentation of administration also increased from baseline (Time 1). By the end of Cycle 1, 40% of all infants were receiving sucrose compared to the 10% documented at Time 1 (baseline) which represented an absolute increase of 30%. During Cycle 1, multifaceted KT strategies using a combination of educational outreach, educational materials, reminders, and audit and feedback appeared to contribute to the increase in sucrose ordering and documentation of administration. For example, in September 2008, at the peak of sucrose ordering, all four types of KT strategies were delivered.
Table 19

*Chart Audits of Sucrose Practices for Cycles 1 and 2*

<table>
<thead>
<tr>
<th>Month and year</th>
<th>Sucrose ordered on admission + within first 24 hrs No. (%)</th>
<th>Documentation of administration on MAR in first 24 hours of infants who had sucrose ordered No. (%)</th>
<th>Documentation of administration on MAR in first 24 hours of all eligible infants No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec -07 Baseline</td>
<td>N/A</td>
<td>N/A</td>
<td>3/30 (10.0)</td>
</tr>
<tr>
<td>(Time 1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycle 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>July -08</td>
<td>7/28 (25.0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Aug -08</td>
<td>11/26 (42.3)</td>
<td>7/11 (63.6)</td>
<td>7/26 (26.9)</td>
</tr>
<tr>
<td>Sept-08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct -08 End of cycle 1</td>
<td>22/30 (73.3)</td>
<td>12/22 (54.5)</td>
<td>12/30 (40.0)</td>
</tr>
<tr>
<td>Nov-08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycle 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec-08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-09</td>
<td>11/12 (91.7)</td>
<td>6/11 (54.5)</td>
<td>6/12 (50.0)</td>
</tr>
<tr>
<td>Feb-09</td>
<td>13/24 (54.2)</td>
<td>6/13 (46.1)</td>
<td>6/24 (25.0)</td>
</tr>
<tr>
<td>Mar-09 End of cycle 2</td>
<td>19/30 (63.3)</td>
<td>18/19 (94.7)</td>
<td>18/30 (60.0)</td>
</tr>
</tbody>
</table>

*Note.* MAR = medication administration record; N/A = not applicable at time of audit; No. = number; Aug = August; Sept = September; Oct = October Nov = November; Dec = December; Jan = January; Feb = February; Mar = March.
**Cycle 2 chart audits.** Cycle 2 occurred between December 2008 and March 2009. During Cycle 2, RPC members conducted their own two chart audits as an audit and feedback strategy (Table 19). Sucrose documentation of administration peaked in January 2009 to 50%, decreased in February 2009 to 25%, and was maintained at 60% by the end of Cycle 2 (Time 2), representing an absolute increase of 50% from Time 1 (baseline). For those infants who had a sucrose order in their charts, 94.7% were given sucrose as documented in their charts. As the aim in Cycle 2 was to improve documentation of sucrose administration to 75%, this practice aim was achieved for those infants who had orders in their charts. The baseline pain practice audit (Time 1) using the CPPR database was repeated at the end of the EPIC intervention (Time 2) (Tables 20 to 23).

Table 20  
*Time 2 Demographic and Clinical Characteristics of Study Infants (N =30)*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>15 (50.0)</td>
</tr>
<tr>
<td>Medical</td>
<td>24 (80.0)</td>
</tr>
<tr>
<td>Surgical</td>
<td>6 (20.0)</td>
</tr>
</tbody>
</table>

*Note.* No. = number; Medical refers to infants admitted with a primary medical diagnosis (e.g., prematurity, respiratory distress; Surgical: refers to infants admitted with a primary surgical diagnosis (e.g., gastroschisis, duodenal atresia).
Table 21

*Time 2 Top 10 Frequency of Painful Procedures (N = 30 infants)*

<table>
<thead>
<tr>
<th>Painful procedure</th>
<th>Frequency of performance across all infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suctioning: endotracheal</td>
<td>80</td>
</tr>
<tr>
<td>Tape removal from skin</td>
<td>72</td>
</tr>
<tr>
<td>Capillary sampling</td>
<td>59</td>
</tr>
<tr>
<td>Venepuncture/ phlebotomy</td>
<td>34</td>
</tr>
<tr>
<td>Peripheral intravenous attempt or insertion</td>
<td>32</td>
</tr>
<tr>
<td>Suctioning: oral or nasal</td>
<td>27</td>
</tr>
<tr>
<td>Scraping/swabs: nasopharyngeal swabs</td>
<td>27</td>
</tr>
<tr>
<td>Scraping/swabs: culture/specimen</td>
<td>25</td>
</tr>
<tr>
<td>Nasogastric tube attempt or insertion</td>
<td>17</td>
</tr>
<tr>
<td>Umbilical line attempt or insertion</td>
<td>11</td>
</tr>
<tr>
<td>Total frequency for top 10 painful procedures</td>
<td>384</td>
</tr>
</tbody>
</table>
### Table 22

**Time 2 Pharmacologic Interventions (n =20)**

<table>
<thead>
<tr>
<th>Pharmacologic intervention</th>
<th>No. infants</th>
<th>Time 2 frequency of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opioids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl bolus</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fentanyl infusion</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Morphine bolus</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Morphine infusion</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Sucrose</td>
<td>18</td>
<td>40</td>
</tr>
<tr>
<td><strong>Non-opioids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

*Note. No. = number.*

### Table 23

**Time 2 Physical Interventions (n =27)**

<table>
<thead>
<tr>
<th>Physical interventions</th>
<th>No. infants</th>
<th>Time 2 frequency of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort positioning/ bundling/ containing /swaddling</td>
<td>24</td>
<td>56</td>
</tr>
<tr>
<td>Non-nutritive sucking (e.g. pacifiers)</td>
<td>16</td>
<td>36</td>
</tr>
<tr>
<td>Comforting/reassurance</td>
<td>10</td>
<td>27</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Healing touch/therapeutic touch</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Facilitated tucking</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Skin to skin</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*Note. No. = number.*
**Time 2 painful procedures.** Overall, all 30 patients had at least one or more painful procedures documented in their charts within the first 24 hours of admission to the NICU. For the 30 infants, a total of 473 painful procedures were documented as being performed during this time (M = 8.63, SD = 3.23 per infant, Mdn = 9.00, IQR = 4.00). The same top five painful procedures were documented at Time 1 and at Time 2 (Tables 12 and 21) and were listed in the top 10 painful procedures (n = 384), which represented 81.2% of all painful procedures (Table 21). There were no significant differences between the mean number of painful procedures documented between Time 1 (M = 8.90, SD = 3.58), and Time 2 (M = 8.63, SD = 3.23, t (58) = 0.30, p = .763.

**Time 2 pharmacologic and physical interventions.** Twenty-nine of the 30 (96.7%) infants received a pain management intervention within the first 24 hours of admission to the NICU compared to 22/30 (73.3%) at Time 1, which was a statistically significant increase (Fisher’s Exact test, p = .026). Twenty of the 30 (66.7%) infants had any analgesic documented in their chart; however, this was not significantly different from Time 1, \(\chi^2(1) = 1.11, p = .292\).

The most frequently administered analgesic was sucrose, administered 40 times to 18 infants (Table 22). All 30 infants were eligible to receive sucrose. There was a statistically significant increase in the documentation of sucrose administration at Time 2 (n = 18, 60%) compared to Time 1 (n = 3, 10%), \(\chi^2(1) = 16.48, p = .001\). There was a statistically significant reduction in the use of opioids at Time 2 (n = 5, 16.7%) compared to Time 1(n = 12, 40.0%), \(\chi^2(1) = 4.02, p = .045\).

Infants at Time 2 had significantly more physical interventions documented (n = 27, 90.0%) than at Time 1 (n = 11, 36.7%), \(\chi^2(1) =18.37, p = .001\) (Table 23). Specifically, there were statistically significant improvements in the use of pacifiers at Time 2 (n = 16, 53.3%),
compared to Time 1 (n = 5, 16.7%), $\chi^2(1) = 8.86$, $p = .003$. However, it is not known whether the increased use of pacifiers was associated with sucrose use. As with Time 1, no psychological interventions were documented during Time 2.

For 13 of the 30 (43.3%) infants who had undergone a painful procedure, there was documentation of a pain management strategy administered specifically for the procedure. Of these infants, 10 (76.9%) had a pharmacologic, 4 (30.8%) had a physical and 1 (7.7%) had a combination of strategies.

**Time 2 pain assessment.** Documentation of pain assessment improved at Time 2, where all 30 infants received at least one pain assessment within the first 24 hours of admission compared to 29/30 (96.7%) infants who were assessed at Time 1. Although there were no significant differences in the mean number of pain assessments documented using the PIPP at Time 1 and 2, pain assessment practices using the PIPP were high. There was no significant difference in pain intensity scores using the PIPP at Time 2 (M PIPP score = 4.05, SD = 2.12) compared to Time 1 (M PIPP score = 5.09, SD = 2.22), $t (57) = 1.84$, $p = .071$.

**Relationship between KT strategies and pain practice outcomes.** During Cycle 1, there appeared to be a positive association between the KT strategies used and documentation of sucrose orders and administration of sucrose (Figure 3). However, this could not be statistically tested, given the nature of the data, and the small sample sizes. However, during Cycle 2, this association was not observed. A large decrease in the documentation of sucrose ordering and administration occurred between January and February 2009 (even though the number of KT strategies appeared to be increasing) followed by an increase between February and March 2009. In the last month of Cycle 2 (March, 2009), ordering and documentation of sucrose
administration rates began to increase, while the number of KT strategies had decreased (Figure 3).

*Figure 3.* KT strategies vs. sucrose documentation of ordering and administration

*Note.* No KT strategies were introduced in December 2007 as the baseline (Time 1) data were collected during this time.
There was a significant change in the documentation of sucrose orders over time (p = .002) (Table 24). Orders from the end of Cycle 1 to the end of Cycle 2 were significantly more likely to include sucrose when compared to the reference point. Two months into Cycle 1, there was no significant difference in terms of ordering sucrose (although elevated). Ordering at the end of Cycle 1 and the second month of Cycle 2 were particularly high compared to the reference point (OR = 8.25 and 33.00 respectively).

Similarly, there was a significant change in the documentation of administration of sucrose over time (p = .004). Compared to baseline (Time 1), infants in the second month of Cycle 2 and the end of Cycle 2 (Time 2) were more likely to have sucrose administration documented. At the end of Cycle 2 (Time 2), the odds of being administered sucrose were 13 times greater compared to Time 1 (OR = 13.50, 95% CI [3.33, 54.67], p < .001).

**Unit activity logs.** Additional pain related activities that were implemented in the NICU and unit-based changes that were not documented on the PEC were entered by the researcher in the unit activity log (Table 25). The NICU pain committee was involved in a number of unit and hospital wide activities related to pain management. Four pain studies were initiated and eight practice related initiatives were implemented during the course of the study. Of importance were plans to ensure sucrose was stocked in the NICU, and the introduction of sucrose as a hospital wide initiative.
Table 24

Logistic Regressions of Sucrose Administration with Time

<table>
<thead>
<tr>
<th></th>
<th>Logistic regression modeling ordering sucrose</th>
<th>Logistic regression modeling giving sucrose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beta (SE)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Intercept</td>
<td>-1.10 (0.44)</td>
<td>-2.20 (0.61)</td>
</tr>
<tr>
<td>Time (overall)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec 2007 (Time 1 baseline)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>July 2008 (Start of Cycle 1)</td>
<td>0.00</td>
<td>1.00 (Ref)</td>
</tr>
<tr>
<td>Aug 2008</td>
<td>0.79 (0.59)</td>
<td>2.20 (0.69, 6.99)</td>
</tr>
<tr>
<td>Sept-Oct 2008 (End of Cycle 1)</td>
<td>2.11 (0.60)</td>
<td>8.25 (2.54, 26.78)</td>
</tr>
<tr>
<td>Dec 2008 (Start of Cycle 2)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Jan 2009</td>
<td>3.50 (1.13)</td>
<td>33.00 (3.59, 303.41)</td>
</tr>
<tr>
<td>Feb 2009</td>
<td>1.27 (0.60)</td>
<td>3.55 (1.10, 11.46)</td>
</tr>
<tr>
<td>Mar 2009 (End of Cycle 2)</td>
<td>1.65</td>
<td>5.18 (1.67, 16.09)</td>
</tr>
</tbody>
</table>

Note. CI = confidence interval; N/A = not applicable at time of audit; SE = standard error; OR = odds ratio; Ref = reference point; Dec = December; Aug = August; Sept = September; Oct = October; Jan = January; Feb = February; Mar = March.
### Table 25

**Unit Activity Log**

<table>
<thead>
<tr>
<th>Start of initiative</th>
<th>Description of initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2008</td>
<td>Changes to electronic charting for pain assessment and non-pharmacologic management of pain</td>
</tr>
<tr>
<td>Aug 2008</td>
<td>N-PASS study</td>
</tr>
<tr>
<td></td>
<td>16 new nurses hired in the NICU</td>
</tr>
<tr>
<td>Sept 2008</td>
<td>Post-operative pain guidelines</td>
</tr>
<tr>
<td></td>
<td>Sucrose distribution organized by pharmacy in NICU</td>
</tr>
<tr>
<td></td>
<td>Hospital wide sucrose guidelines developed by NICU pain committee and Acute pain service</td>
</tr>
<tr>
<td></td>
<td>5 nursing education days focusing on pain management</td>
</tr>
<tr>
<td>Oct 2008</td>
<td>Parent pain study</td>
</tr>
<tr>
<td>Nov 2008</td>
<td>Study on morphine for non-intubated PICC</td>
</tr>
<tr>
<td>Dec 2008</td>
<td>Development of immunization kits for patient rooms</td>
</tr>
<tr>
<td>Jan 2009</td>
<td>Guidelines developed on use of fentanyl for PICC lines</td>
</tr>
<tr>
<td></td>
<td>Update of post operative pain guidelines</td>
</tr>
<tr>
<td></td>
<td>1 RPC member leaves the NICU</td>
</tr>
<tr>
<td>Feb 2009</td>
<td>5 nursing education days focusing on pain assessment</td>
</tr>
<tr>
<td>Mar 2009</td>
<td>No new pain initiatives</td>
</tr>
</tbody>
</table>

*Note. Jan = January; Feb = February; Mar = March; Aug = August; Sept = September; Oct = October; Nov = November; Dec = December; N-PASS = Neonatal Pain, Agitation, & Sedation Scale; NICU = Neonatal Intensive Care Unit; PICC = peripherally inserted central catheter; RPC = Research Practice Council.*
Focus groups with RPC members and health care professionals. Two focus group interviews were conducted after the completion of the EPIC intervention implementation. The first focus group with the four RPC members was conducted one month following the completion of the EPIC intervention. One RPC member participated by phone and the other three RPC members were interviewed in-person. The second focus group was also conducted one month following completion of the EPIC intervention with nine health care professionals in the NICU. Health care professional participants included two medical fellows, two respiratory therapists and five nurses with a median of 6.0 years (minimum 1 year, maximum 30 years) of clinical experience in this NICU. The focus group sessions took place in a private meeting room during an afternoon break. The duration of each focus group was 45 minutes.

Categories that emerged from transcribed data represented the RPC members and health care professionals’ reflections on the EPIC intervention process, as well as their views about the effectiveness of KT strategies that were used to promote improvement in documentation of sucrose ordering and administration. Two main categories and seven sub-categories emerged from the focus group data and are summarized in Table 26. Most of the sub categories emerged from both focus groups (Table 26). The two main categories were presented to one individual who participated in the RPC focus group and one health care professional from the health care professional focus group as a method of member checking or validating the emerging categories (Russell et al., 2005). Both participants agreed with these categories by reflecting on examples that further supported the categories.

The two main categories that emerged from the focus group data were (a) providing leadership for practice changes, and (b) strategies to facilitate behavioural change. Each category contained sub-categories. The sub-categories under providing leadership for practice
changes (i.e., applying evidence and gaining knowledge and vested interest in the topic/change process) emerged from the RPC focus group data, while the remaining subcategories were derived from both focus groups (Table 26).

Table 26

RPC and Health Care Professionals’ Perspectives on EPIC Intervention Process

<table>
<thead>
<tr>
<th>Main categories</th>
<th>Sub categories</th>
<th>Location of sub categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing leadership for practice changes</td>
<td>Applying evidence and gaining knowledge</td>
<td>FG1</td>
</tr>
<tr>
<td></td>
<td>Vested interest in topic/change process</td>
<td>FG 1</td>
</tr>
<tr>
<td></td>
<td>Role as change agents/champions and advocates</td>
<td>FG 1, FG 2</td>
</tr>
<tr>
<td>Strategies to facilitate behavioural change</td>
<td>Development and education about practice</td>
<td>FG 1, FG 2</td>
</tr>
<tr>
<td></td>
<td>standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Constant reminders to improve practice</td>
<td>FG 1, FG 2</td>
</tr>
<tr>
<td></td>
<td>Raising awareness/understanding</td>
<td>FG 1, FG 2</td>
</tr>
<tr>
<td></td>
<td>Creating momentum for sustainability</td>
<td>FG 1, FG 2</td>
</tr>
</tbody>
</table>

Note. FG 1 = focus group with RPC members; FG2 = focus group with health care professionals.
The focus group interviewer reported participation from a variety of participants in both of the focus group sessions. Therefore, the quotes presented under each of the subcategories are representative of the concepts discussed during the focus group sessions.

**Providing leadership for practice changes.** Focus group participants felt that it was important to have leaders or facilitators implement the EPIC intervention process. The facilitators of the practice change included the four RPC members, additional individuals referred to as unit champions who were identified by RPC members, and health care professionals. Focus group participants felt that applying evidence and gaining knowledge, having a vested interest in pain management, and engaging change agents/champions and advocates were important leadership qualities that could be used to change pain practices in this setting.

**Applying evidence and gaining knowledge.** The RPC members described how they applied different sources of evidence and gained new knowledge regarding their pain practice change. As part of their training provided by the researcher during Phase 1 of EPIC, RPC members drew upon research evidence, their own tacit clinical expertise, experiences from other health care professional practices, results of an audit of their current pain practices, and the KT literature to plan their evidence based practice change and the KT strategies to implement to induce and maintain the change. RPC members were leaders in this pain practice initiative. The RPC members were aware of the current research evidence to support sucrose use:

> We had the knowledge of the literature about the intervention...we had that evidence. We are up to date on the current literature and neonatal pain (Focus Group 1, p. 9, lines 10-12, 19).

RPC members felt that they benefited from their participation in the EPIC implementation by gaining new knowledge and interest in sucrose, learning about effective KT
strategies, the behavioural change process, and process evaluation, and how to apply the EPIC process to facilitate future practice changes. One of the challenges in the RPC member training was that the concept of process evaluation was not entirely clear to them; however, through examples provided by the researcher and by implementing the EPIC process, their knowledge about this concept increased. The RPC members’ skill acquisition of the EPIC intervention implementation process contributed to implementation fidelity (Borrelli, et al., 2005):

I think if we decide on other things we want to implement or change we could use the same process. We’ve learnt a lot about how to approach those things so now it’ll just be in different aspects of our role (Focus Group 1, p. 28, lines 21-22; p.29, lines 4-5).

Vested interest in participation. As members of the NICU pain committee, and as front line clinicians, the RPC members stated that they had shared a “vested interest” in pain management in the NICU (Focus group 1, p. 24, line 9). All RPC members volunteered to participate on this leadership team. Interest in learning about the audit and feedback process was the “buy-in” for one of the RPC members to participate in the study (Focus group 1, p.2, line 1). The RPC as a group was committed to improving sucrose use in the NICU. One RPC member stressed the importance of having appropriate support (e.g., content expertise from the unit pain committee) to lead and implement their practice initiative:

…commitment to the intervention. I’ve been convinced that you know, it’s a practice that we want to change. We believed that sucrose was the right thing…and I think we being members of the pain committee, tapped into the right people for the RPC. To be effective, you really need…sort of a concerted effort in the strategies…all the right people with the proper links came together (Focus Group 1, p.23, lines 1-5, 16-18).

Role as change agents/champions and advocates. RPC members also felt that they were in positions of leadership and influence as they had professional relationships with the unit management team and were able to reach a large number of staff on a consistent basis. They
referred to themselves as advisors, and “facilitators or promoters of [pain] practices” (Focus group 1, p. 4, lines 6-7). In addition, the RPC members had a collaborative relationship with each other and often “fed off” each other when planning their KT strategies (Focus group 1, p.7, line 3). In terms of their level of involvement in the EPIC process, RPC members participated in identifying and implementing KT strategies in the unit. Two staff nurses, who were regarded by the RPC members as pain champions, assisted in implementing some of the KT strategies. While health care professionals did not specifically refer to RPC members as the leaders of the practice change, they stated that nurse practitioners and staff nurses advocated for this practice change for infants with families and unit leaders. For example, staff nurses, through informal discussion, advocated for infants and reminded physicians and nurse practitioners to order sucrose:

The bedside [staff] nurses are really good at reminding us [physicians or nurse practitioners] and now I’m starting to remember as well that I need to get sucrose before I do something (Focus Group 2, p.14, lines 5-6).

RPC members, therefore, demonstrated their leadership or facilitator skills to promote sucrose use in the NICU through their established interest in pain management and by applying or translating their knowledge about the EPIC intervention process and sucrose for procedural pain into practice. Staff nurses were also seen as local champions who demonstrated their leadership by reminding staff to order sucrose and by administering sucrose.

**Strategies to facilitate behavioural change.** The second main category focused on KT strategies for facilitating behavioural change. Strategies were described by participants in terms of the development and education about practice standards, constant reminders, and the use of KT strategies to raise awareness/understanding of the practice change and to generate a momentum for sustainability.
Development and education about practice standards. RPC members emphasized the importance of educational strategies to ensure that staff understood the rationale for administering sucrose for procedural pain. Health care professionals emphasized the need to have clear instructions regarding sucrose dosing guidelines. The sucrose clinical practice guideline resulted in considerable discussion among the health care professional group in terms of the availability of sucrose on the unit, and the lack of clarity regarding sucrose administration. Sucrose was stocked in patient rooms but was not available in individual standardized containers for patients. For example, having sucrose available in individual doses at the bedside would make it easier to administer during a painful procedure:

It doesn’t become another step when they [nurses] ask me to show up to do whatever I do or you know consult on stuff so if I see something, boom it’s there, it gets done sort of like part of the procedure all of a sudden, and not an extra step (Focus Group 2, p. 19, lines 9-11).

Moreover, there were discrepancies raised about the dose, frequency and documentation of sucrose. Health care professionals spoke about not always administering the full dose ordered and documenting practices for partial doses given. For example, health care professional participants agreed on the need to clarify documentation of sucrose dosages:

I know one day the baby was allowed a cc [of sucrose] and we only used maybe 0.3 of it and the baby was fine. I figured well might need it [sucrose] again soon so why sign for it 15 times in one dose, right? (Focus Group 2, p.20, lines 1-2, 4-5).

Some health care professionals were documenting sucrose on the NICU computerized information management system instead of the medication administration record (MAR). Participants noted that sucrose was not necessarily always documented when given. There was a sense that sucrose was being administered more frequently than it was being documented in
patient charts. Overall, participants communicated a need for clarification of these issues and further education about sucrose administration.

*Constant reminders to improve practice.* KT strategies that were visible to staff, especially the stickers on admission orders and the MAR were viewed as constant reminders by both the RPC members and health care professionals. Posters were placed in strategic locations such as the staff washrooms and staff lounge. One health care professional participant stated that instructions on how to administer sucrose on the unit posters were helpful and the posters served as a reminder as it “jogged your memory” to obtain a sucrose order (Focus group 2, p.13, line 3). Another health care professional felt that posters about sucrose were informative for staff who did not access admission order sheets or the MAR and, therefore, would not have seen the reminder sticker. The unit newsletter was sometimes identified as untimely; however, it was still an effective KT strategy especially for new staff or administrative groups as the information served as reminders about current activities in the unit. Screen savers visible on desktop computers in the unit acted as “quick reminders” for health care professionals to order and document administration of sucrose (Focus Group 2, p. 4, line 7). Health care professionals agreed that no single KT strategy was completely effective. Instead, a combination of one to one education, sucrose champions, stickers, and posters were viewed as an effective group of strategies to promote practice changes:

> I think if we had done anything [KT strategy] just by itself then there would have been things that didn’t work but I can’t see one thing that I thought didn’t work when it was rolled out as a package…education and champions and posters (Focus Group 2, p.7, lines 12-14).
RPC members reported that visual reports of the practice change based on the chart audits were effective strategies. Health care professionals stated that they were informed that sucrose practices had improved; however, feedback from the audits did not appear to reach all staff.

Although email reminders could be used, they were not viewed as effective strategies by health care professionals as there was often not enough time during a work day to read email messages.

RPC members, along with two nurses, who had been supported to work on pain projects in the NICU, were regarded by unit health care professionals as visual and verbal reminders in the unit:

And I think the fact that we walked around or the other nurses and I walked around gives them somebody they know [who] is involved now so yeah we’re responsible for the posters but they know who that is now and so if they do have a question and they see one of us they’ll say oh can you have an [in-service] about sucrose. So it’s not just when we walk around now it’s oh, they’re the resource (Focus Group 1, p. 17, lines 7-11).

Educational outreach sessions involving one-to-one bedside nursing rounds were delivered to 20 staff nurses during Cycle 1. Roving in-services were delivered to 53 staff during Cycle 2. Although the reach was small, (i.e., 53/203 (26.1%) staff), RPC members and health care professionals regarded these visible and verbal strategies as essential for promoting the practice change. Health care professionals and RPC members highlighted the importance of having informal discussions at the bedside with peers, or one-to-one teaching moments as constant reminders. However, these one-to-one educational outreach strategies were viewed as being challenging to capture or document:

It’s kind of hard to capture those one to one teaching points but I was just thinking about a nurse who came and said you know I got a sucrose order but it’s not right. It’s only ordered for you know three times a day not four times a day and it’s the same person always ordering three versus four. So I just went to the person and said did you know the baby’s got to have it four times a day and they said oh no I didn’t know that. So it’s hard to capture those points and those strategies but they are important I think (Focus Group 1, p. 18, lines 4-9).
Raising awareness/understanding. Despite some resistance to change from some experienced health care professionals and concerns about the over-use of sucrose, witnessing the effectiveness of sucrose in relieving pain in infants helped to raise the level of awareness of the effectiveness of sucrose according to RPC members and health care professionals. For example, observing sucrose use in clinical care helped to raise awareness, knowledge and belief in the effectiveness of sucrose for procedural pain in infants:

Actually seeing it [sucrose] being used. If someone is doing it [giving sucrose] while you’re doing the procedure and you actually see that it’s working…great, why not use it the next time (Focus group 2, p.3, lines 5-6).

The focus in the unit to improve sucrose practices contributed to raising the level of awareness in the unit of the importance of pain management in general:

I think for me being part of the research practice [council] kind of well how it affected my own practice, just to see the use of sucrose actually work. I think just uh being part of this council just made me be more out there with nurses and seeing how the sucrose was being administered, and how it was working...My sense is that the awareness in general about pain has been increased with this [EPIC] intervention (Focus Group, p.4, lines 13-14, 16-18; p.30, lines 13-15).

Creating momentum for sustainability. RPC members emphasized the importance of having financial and human resources support from both the unit and the organization. Having dedicated personnel, links to an external advisory group, and time to continue to maintain the KT strategies (e.g., reminder stickers) was essential. For example, two staff nurses assisted the RPC members with organizing the reminder stickers, which were often missed due to charts being accessed from multiple locations, rather than a single organized location, and participating in nursing education sessions related to improving documentation of sucrose administration. Additional support from the unit pain committee members and other pain experts in the unit (e.g., pharmacist) was described by an RPC member as a “luxury” (Focus group 1, p.11, line 10).
The researcher was described as an external support who assisted the RPC members to organize their biweekly meetings and to develop some of the KT strategies:

I think that one having the researcher spurring us on. Like you know we wanted to do this on our own anyways. The speed at which it happened and the actual tightness of the process and the do and then audit and then change and then add that was all driven by her study and so that made it very tight. Having [additional Nurse 1] and [additional Nurse 2] facilitating this made a huge difference. I don’t think we would have had as tight and as effective without having them [dedicated staff] around (Focus Group 1, p. 10, lines 5-10).

She [researcher] was the leader right. So the one who coordinated getting us together, making us think of ideas and then doing some of the leg work around making the poster, making the sticker. Without her coordinating the four of us it wouldn’t have happened (Focus Group 1, p. 21, lines 5-7).

So sustainability I think is what we’re talking about. You probably require regular meetings and with the designated personnel to kind of keep things going you have momentum. It would be hard unless you had part of your um FTE [full time equivalent] relegated to that role [external support] (Focus Group 1, p.13, lines 6, 8-10; p.22, lines 5-6).

To facilitate sustainability of the practice change, both the RPC members and health care professionals spoke about the importance of using constant reminders to avoid the practice change from becoming lost in competing clinical priorities:

As a [health care professional], you are thinking of the acute things like the antibiotics and ventilation. Like you tend to forget about things like sucrase. So it’s not that you don’t want to recommend it you just forget about it, so it would be good to keep the stickers (Focus Group 2, p.7, lines 3-6).

Health care professionals and RPC members felt that sucrase use would be maintained as part of everyday practice, had received buy-in from staff (e.g., residents) as a hospital-wide initiative, had demonstrated proof that it worked, and knew that, in the near future, ordering sucrase would be under the nurses’ jurisdiction:
The residents who actually do the ordering, I think it’s sustainable in part because it’s a hospital wide initiative. You know it [sucrose] works so you gotta keep giving it. I think it [giving sucrose] will be sustainable because it [ability to order sucrose] will give the nurses that extra power of autonomy to provide better care for the patient (Focus group 1, p.14, lines 6-8; p.19, lines 15, 18-19).

I think it’ll go on because it seems like just a natural thing to do now like something you just do. So it won’t be a new thing anymore. It will just be the thing to do (Focus Group 2, p.5, lines 13-14).

**Summary of Study 2.** The construct validity of the PEC was achieved through assessing the fidelity of the EPIC intervention implementation. The steps of the EPIC intervention were implemented by a RPC. In Phase 1 of EPIC, the RPC members were trained by the researcher to implement the EPIC intervention and identified through different sources of evidence the need to improve sucrose administration practices. In Phase 2, RPC members delivered 22 KT strategies during Cycle 1 and 21 KT strategies during Cycle 2. The most useful KT strategy during Cycle 1 was a visual reminder delivered using a sticker on the medication administration record, and the least useful was an audit and feedback strategy using email as the method of disseminating the audit findings. During Cycle 2, the most useful KT strategies were roving in-services for staff, reminder stickers, reminder posters, and feedback to the NICU pain committee. Enactment of sucrose ordering and documentation of administration was reported in the audit and feedback strategies conducted during and at the end of the EPIC intervention implementation. By the end of the EPIC intervention, there was a statistically significant increase in the use of sucrose compared to baseline. The RPC members met both of their practice aims, which were to improve sucrose administration practices. Overall, the EPIC intervention was delivered with high fidelity, and was associated with outcome improvement, which provides support to the construct validity of the PEC.
Categories that emerged from the focus groups with the RPC members and health care professionals indicated that providing leadership for practice changes was a key role of the RPC members. KT strategies were successfully delivered as constant reminders that raised awareness in the unit about sucrose use, promoted understanding of the practice change, and created momentum for sustaining this pain practice change.

**Study 3: Feasibility and Clinical Utility of the PEC**

**Content validity.** The purpose of Study 3 was to determine the feasibility and clinical utility of the PEC with the research nurses/coordinators from the TROPIC study (Stevens et al., 2008). Before distributing the PEC Feasibility and Clinical Utility questionnaire, the content validity of the items was assessed. The questionnaire was sent electronically in April and May 2009 to three Co-Investigators and two core team members from the TROPIC study (Stevens et al., 2008) who were familiar with the PEC. After two email reminders, four out of five questionnaires were returned. Two additional Co-investigators were targeted and a total of six out of seven completed questionnaires were returned.

All eight items in the PEC feasibility and clinical utility questionnaire were retained as their respective I-CVIs were over 0.80. These findings supported the questionnaire’s content validity.

**Feasibility and clinical utility of the PEC.** Eleven research nurses/coordinators from the TROPIC study (Stevens et al., 2008) had experience using the PEC. In June 2010, an email message was sent to these 11 research nurses/coordinators inviting them to participate in completing the on-line questionnaire. An email reminder was sent one week after the initial email request. A total of 10/11 (91%) participants completed the questionnaire; their responses reflected their experience using the PEC during the first three out of four Cycles of change as
part of the TROPIC study (Stevens et al., 2008). This sample size was adequate for the descriptive purpose of this study.

The research nurse/coordinators degree of participation in using the PEC was variable during the first three out of four Cycles of change in the TROPIC study (Stevens et al., 2008) (Table 27). Of the 10 respondents, six had experience using both Phase 1 and Phase 2 PEC forms, whereas four had only completed Phase 2 PEC form. Results of the ratings for the feasibility and clinical utility of the PEC for all respondents (N = 10) are summarized in Table 28. In Table 29, the ratings for the research nurse/coordinators who had used both Section 1 and 2 of the PEC (n = 6) and those who only used Section 2 of the PEC (n = 4) are reported.
Table 27

Research Nurse/Coordinator Use of the PEC

<table>
<thead>
<tr>
<th>Components of the PEC</th>
<th>Research nurse/coordinator use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
</tr>
<tr>
<td>Section 1: Phase 1 preparation phase PEC</td>
<td>6 (60.0)</td>
</tr>
<tr>
<td>Section 2: Phase 2 implementation and change phase PECs</td>
<td></td>
</tr>
<tr>
<td>Educational outreach PEC</td>
<td>9 (90.0)</td>
</tr>
<tr>
<td>Educational materials PEC</td>
<td>9 (90.0)</td>
</tr>
<tr>
<td>Reminder PEC</td>
<td>9 (90.0)</td>
</tr>
<tr>
<td>Audit and feedback PEC</td>
<td>9 (90.0)</td>
</tr>
<tr>
<td>Completion of cycles during phase 2 preparation phase of EPIC intervention</td>
<td></td>
</tr>
<tr>
<td>One cycle</td>
<td>3 (30.0)</td>
</tr>
<tr>
<td>Two cycles</td>
<td>2 (20.0)</td>
</tr>
<tr>
<td>Three cycles</td>
<td>5 (50.0)</td>
</tr>
</tbody>
</table>

*Note. EPIC = Evidence-based Practice Identification and Change (Lee et al., 2009); No. = number; PEC= Process Evaluation Checklist.*
### Table 28

**Feasibility and Clinical Utility of the PEC for All Respondents \( (N =10) \)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Mdn</th>
<th>Min, Max</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Feasibility:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. The instructions for using the PEC are easy to understand and follow.</td>
<td>3.00</td>
<td>2.00, 5.00</td>
<td>3.40</td>
<td>0.84</td>
</tr>
<tr>
<td>2. Structure of the 5 PEC surveys is easy to understand and follow.</td>
<td>3.00</td>
<td>2.00, 5.00</td>
<td>3.30</td>
<td>0.82</td>
</tr>
<tr>
<td>3. On-line format is easy to complete.</td>
<td>3.50</td>
<td>2.00, 5.00</td>
<td>3.30</td>
<td>1.06</td>
</tr>
<tr>
<td>4. The length of the PEC is appropriate for use when evaluating EPIC.</td>
<td>3.00</td>
<td>2.00, 4.00</td>
<td>3.30</td>
<td>0.67</td>
</tr>
<tr>
<td>5. Method of scoring is easy to understand and follow.</td>
<td>3.50</td>
<td>1.00, 5.00</td>
<td>3.40</td>
<td>1.07</td>
</tr>
<tr>
<td>6. Information obtained from PEC can be easily interpreted.</td>
<td>3.00</td>
<td>2.00, 5.00</td>
<td>3.00</td>
<td>1.05</td>
</tr>
<tr>
<td>7. PEC would be easy to incorporate in my practice setting.</td>
<td>3.00</td>
<td>1.00, 4.00</td>
<td>2.70</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Clinical Utility</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Information from the PEC could be used to guide and plan practice change interventions.</td>
<td>3.00</td>
<td>2.00, 5.00</td>
<td>3.05</td>
<td>1.07</td>
</tr>
</tbody>
</table>

*Note.* EPIC = Evidence-based Practice Identification and Change (Lee et al., 2009); M = mean; SD = standard deviation; Mdn = median; Min = minimum; Max = maximum; PEC = Process Evaluation Checklist.
Table 29

*Feasibility and Clinical Utility of the PEC (n = 6; n = 4 respondents)*

<table>
<thead>
<tr>
<th>Question</th>
<th>Mdn</th>
<th>Min, Max</th>
<th>M</th>
<th>SD</th>
<th>Mdn</th>
<th>Min, Max</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>3.00</td>
<td>3, 4</td>
<td>3.17</td>
<td>0.41</td>
<td>4.00</td>
<td>2.00, 5.00</td>
<td>3.75</td>
<td>1.26</td>
</tr>
<tr>
<td>2.</td>
<td>3.00</td>
<td>3, 4</td>
<td>2.83</td>
<td>0.41</td>
<td>4.00</td>
<td>3.00, 5.00</td>
<td>4.00</td>
<td>0.82</td>
</tr>
<tr>
<td>3.</td>
<td>3.00</td>
<td>2, 4</td>
<td>3.00</td>
<td>0.89</td>
<td>4.00</td>
<td>2.00, 5.00</td>
<td>3.75</td>
<td>1.26</td>
</tr>
<tr>
<td>4.</td>
<td>3.00</td>
<td>2, 4</td>
<td>3.17</td>
<td>0.75</td>
<td>3.50</td>
<td>3.00, 4.00</td>
<td>3.50</td>
<td>0.58</td>
</tr>
<tr>
<td>5.</td>
<td>3.00</td>
<td>1, 4</td>
<td>3.00</td>
<td>1.09</td>
<td>4.00</td>
<td>3.00, 5.00</td>
<td>4.00</td>
<td>0.82</td>
</tr>
<tr>
<td>6.</td>
<td>2.50</td>
<td>2, 4</td>
<td>2.67</td>
<td>0.82</td>
<td>3.50</td>
<td>2.00, 5.00</td>
<td>3.50</td>
<td>1.29</td>
</tr>
<tr>
<td>7.</td>
<td>2.50</td>
<td>2, 4</td>
<td>2.67</td>
<td>0.82</td>
<td>3.00</td>
<td>1.00, 4.00</td>
<td>2.75</td>
<td>1.26</td>
</tr>
<tr>
<td>8.</td>
<td>2.50</td>
<td>2, 4</td>
<td>2.83</td>
<td>0.98</td>
<td>3.25</td>
<td>2.00, 5.00</td>
<td>3.38</td>
<td>1.25</td>
</tr>
</tbody>
</table>

*Note.* M = mean; SD = standard deviation; Mdn = median; Min = minimum; Max = maximum; PEC = Process Evaluation Checklist.
Overall, results for the feasibility of the PEC were positive. Most of the questions had a median (Mdn) score of at least 3 out of 5 indicating feasibility of the PEC. In question 6, information obtained from the PEC was viewed by all respondents as easy to interpret (Mdn score = 3.00) (Table 28); however, respondents who completed both Sections 1 and 2 of the PEC found the interpretation of the information to be only somewhat easy to interpret (i.e., Mdn score = 2.50) (Table 29). In question 7, all respondents and those who had only completed Section 2 of the PEC reported that the PEC would be easy to incorporate into practice settings (Mdn score = 3.00) (Table 28 and 29); one respondent who only completed Section 2 of the PEC felt that the PEC was not at all easy to use in practice. Respondents who had completed both Section 1 and 2 reported that the PEC was somewhat easy to use in practice (Mdn score = 2.50) (Table 29). One respondent noted that clinicians might require assistance to complete the checklist due to its length and time required to respond/answer its items. Repetition of items in the PEC, and the need for more space to accommodate additional comments were also mentioned as concerns about the PEC. As one respondent commented:

> The tool [PEC] is fairly user-friendly but the individual RPC members seem to struggle with it unless they are guided by the research nurse. It is a detailed tool, almost repetitive in some areas, and can be very time consuming when there are many KT strategies. Overall, I think it is good tool and the qualitative data is very helpful but I'm not sure that staff would take the time to fill it out if it was incorporated into the practice setting.

In addition, one respondent commented that some RPC members might have been more comfortable than others at group meetings when discussing usefulness scores related to the KT strategies implemented.

In terms of the clinical utility of the PEC, all respondents felt that the information from the PEC could be used to guide and plan practice change interventions (Mdn score = 3.00)
Four respondents felt that the PEC was somewhat useful to guide implementation of KT strategies; three thought the PEC was useful, two stated that the PEC was very useful, and one respondent thought that the PEC was extremely useful. Respondents who had only completed Section 2 of the PEC also agreed that the PEC was clinically useful (Mdn score = 3.25). The six respondents who had used Sections 1 and 2 of the PEC, however, rated the PEC as being somewhat useful (Mdn score = 2.50) to guide and plan practice change interventions (Table 29).

**Summary of Study 3.** Despite the variability in the use of the PEC by research nurses/coordinators from the TROPIC study (Stevens et al., 2008) there was preliminary support for the feasibility and clinical utility of the PEC during their participation in the first three Cycles of their practice changes.
CHAPTER SIX

Discussion

In this chapter, the main results are discussed within the context of the existing conceptual and empirical literature.

Validation of the Process Evaluation Checklist (PEC)

Many fidelity measures have been developed in the health and social sciences to assess whether an intervention has been implemented as planned. Although these measures capture the concepts related to fidelity of intervention implementation, there is a lack of standardized measures of fidelity (Dusenbury et al., 2004). Existing measures are intervention specific and capture the delivery of particular elements of a specific intervention. Moreover, few of these measures are theoretically based, and assess the key domains of fidelity proposed in the framework suggested by Bellg et al. (2004) and Borrelli et al. (2005). Consequently, the available measures could not be meaningfully adapted to monitor the fidelity of the multidimensional and complex EPIC intervention process. Based on the shortcomings of existing measures, the overall purpose of this study was to develop and validate the process evaluation checklist (PEC) designed to evaluate the fidelity of the EPIC intervention implementation.

**Face and content validity of the PEC.** Overall, face validity of the PEC was achieved. However, as this process involved subjective judgment by experts, assessing a measure for face validity was considered a minimal requirement for ascertaining the relevance of the items’ content in reflecting the concept and the acceptability of the items in a measure (Streiner & Norman, 2008). Therefore, content validity of the PEC was examined using a systematic approach, as recommended by Lynn (1986) and Streiner and Norman (2008). The PEC had
acceptable content validity (Yamada et al., 2010). The items and scale/subscales in the PEC met
the content validity index (CVI) requirements for establishing content validity. An item content
validity index (I-CVI) of at least 0.78 is considered to be acceptable agreement among the expert
raters (Polit et al., 2007). The minimum I-CVI for items on the PEC was 0.6 and the maximum
was 1.0 (indicating perfect expert agreement on the item importance/relevance). The audit and
feedback subscale items that evaluated the usefulness of the methods or modes of delivery (e.g.,
poster format) used to disseminate the audit and feedback strategies were similar to the items
assessing the usefulness of reminders and educational materials, yet they generated the lowest
I-CVIs.

An acceptable scale content validity index (S-CVIs) varies between 0.8 and 0.9 (Polit &
Beck 2006; Polit et al., 2007). All subscales of the PEC met this criterion for the S-CVIs except
for the subscale for audit and feedback, where lowest S-CVIs were found (i.e., 0.3). However,
when the S-CVIs were computed using an overall summary question on the usefulness of audit
and feedback as a KT strategy as a whole, the scores of 1.0 indicated a high level of content
validity (Yamada et al., 2010).

It is unclear why the CVIs for the PEC subscale representing audit and feedback were
low compared to the subscales representing the KT strategies for educational materials and
reminder given that the items tapped into comparable content. One possible explanation is that
the audit and feedback subscale was the last of the KT strategies to be rated in the questionnaire;
therefore, repetition of similar items and rater fatigue might have contributed to the missing
ratings for the audit and feedback subscale which could have represented an order effect
(Yamada et al., 2010). Another potential explanation for the low CVIs is that the evaluative
component and feedback process of the audit has been described as negative or punitive in
nature, and could have contributed to a lack of buy-in regarding this KT strategy (Hysong, Best, & Pugh, 2006). The use of audit and feedback strategies has had modest positive effects on performance outcomes and is therefore theoretically supported to some degree in the literature as an effective KT strategy (Hysong, 2009; Jamtvedt et al. 2006). To maintain consistency with similar items used in the subscales for reminders and educational materials, the items in the PEC subscale assessing the usefulness of the audit and feedback were retained and were found accurate in reflecting this KT strategy in later use of the PEC. Overall, the essential steps in Phases 1 and 2 of the EPIC intervention process were captured by the PEC; therefore, content validity of the PEC was achieved.

**Construct validity of the PEC.** The EPIC intervention process was captured by the PEC in relation to key components of fidelity. Qualitative data from the focus group interviews with RPC members and health care professionals where appropriate, were used to support/confirm the quantitative and qualitative descriptive data collected using the PEC, which further contributed to the construct validity of the PEC. These qualitative findings provided information about the practice environment required to successfully improve sucrose practices. Additional information gained from the focus groups regarding the fidelity of the EPIC intervention implementation could be used to revise or modify the PEC. These findings illustrate the iterative nature of determining construct validity. Overall, the EPIC intervention was delivered with a high degree of fidelity and the PEC accurately captured the key activities related to the steps of the EPIC intervention. Each step of the EPIC intervention is discussed below.

**Step 1: Identifying RPC members and credentials.** RPC members were the leaders/facilitators of the pain practice change. They were a multidisciplinary group of senior health care professionals who were involved in and committed to improving pain management in the
NICU and could reach a large number of NICU staff. Thus, they were experts in and committed to improving pain management. The PEC contains items that inquire about the RPC members’ expertise. RPC members’ expertise and commitment was also confirmed with categories emerging from the focus group sessions. RPC members were described as facilitators of change. Any challenges encountered by RPC members regarding their role and their commitment to delivering the KT strategies were discussed during regular meetings with the researcher. Other than one RPC member who transferred to another unit during Cycle 2, no barriers to continuing as RPC members were reported. Any changes to RPC membership would be important to collect especially in evaluating the sustainability of the EPIC intervention implementation. The unit’s health care professionals were not requested to formally evaluate the role of RPC members. This aspect of process/fidelity may be assessed in future implementation of the EPIC intervention as a means for examining the contribution of the RPC and health care professionals’ interactions to the success of the intervention.

Characteristics of the intervention providers could influence or contribute to the degree of intervention effectiveness (Sidani & Braden, 1998). Therefore, it was important to identify intervention providers based on the inclusion criteria determined for study Study 2. Documentation of the RPC members’ credentials and reasons for participating in the study could explain why an intervention worked or did not work, account for variability of intervention delivery and subsequent outcome achievement, and increase statistical power (Sidani & Braden, 1998).

Wakefield et al. (2003) reported that physicians who had a commitment to change were more likely to change their prescribing practices. In a complex intervention study to improve breastfeeding rates using health care professionals as coaches, information about the coaches
regarding their commitment to the intervention and relationships with others could impact breastfeeding rates (Hoddinott, Pill, & Chalmers, 2007). In study groups where breastfeeding rates improved, health care professionals demonstrated commitment to the intervention and in groups where rates did not improve, health care professionals’ support for the intervention was viewed as weak (Hoddinott, et al., 2007). From the fidelity measures discussed in the literature review in Chapter Two, none of the measures included items about the provider credentials; therefore, unless collected elsewhere, it would not be possible to determine whether the qualities of the intervention providers could have contributed to study outcomes. In contrast, the PEC contains items inquiring about such characteristics.

RPC members applied the evidence supporting sucrose, and gained new knowledge/skills about the implementation process through their training sessions with the researcher. This application of evidence is considered an important characteristic of the PARiHS framework sub-element of leadership within the main element of context (Rycroft-Malone, 2010). As transformational leaders of the practice change, RPC members worked collaboratively as a team. The transformational leadership approach was effective, as RPC members were able to challenge and support health care professionals to improve their sucrose administration practices without being controlling. These strong multidisciplinary relationships and collaboration increase the likelihood that evidence is implemented into practice, and could have contributed to the significant improvement in sucrose administration practices (Davies, Edwards, Ploeg, & Virani, 2008; Fitzgerald, Dopson, Ferlie, & Locock, 2005; Rycroft-Malone et al., 2004).

One additional item that could be incorporated into to the PEC is an open ended question that explores changes in the RPC membership such as replacement of RPC members or the addition of new RPC members or other individuals who assisted with the intervention
implementation. This item could provide information about the providers’ continuity and level of ongoing commitment as both are critical for smooth implementation of the intervention over time (Sidani & Braden, 1998).

**Step 2: Training of RPC members.** RPC members rated the training sessions as useful to very useful. The only barriers to attending the training sessions were related to scheduling conflicts. Standardization of training sessions tends to promote higher adherence to a study intervention and therefore, contributes to higher implementation fidelity (Carroll et al., 2007; Leathem et al., 2009; Salyers et al., 2009). Training of the RPC members as the intervention providers represents a potential moderator of implementation fidelity, where inadequate training that is perceived as not helpful prevents providers from acquiring the cognitive and behavioural skills required to carry out the intervention activities as designed (Carroll et al., 2007; Sidani & Braden, 1998). For example, in the Evidence-based Practice for Improving Quality (EPIQ) study by Lee and colleagues (2009), not all components were implemented on a consistent basis. This intervention included a three-day critical appraisal workshop and similar topics covered in the EPIC intervention in Study 2 of the present research. Documenting aspects of provider training such as the usefulness of the training received, and barriers to attending training sessions could have provided insight into why the intervention was not implemented as planned across participating sites. According to the PARiHS framework, ‘low’ regard for research evidence, and lack of support to attend training sessions indicating a ‘low’ practice culture affect intervention implementation (Rycroft-Malone, 2010).

Ongoing assessment and evaluation of training for intervention providers has been used to ensure adherence to the study protocol and prevent intervention drift (Bellg et al., 2004; Borrelli et al., 2005; Resnick, Bellg et al., 2005; Sidani & Braden, 1998). Furthermore, ongoing
monitoring of intervention providers’ performance provides opportunities to identify and correct any errors in comprehension and implementation of the intervention process thereby promoting fidelity (Resnick, Bellg et al., 2005). The researcher provided a brief booster session on quality improvement methodology at a regularly scheduled meeting prior to Cycle 2. Boosters have been used to effectively reinforce or sustain skills that focus on changing behaviours or practices (Whisman, 1990). To document ongoing training, the PEC could be revised to collect information about the number of RPC member meetings, and additional booster/ training sessions offered to maintain their skills throughout the EPIC intervention implementation period.

The concept of process evaluation/intervention fidelity, which was not included in the training sessions, was initially not clear to RPC members. However, as the study progressed, their knowledge about intervention fidelity increased as the researcher completed the PEC tools with them during regular meetings. The concept of intervention fidelity and how to measure it by using the PEC should be added to future EPIC training sessions. Key concepts to include in a discussion about intervention fidelity are related to the risk of committing a Type 3 error (Sidani & Braden, 1998), which is defined as interventions not being delivered as planned. This type of error can reduce the power to detect significant effects of an intervention (Mowbray et al., 2003).

Overall, information about the training of the intervention providers (i.e., RPC members) is an important component of fidelity as described by Bellg et al. (2004), and Borrelli et al. (2005). Information collected on the PEC for Study 2 regarding the training was comprehensive, and therefore, further supports the relevance of respective items in capturing this aspect of fidelity.

Based on their training sessions, RPC members identified their pain practice aim based on the three of four sources of evidence described in the PARiHS framework; research evidence,
clinical experience, and local data (i.e., chart audit) from the NICU (Rycroft-Malone, 2010). The qualitative data from the focus group with RPC members expanded on their use of evidence to identify their pain practice change. First, RPC members felt that the research evidence based on a Cochrane systematic review (Stevens et al., 2004, 2010) on sucrose for procedural pain was robust and credible. Second, based on their clinical experience (i.e., witnessing sucrose working in practice), expertise, and consensus, RPC members decided that improving sucrose use was an important pain practice initiative. Third, RPC members used new evidence presented at their training sessions (i.e., evidence-based KT strategies and QI methods) to plan and support their practice change strategies. Although patient (i.e., parent) experiences were not assessed, RPC members used strong sources of evidence to identify their pain practice change (Rycroft-Malone, 2010). Therefore, paying attention to the essential sources of ‘high’ evidence as presented in the PARiHS framework assisted the RPC members to identify their pain practice change and could have contributed to the success of the sucrose administration practices.

**Step 3: KT strategies delivered/implemented, and received during EPIC.** Pertinent subscales of the PEC were used to collect information about the four types of KT strategies (i.e., educational outreach, educational materials, reminders, and audit and feedback) implemented during Study 2. Educational outreach sessions were the most frequently delivered strategy during Cycle 1 and reminders and audit and feedback were the most frequently applied KT strategy during Cycle 2. This sequence of beginning with the adoption of practice guidelines using educational outreach sessions, followed by system-based strategies such as reminders and audit and feedback is thought to facilitate the sustainability of practice changes (Davis & Davis, 2009). Similarly, Grimshaw et al. (2004) reported that the most common multifaceted strategies
for guideline dissemination were educational interventions (i.e., educational materials, educational meetings), followed by reminders, and audit and feedback.

With the PEC, data were collected on the type and content of the KT strategy, method of delivery (e.g., reminder sticker that stated “give and sign for sucrose”), the dose or frequency with which the KT strategy was applied, reach, and duration. Collecting information regarding the dose of KT strategies applied help explain variability in the delivery of the strategies, which may affect the degree of success of sucrose practices. For example, PEC and focus group data indicated that RPC members described challenges in ensuring that reminder stickers were placed on all patients’ admission orders. Inconsistencies in this process could have affected the enactment or administration of sucrose (i.e., sucrose administration practices). Although the implementation of education days for nurses’ and residents’ and fellows’ orientations were based on pre-planned dates, one of the limitations of the roving in-services was the inability to pre-determine the dose of this strategy. Roving in-services were implemented based on whether staff had available time to meet with RPC members, which could explain the limited coverage or reach of this strategy. Interestingly, this strategy was rated by RPC members and health care professionals as being very useful. Future applications of roving in-services could include apriori plans to ensure wider reach of this KT strategy.

The degree of reach documented on the PEC for static materials as KT strategies aimed at all health care professionals in the unit such as posters was challenging to quantify especially since there were numerous existing posters in the unit, and fluctuations in the number of staff occurred during the course of the study. The number of individuals targeted in the unit was used to quantify the reach of these materials. This method of determining reach is consistent with a study that evaluated the implementation of community heart health interventions, where reach of
the interventions was replaced by information about the targeted audience rather than the actual numbers of individuals receiving the intervention (Riley et al., 2008). Actual reach of KT strategies could be more accurately collected by interviewing key staff members who were directly exposed to the KT strategies and through non-participant observation (Breitenstein et al., 2010). These additional strategies, however, have their own limitations. For example, although observation provides an opportunity to collect objective information including non-verbal cues from participants, this method is costly and time consuming, as observers would need to be hired and trained (Breitenstein et al., 2010; Sidani & Braden, 1998). In addition, it would be challenging to determine how health care professionals in a busy patient unit process written educational materials such as posters in the unit, even if they were to stop and read them. Interviewing participants is also expensive and time consuming and there is a potential for both participant and interviewer bias (Sidani & Braden, 1998).

Provider adherence to the delivery of the KT strategies was monitored by the researcher during regular biweekly meetings with RPC members. These meetings served as a means to discuss and document on the PEC, any deviations to, and barriers and facilitators of the KT strategies delivery which influence the fidelity of an intervention implementation (Leathem et al., 2009; Radziewicz et al., 2009; Resnick, Bellg et al., 2005, Resnick, Inguito et al., 2005; Spillane et al., 2007). The PEC was comprehensive in operationalizing this aspect of fidelity and useful in guiding discussions with the RPC members. Adherence to the intervention as designed is considered a critical component of implementation fidelity (Carroll et al., 2007). High fidelity is thought to occur if all of the subcategories of adherence (i.e., dose, frequency, duration, reach) to the intervention are followed (Carroll et al., 2007). Overall, the PEC included the appropriate items to reflect the dose, reach, and duration of the intervention and included methods to ensure
high adherence to the delivery process, which further strengthened the construct validity of the PEC.

The PEC captured the steps of the EPIC that the RPC members applied. Qualitative results from the focus group sessions provided supplemental information about RPC members’ facilitator roles, skills, and attributes, and tapped into other facilitator roles (Harvey et al., 2002) that became evident during the Phase 2 Implementation and Change Phase; this information corresponded to Section 2 of the PEC (Harvey et al., 2002). Three types of facilitator roles, skills and attributes were identified. First, RPC members as internal facilitators demonstrated a holistic approach to changing practice. They enabled and helped staff to improve their sucrose practices by delivering KT strategies in the form of constant reminders, and encouraging them to critically reflect on their practices. Second, two staff members in the unit were viewed by RPC members and health care professionals as the unit pain practice champions. These internal facilitator/champions promoted sucrose practices by using task and enabling skills. Task-oriented skills included assisting RPC members to ensure that reminder stickers were replenished, and chart audits were completed. Enabling skills consisted of reminding staff to document ordering and administration of sucrose on the medication administration record. Third, RPC members regarded the researcher as an external facilitator. The researcher fostered communication with RPC members and ongoing monitoring of the implementation process by coordinating regular meetings to facilitate discussion about the implementation process, and to assist them to develop their KT strategies. These activities tapped into the researcher’s task-based technical and project management skills (Dogherty, Harrison, & Graham, 2010; Rycroft-Malone, 2004; Stetler et al., 2006). Additionally, the researcher enabled RPC members to reflect
on the results from pain practice audits and to identify and tailor KT strategies to promote sucrose administration practices in the unit (Rycroft-Malone, 2004).

Current literature on facilitator roles includes both individuals and groups who facilitate the process of change (Dogherty et al., 2010; Kitson et al., 2008). There was a combined approach to facilitating the EPIC intervention implementation (Dogherty et al., 2010; Stetler et al., 2006) where the RPC members, along with the support of the researcher and key unit champions, developed and delivered KT strategies to improve sucrose practices. These roles are consistent with the findings reported by Dunbar et al. (2006) and Stevens, Lee et al. (2007) where unit champions assisted the multidisciplinary team to introduce or promote pain practice changes. Achieving high facilitation required a combination of both task and enabling approaches to changing sucrose practices, which underscores the complexity and multifaceted nature of the facilitation process. As skilled facilitators, these individuals tailored their role to the needs of a practice change (Rycroft-Malone, 2010).

RPC members, as members of the unit pain committee, and health care professionals participating in the focus group session stressed the importance of ‘creating momentum for sustainability’ by securing dedicated personnel such as pain champions, which contributed to the strong receptive context (Rycroft-Malone, 2010; Scheirer, 2005). These resources were viewed by the RPC as a ‘luxury’ but necessary in order to maintain the practice change. Similarly, Davies et al. (2006), and Ellis et al. (2007) stressed the importance of including pain champions and multidisciplinary pain committees where possible to support the sustainability of practice changes. Johnston and colleagues (2007) reported that although the use of coaches as pediatric pain champions contributed to improved nursing pain assessment and use of nonpharmacologic interventions, significant site differences existed. The site differences could have been related to
contextual factors of the participating units such as the unit/organizational culture and leadership. Contextual factors are not clearly addressed in the conceptualization of fidelity but should be considered in future studies.

During Study 2, sucrose had become a hospital wide initiative/priority, and therefore, fits with the strategic plan of the organization (Rycroft-Malone, 2004). RPC members’ access to the unit pain committee and pharmacy represented supportive professional networks that are characteristic of a strong receptive context (Rycroft-Malone, 2004). Organizational fit and staff buy-in of the practice change within a receptive context are potential strategies for sustaining practice changes (Davies et al., 2006; Davies, Tremblay, & Edwards, 2010; Jordan- Marsh et al., 2004; Scheirer, 2005).

When responding to PEC items, RPC members noted that competing unit priorities, busyness of the unit, and dedicated time to implement KT strategies such as the roving in-services were barriers to their delivery. These barriers to delivery of KT strategies described in the PEC were also confirmed by RPC members during their focus group session. The convergence of findings supported the construct validity of the PEC. Similar results were reported by Kavanagh and colleagues (2010); nurses reported that competing priorities precluded their ability to implement KT strategies as planned to improve pediatric pain management. Stevens, Riahi et al. (2011) also reported that delivery of strategies to improve guideline use in NICUs was challenging to implement due to a lack of time and resources.

Receipt refers to whether the KT strategies implemented were received and understood by participants (Bellg et al., 2004; Borrelli et al., 2005; Resnik et al., 2005). For this study, receipt was operationalized with PEC items assessing the degree of usefulness of the KT
strategies implemented from the perspective of the RPC members and health care professionals where possible.

All four types of KT strategies were considered useful in promoting sucrose use. Colourful stickers and posters, and roving in-services were effective visual reminders according to the RPC members. These strategies were comparable to those found effective to communicate practice changes: teaching moments, bedside teaching, and visually appealing posters (Stevens, Lee et al., 2007). Dunbar et al. (2006) also reported the effectiveness of using reminder stickers to promote compliance in assessing pain. Emails as a method to deliver information about the progress of the practice change were not perceived by RPC members as useful as stickers or posters because emails were not always read by staff. Stevens, Lee et al. (2007) reported similar findings where emails were viewed as ineffective for disseminating practice change information due to health care professionals’ lack of time to read them.

All KT strategies in this study were multifaceted. For example, the first KT strategies introduced during the first month of Cycle 1 included a combination of educational outreach and reminder stickers (Figure 3). In Study 2, cumulative KT strategies were delivered during Cycle 1 and Cycle 2. Current reviews on the effectiveness of single versus multifaceted strategies have produced conflicting results (Grimshaw et al., 2004; Hakkendes & Dodd, 2009; Prior et al., 2008; Wensing, Bosch, & Grol, 2009). The opportunity to collect data about the receipt/usefulness of the KT strategies from the perspective of the RPC members and staff is a strength of the PEC. Such data assists in identifying the most effective components of multifaceted KT strategies. In the EPIQ evaluation study by Lee et al. (2009), information about the delivery (i.e., dose, reach, duration), and receipt (i.e., usefulness) of the KT strategies used to reduce nosocomial infection and chronic lung diseases could have been used to determine the
degree to which components of the EPIQ intervention were consistently implemented, and whether specific KT strategies were effective in promoting these practice changes. Similarly, in the TROPIC study (Stevens et al., 2008) knowledge about the usefulness of the KT strategies could provide additional insight into whether the strategies themselves contributed to the improvement in pediatric pain practices.

Qualitative findings from the focus group sessions with health care professionals were consistent with the findings from the PEC in terms of the usefulness of constant visual reminders and multifaceted strategies to improve sucrose use. RPC members reported that the audit and feedback strategies aimed at the pain committee and the RPC members in the form of face-to-face meetings with written results of the audit were considered to be very useful and effective strategies to report the progress of the practice change. Health care professionals reported that the feedback reports had not reached all staff. The limited reach might be related to the method and timing used to deliver the feedback. An email message was used as a KT strategy to provide feedback regarding the progress of sucrose documentation for Cycle 1. Current empirical evidence does not support the effectiveness of using emails to reach target populations (Stevens, Lee et al., 2007). The email report that included a graph of the progress of sucrose ordering was fed back to staff by RPC members at the end of the year near the holiday season (i.e., December) when staff might not have accessed their email. Moreover, there was a delay in the dissemination of the unit newsletter that included Cycle 1 audit results as the newsletter was disseminated at specific times during the year. Although the unit newsletter was a key communication tool in the NICU, the timing of this activity was influenced by the unit context/culture and was beyond the control of the researcher. The researcher provided more timely and frequent feedback reports (i.e., within Cycle audits) to RPC members during the
regularly scheduled RPC member meetings. These findings are consistent with studies evaluating audit and feedback, indicating that frequent, actionable, and timely feedback contributes to the usefulness of audit and feedback as a KT strategy (Hysong, 2009; Hysong et al., 2006). Based on the discrepancies reported by RPC members and health care professionals regarding the usefulness and reach of the audit and feedback strategies, future use of audit and feedback strategies should consider provision of feedback reports in a timely manner.

Additional educational and reminder strategies that were not captured using the PEC were discussed during the focus group sessions. These KT strategies included the use of unit staff/champions and teaching moments that were often unplanned. RPC members might not have been aware of these activities and therefore, these strategies might have been challenging to document using the PEC. Unit staff/champions, who have a regular presence in their workplace setting, have contributed to the successful implementation of pain management strategies including sucrose use (Dunbar et al., 2006; Ellis et al., 2007). Teaching moments were also effective strategies to improve policy use in NICUs (Stevens, Lee et al., 2007). Future refinements of the PEC could include additional items to capture these two additional modes of delivery where possible.

An interesting point raised during the focus group sessions that could have contributed to the variability in the degree of sucrose use/enactment was health care professionals’ lack of consensus or comprehension regarding the correct dose and frequency of administration for sucrose, and the need to develop and educate staff about the sucrose practice guideline/standard. There was also evidence of a lack of understanding about the purpose or use of the reminder stickers that were placed on admission orders as some staff had interpreted the sticker as an order to give sucrose.
One reason for this knowledge gap might be related to the type of educational strategies used to promote sucrose use. According to the data collected using the PEC, nurses attended mandatory large group educational outreach sessions where a number of practice updates were discussed, including a 15-minute review of the sucrose guideline. Current evidence on educational sessions supports the use of small-group sessions with an opinion leader rather than large group sessions that have little impact on practice changes (Davis & Davis, 2009; Frankel, 2009; Thompson et al., 2007). However, using interactive sessions have been effective methods to improve practice skills related to guideline use (Davies et al., 2008). Qualitative results from the focus group sessions with health care professionals suggest that opportunities to observe sucrose working in practice were effective methods to foster its use in practice. Witnessing the positive effects of sucrose has facilitated buy-in and use or enactment of this practice change (Stevens, Riahi et al., 2011).

The discrepancies reported by health care professionals regarding their comprehension of sucrose administration practices could be accounted for by competing priorities in the unit. Stevens, Lee et al. (2007) reported that health care professionals in the NICU were often inundated with information and did not have time to comprehend practice information. Stevens, Riahi et al. (2011) also evaluated the use of guidelines, policies and procedures in neonatal units where they reported that a lack of follow-up with staff to discuss or clarify details/issues related to new or revised guidelines or policies hindered guideline use. These discrepancies in practice could also be related to differences in the unit practice culture. McCormack and colleagues (2002) suggest that there are multiple cultures within a practice setting that have their own values, assumptions, beliefs, and priorities, which could have influenced how sucrose information was disseminated in the unit. Although intervention receipt was operationalized as
the usefulness of the KT strategies implemented, Bellg et al. (2004), and Borrelli et al. (2005) defined receipt of the intervention to include participant comprehension of the intervention and ability to perform the necessary skills to achieve enactment. As sucrose guidelines had existed in the unit for approximately three years, information about sucrose administration directed at staff nurses during education sessions was considered a review (Nurse Practitioner, personal communication, March 8, 2011). The PEC could be refined to assess health care professionals’ understanding of the sucrose clinical practice guidelines. Knowledge deficits related to pain management have been associated with poor pain management practices (Strauss, Tetroe, Graham, Zwarenstein, & Bhattacharyya, 2009; Twycross, 2010). Overall, the PEC provided a thorough account of the receipt/usefulness of all KT strategies received, which adds further support to the fidelity of the EPIC intervention and the construct validity of the PEC.

**Step 4: Enactment of the practice change.** Overall, the RPC members’ pain practice aimed to improve sucrose ordering and documentation of administration were achieved. By the end of the study, documentation of sucrose administration demonstrated an absolute improvement of 50% compared to baseline. Compared to baseline rates for documentation of ordering and administration of sucrose, there were both statistically and clinically significant improvements over time. These findings represented a positive change in practice behaviours by health care professionals in the unit. Despite the success of the practice change, sucrose ordering and documentation of administration rates were variable within Cycle 2. Stickers were placed on the admission sheets and the MAR to remind staff to order, give and document sucrose administration; however, the frequency of use of stickers was inconsistent, and the level of comprehension regarding sucrose administration practices might account for variability in rates for ordering and documentation of administration. The February 2009 audit was conducted
during the month when four new KT strategies were being introduced. The audit therefore might not have captured the effects of these KT strategies during the month and could be more reflective of the previous month’s KT strategies indicating a possible carry over effect.

The use of multifaceted KT strategies appeared to correspond to improved sucrose documentation of ordering and administration, which provided some support to the construct validity of the PEC. However, it was not possible from this case study to determine the optimal dose of KT strategies that were required to successfully implement sucrose into practice. Using the PEC, assessment of KT strategies used to improve sucrose practices is required over a longer time period to assess the optimal dose for sustainability of this practice change.

Based on the audit conducted at Time 2, an interesting finding was the potential influence that the EPIC intervention process might have had on other pain practices in the unit. Further improvements in the enactment of pain practices in general were noted at Time 2 (i.e., end of EPIC intervention). Compared to Time 1 (i.e., baseline), at Time 2 there were less painful procedures performed during the first 24 hours of admission, more pain assessments conducted, significantly more sucrose and physical interventions used, and significantly less opioids given. An explanation for the reduction in opioids given was that there were fewer surgical infants at Time 2 compared to Time 1 and these infants were in the preoperative phase during data collection and did not require opioid analgesics.

Additionally, eight pain practice initiatives were implemented during the course of the study entailing plans to implement hospital wide sucrose guidelines. Qualitative findings from the focus group sessions indicated that sucrose practice improvements contributed to raising awareness of the importance of pain management in general as seen in the introduction of three new pain guidelines, three pain studies, revisions to electronic charting related to pain
assessment and management, and the development of pain management immunization kits (Table 25). These improvements in pain practices and implementation of other pain initiatives reflected a practice culture that valued the importance of pain assessment and management. In the cluster randomized control trial evaluating EPIQ (Lee et al., 2009) NICUs randomized to reduce nosocomial infection (NI) or bronchopulmonary dysplasia (BPD), NI rates were reduced in both groups indicating potential spread in practice improvements. This ‘spill over’ change/improvement in practice may be related to the use of quality improvement methods focused on changing health care professionals’ practice behaviours (Lee et al., 2009).

Multiple methods were used to evaluate the enactment of sucrose practices, which represented/illustrated a ‘strong’ approach to evaluation (McCormack et al., 2002). During Phase 2 of the EPIC intervention, audits of the practice changes, and assessment of the usefulness of KT strategies implemented during, and at the end of each Cycle were conducted. Results of the audit were fed back to the NICU staff and RPC members. Audit and feedback strategies represented the ‘hard outcome data’ that yielded information about the degree of sucrose enactment within the context of the NICU setting (McCormack et al., 2002). Usefulness scores represented the ‘soft data’ that were used to evaluate the receipt of the KT strategies (McCormack et al., 2002). Feedback from the users of the KT strategies is considered equally important sources of information, and should be incorporated in the audit and feedback process (McCormack et al., 2002).

Overall, the PEC captured the enactment of sucrose use through the audit and feedback process, which supports the steps of the EPIC intervention and therefore, the construct validity of the PEC. Qualitative findings from the focus group provided additional information regarding issues related to health care professionals’ knowledge about the sucrose guideline.
Feasibility and clinical utility of the PEC. The questionnaire that was used to assess the feasibility of the PEC from the perspective of the research nurses/coordinators from the TROPIC study (Stevens et al., 2008), incorporated commonly used components of feasibility including the clarity of instructions, structure of the PEC, ease of use as an on-line measure, length of the PEC, method of scoring, interpretation of the information obtained with the PEC measure, and ease of use in the practice setting (Gelinas, 2010; Stevens & Gibbins, 2002). Overall, feedback from the research nurses/coordinators indicated that the PEC was feasible during the EPIC intervention implementation. In general, respondents felt that they were able to interpret the information obtained from the PEC and easily incorporate the PEC into their practice setting. However, the composition of the RPCs or their degree of interest in participating as RPC members might have influenced their level of comfort when completing sections of the PEC. These components representing the feasibility of the PEC (e.g., time to complete the measure) could influence the clinical utility of a measure as feasibility is one aspect of clinical utility (Smart 2006; Stevens & Gibbins, 2002; Voepel-Lewis et al., 2008).

From the researcher’s perspective, the PEC was considered clinically useful in assisting RPC members to identify and use the most appropriate KT strategies to promote sucrose practices in Study 2. RPC members in Study 2 used the information from the PECs to tailor their KT strategies during the study. For example, a poster was developed to inform health care professionals about the sucrose clinical practice guidelines. This KT strategy was rated as very useful; however, health care professionals who provided feedback thought that the poster included too much information, and that the dosing guidelines required further clarification (e.g., request from health care professionals to include maximum sucrose doses and contraindications for using sucrose). Based on this feedback, the RPC members decided to develop a new poster.
Results of the pain practice audits also helped RPC members to decide whether to add or continue with existing KT strategies that had been implemented. For example, RPC members rated the visual reminder stickers to order sucrose as a very useful KT strategy. Therefore, in Cycle 2, reminder stickers were used to promote a second practice aim, which was to improve sucrose documentation of administration. The research nurses/coordinators from the TROPIC study (Stevens et al., 2008) also rated the PEC was clinically useful for guiding and planning pain practice change interventions. However, a research nurse/coordinator from this study commented that some RPC members struggled with completing the PEC and required guidance from others. This comment related to the feasibility of the PEC underscores the importance of having a receptive context, and the importance of securing sufficient human resources to implement the EPIC intervention (Rycroft-Malone, 2010). Smart (2006) conceptualized the clinical utility of an innovation as being multidimensional and proposed that the appropriateness, accessibility, practicability and acceptability of an innovation be considered. Moreover, elements of work practice or the context in which the innovation (i.e., PEC) was implemented should be included when assessing clinical utility (Smart, 2006). Future assessments of the feasibility and clinical utility of the PEC could be expanded to include aspects of the work practice context that could influence its use (Rycroft-Malone, 2010). For example, an open ended question could be added to the clinical utility measure to determine whether there were aspects of the practice context that could explain why the PEC was or was not used in the clinical setting. Determining the feasibility and clinical utility of a measure is essential when applying it into clinical practice. Preliminary support for the feasibility and clinical utility of the PEC in Study 3 was achieved, based on the reports from the researcher and the research nurses/coordinators from the TROPIC study (Stevens et al., 2008).
CHAPTER SEVEN

Implications and Conclusions

In this chapter, the significance, strengths, and limitations of the studies are discussed. Implications for theory, research, practice, policy, and knowledge translation (KT) are presented.

Summary and Significance

Although international pain guidelines and standards have been developed to promote adequate pain management for infants in NICUs, pain management in these hospitalized infants remains suboptimal suggesting a gap in translating evidence into clinical practice. Translating research evidence into clinical practice is a complex process that involves changing or modifying clinician behaviours. To address this gap, a KT intervention, EPIC (Lee et al., 2009) was implemented in a single NICU setting. The EPIC intervention was guided by the PARiHS framework (Kitson et al., 1998; Rycroft-Malone, 2004). A RPC consisting of four health care professionals delivered multifaceted KT strategies to improve sucrose administration practices in the unit. The process of delivering the EPIC intervention as planned (i.e., fidelity) is not well delineated. There was no valid measure that could be used to evaluate the EPIC intervention implementation.

Reporting details of the implementation of interventions (i.e., implementation fidelity) is gaining attention in complex behavioural change interventions (Michie et al., 2009). Knowledge about fidelity could help to explain (a) what aspects of the intervention worked or did not work, (b) whether the intervention could have influenced the direction of the study outcomes, and (c) how to replicate the intervention within the arena of intervention research (Carroll et al., 2007; Michie et al., 2009). The development of psychometrically sound measures to monitor implementation fidelity was required.
Three studies were conducted to develop and test prospectively, the face, content and construct validity, feasibility, and clinical utility of a PEC to determine the fidelity of implementing EPIC, a complex KT intervention, in a complex hospital unit environment. Development of the PEC was guided by an evidence-based intervention fidelity framework (Bellg et al., 2004; Borrelli et al., 2005). Results of Study 1 supported the face and content validity of the PEC.

In Study 2, the construct validity of the PEC was achieved in a clinical setting by using the PEC to monitor the EPIC intervention implementation. Each step of the EPIC intervention was recorded using the PEC in a prospective mixed methods case study of one clinical unit. The study included a preparation phase and an implementation and change phase. The practice change was implemented over two, three month Cycles of change by the RPC who were considered the facilitators and leaders in the unit. Using the PEC, the obtained data indicated that the RPC members implemented the intervention with high fidelity. The components that contributed to ‘high’ intervention fidelity included (a) inclusion of RPC members who demonstrated strong, multidisciplinary leadership and facilitation qualities, and an interest in pain practices, (b) comprehensive training sessions for RPC members on how to implement the EPIC intervention, (c) thorough monitoring by the RPC regarding the delivery of KT strategies and usefulness of the strategies implemented, and (d) evaluating the degree of sucrose administration practices (i.e., enactment). Documenting the successful implementation of the EPIC phases provided support for the construct validity of the PEC in capturing the steps of the EPIC intervention.

Data collected using the PEC indicated that the KT strategies applied in Study 2 were multifaceted and delivered in a sequence beginning with educational outreach strategies,
followed by educational materials, reminders, and audit and feedback. This sequence of strategies represents a common approach to achieving effective KT (Davis & Davis, 2009). Effective strategies to promote sucrose practices included visual reminders that were delivered in the form of stickers, posters, and interactive educational interventions that included roving in-services and one-to-one teaching sessions for staff, and face-to-face feedback sessions. Although variability in sucrose practices occurred during Cycle 2, there was a statistically significant improvement in the documentation of sucrose ordering and administration compared to baseline rates. RPC members met their pain practice aims to improve ordering and sucrose documentation of administration.

The PARiHS framework was helpful in both guiding and explaining the EPIC intervention implementation process. The interplay of the three key PARiHS elements (i.e., evidence, context, and facilitation) and their sub elements contributed to improved clinical practices (i.e., sucrose administration practices). Data from the PEC were in line with findings from the focus group in that high levels of evidence were used to determine the RPC members’ practice aims. The practice environment (e.g. context) in which the EPIC intervention was implemented was deemed important in relation to potential factors that could have influenced the success of sucrose practices. In terms of context, or more specifically, unit culture, the participating hospital unit and organization were receptive to sucrose as a pain practice change. For example, organizational commitment was demonstrated by support received by the institution’s pain centre, and pain as a key indicator in the hospital strategic plan. RPC members were interested in improving sucrose practices, and had appropriate leadership skills and attributes to facilitate the practice change. The complexity of the facilitation process including
the role of external and internal facilitators strengthened the EPIC intervention implementation process.

Once the construct validity of the EPIC was established, it was important to test the feasibility and clinical utility of the PEC (Study 3) to determine the extent to which the PEC could be potentially used in clinical practice. The research nurses/coordinators from the TROPIC study (Stevens et al., 2008) provided preliminary support for the feasibility and clinical utility of this checklist.

**Strengths**

Process evaluations of complex behavioural change interventions are not well documented in the literature (Carroll et al., 2007; Hasson 2010; Helfrich et al., 2010; Michie et al., 2009). The main strength of this study was development of the PEC and the comprehensive prospective evaluation of the fidelity in implementing a complex KT intervention, EPIC, using the PEC. The PEC demonstrated acceptable psychometric properties (e.g. validity) as well as feasibility and clinical utility. First, face and content validity were achieved. Second, the PEC was evaluated in a clinical setting to determine the fidelity of the EPIC intervention implementation. The steps in this complex intervention were implemented with high fidelity, thus supporting the construct validity of the PEC.

As very few studies in implementation research have applied theories (Davies, Walker, et al., 2010), a strength of this study was the application of conceptual frameworks. The development of the PEC was guided by an evidence-based fidelity framework (Bellg et al., 2004; Borrelli et al., 2005). Components of the fidelity framework were used to guide data collection about the EPIC intervention steps and components of intervention fidelity. The PARiHS framework was used to guide the EPIC intervention implementation and evaluation. By
implementing the EPIC intervention that was guided by elements and sub elements of the PARiHS framework, information was obtained about the processes that could have contributed to the success of the intervention implementation such as the sources of evidence used to determine the pain practice change (ICEBerg, 2006). In addition, examining the fidelity of the EPIC intervention implementation using the PEC provided insights into the “black box” of the EPIC intervention (Hasson, 2010; Hulscher et al., 2003). For example, using the PEC to collect information on the usefulness of the KT strategies implemented revealed that reminder stickers were one of the most useful strategies to promote sucrrose administration practices in the unit.

The prospective concurrent embedded mixed methods design to test the PEC in a clinical setting was a strength in Study 2. In this study design, the quantitative results from the PEC predominated (Cresswell, 2009) over the qualitative descriptive data. The qualitative results from the focus groups confirmed some of the data collected using the PEC and also provided a more comprehensive, expanded/enhanced understanding about the components of intervention fidelity, and the context, or environment in which the EPIC intervention was implemented. The embedded qualitative data provided in more depth, a description of the activities within the EPIC steps that could not be quantified, such as issues related to raising the awareness of pain, and creating momentum for sustainability. Methods to ensure rigor of the qualitative data were implemented. For example, two coders independently analyzed focus group data to ensure criticality and integrity of the data.

Limitations

There were several limitations with respect to the study samples and data collection process. The PEC was validated for one KT strategy (i.e., EPIC) in a single tertiary care NICU setting that focused on one pain practice change. The relationship between the KT strategies
implemented and the pain practice outcomes could not be fully estimated, thus limiting the
generalizability of results beyond the participating NICU. In Study 3, the clinical utility of the
PEC was evaluated with the research nurses from the TROPIC study (Stevens et al., 2008) since
they had experience using the PEC. Although the sample of research nurses/coordinators who
completed the questionnaire about the feasibility and clinical utility of the PEC, although small
(N=10) represented 91% of available research nurses/coordinators with experience using the
PEC. The variability in the research nurses’/coordinators’ use of the PEC in a different study
with three out of the four Cycles of change might have influenced the results regarding the
feasibility and clinical utility of the PEC (Stevens et al., 2008). Collecting data from these
research nurses/coordinators following completion of the four Cycles might have provided time
for these individuals to gain additional experience in completing the PEC, which might have
influenced the results. This option was not possible due to timing constraints as the TROPIC
study (Stevens et al., 2008) was still in progress at the time of data collection for Study 3.

The retrospective nature of the chart review data that represented the pain practices in the
NICU at Time 1, end of Cycle 1, and Time 2 in Study 2 might not have represented the true
quality of care provided. Clinical information documented in the charts could have been
subjected to recording bias (Luck, Peabody, Dresselhaus, Lee, & Glassman, 2000). For example,
participants from the health care professional focus group in Study 2 noted that they thought that
unit staff members were using sucrose more than it was being documented. Although a
prospective observational review of pain practices was an alternative approach to collecting pain
practice data, this method was not feasible within the timeframe for Study 2. The prospective
observation approach could also be prone to a Hawthorne effect, where health care professionals’
behaviours could have improved because their practice was being observed (Streiner & Norman, 2008).

The researcher completed the PEC with the RPC members during regularly scheduled meetings; therefore, the RPC member ratings about the usefulness of the training sessions and KT strategies implemented might have been subjected to social desirability bias; that is, RPC members might have provided acceptable responses that conformed to the researcher’s expectations when completing the PEC (Streiner & Norman, 2008). To minimize social desirability bias, the researcher explained during the RPC member training that the purpose of rating the usefulness of the training and KT strategies implemented in a group setting would facilitate tailoring of the EPIC process and KT strategies. Study participants were informed that their responses and identities in all studies were kept confidential. RPC members (not the researcher) were responsible for the content and the delivery of all KT strategies implemented. Focus group sessions were conducted by a neutral individual. Study 2 results were not all positive. For example, not all methods used to deliver KT strategies such as the use of emails were rated as being highly useful. RPC members did not attend all biweekly meetings with the researcher. Additionally, the progress of the practice change was variable in Cycle 2. To further minimize social desirability bias, the PEC should be measured by a trained individual other than the researcher, and future studies could include an assessment of social desirability bias (Streiner & Norman, 2009).

During the implementation of the PEC in Study 2, there were several limitations regarding the data collected with Section 2 of the PEC. First, collecting information about the reach of educational materials and other materials posted in the unit was challenging; therefore, the targeted/estimated reach was used as a proxy for the actual number of people who were
exposed to these materials. Second, educational outreach sessions that involved teaching moments, might have been missed as they were often spontaneous and unplanned. Third, the progress of the KT strategies, and the usefulness of the RPC member training, and KT strategies implemented was reported to the researcher by the RPC members. Although the RPC members incorporated the feedback obtained from discussing the usefulness of KT interventions with health care professionals on the unit when possible, the usefulness scores might have represented a more socially desirable, biased view from the perspective of the RPC members who volunteered to participate as facilitators in the study and might have had more interest in changing pain practices in the unit (Streiner & Norman, 2008).

Implications for Theory

Intervention fidelity. Intervention fidelity is becoming increasingly important to monitor in KT research due to the complexity involved in changing health care professionals’ behaviors and the need to account for the variability in the effectiveness of interventions (Jamtvedt et al., 2006; O’Brien et al., 2007). However, there is no universal agreement regarding the definition of fidelity, key components of this concept, and standardized methods to measure whether an intervention was implemented as planned (Gearing et al., 2011). As intervention fidelity is used to evaluate aspects of interventions that have or have not been implemented, current available measures are intervention-specific and need to be standardized and customized to the intervention under review (Song, Happ, & Sandelowski, 2010). The content of existing fidelity measures captures the activities to be performed for specific interventions and could not be adapted for use with the EPIC intervention. Therefore, there was a need to develop a standard method to measure the steps specified within the 2 Phases of EPIC. The five concepts from the
fidelity framework by Bellg et al. (2004), and Borrelli et al. (2005) were used to guide the
development of the PEC.

Recent conceptualizations of fidelity have emerged and are reviewed in the context of the
PEC. Carroll et al. (2007) reviewed the implementation fidelity research from 2002-2007 and
developed a new framework for evaluating implementation fidelity in complex interventions.
Their framework was based on the core component of adherence and four subcategories
including (a) content, (b) coverage, (c) frequency, and (d) duration. Content included details
about the intervention, while coverage, frequency, and duration referred to the reach, and dose of
the intervention (Carroll et al., 2007). The authors identified four factors that were thought to
moderate the delivery of the intervention process either alone or in combination; these included
(a) intervention complexity, (b) facilitation strategies, (c) quality of delivery, and (d) participant
responsiveness. In terms of intervention complexity, simple interventions or interventions that
were described in sufficient detail would likely be implemented with higher fidelity. Carroll and
colleagues defined facilitation strategies as methods used to standardize the intervention process
by including study procedure manuals, training, and monitoring and providing feedback for
individuals who were responsible for delivering the intervention (Carroll et al., 2007). If an
intervention had not been delivered appropriately, the quality of delivery could be viewed as
poor, which could influence the success of intervention implementation (Carroll et al., 2007).
These activities demonstrated the consistency with the PARiHS element of facilitation whereby
the external facilitator (i.e., the researcher) provided training to the internal facilitators (i.e., RPC
members), and monitored the delivery of the EPIC intervention. Finally, participant
responsiveness referred to the level of acceptance or enthusiasm of the individuals, and
organizations responsible for delivering the intervention, as well as the recipients of the
intervention. Participant responsiveness could be measured by evaluating the degree of usefulness, understanding, or enactment of the intervention (Carroll et al., 2007). Hasson (2010) proposed, two additional moderators that could influence intervention fidelity (a) context or organizational culture in which the practice change occurred, and (b) methods used to recruit study participants. The authors proposed plans to apply this revised intervention fidelity framework in three study protocols.

More recently, Gearing and colleagues (2011) revised the framework by Bellg et al. (2004) and Borrelli et al. (2005) and proposed what they considered to be a more comprehensive, expanded guide to intervention fidelity and methods that could be used to evaluate intervention implementation. They hypothesized four core components of fidelity including (a) intervention design and protocols, (b) intervention training, (c) monitoring of intervention delivery, and (d) monitoring of intervention receipt. For each of the components, study protocols were developed, execution or delivery of the intervention was explained, and methods to improve and maintain fidelity and delivery of the intervention were described (Gearing et al., 2011). Interestingly, participant enactment, a component of the framework by Bellg et al. (2004), and Borrelli et al. (2005) was not included in this current framework, as the authors felt that enactment was related more to the effectiveness of the intervention, and not to the conceptualization of intervention fidelity.

Despite the introduction of these new or revised intervention fidelity frameworks, overlap exists with the components described in the frameworks proposed by Carroll et al. (2007), Gearing et al. (2011), and the framework used to guide the development of the PEC by Bellg et al. (2004), and Borrelli et al. (2005). Areas of overlap are described in Figure 4. It is clear that similar concepts were used to operationalize intervention fidelity, and that the concept of fidelity
continues to evolve. The PEC provided a comprehensive representation of aspects of intervention fidelity captured by the Bellg et al. and Borrelli et al. framework. In addition, the PEC included the key fidelity components proposed by Carroll et al. and Gearing et al. which is strength of this checklist. As few studies have tested the new fidelity frameworks proposed by Carroll and colleagues, Hasson (2010), and Gearing and colleagues, further prospective research is required to support the use of these conceptualizations of fidelity before considering further revisions to the PEC.

In Study 2, the fidelity concepts in the PEC were used to guide what aspects of fidelity were important to focus on during the EPIC intervention implementation. Moreover, the fidelity components included in the PEC provided valuable information and explanations regarding the “critical factors” of the EPIC intervention delivery/facilitation process. Future prospective KT studies should continue to evaluate the utility of the fidelity framework by testing whether the concepts from these frameworks could be used to explain or predict study outcomes (Rycroft-Malone & Bucknall, 2010).

**PARiHS framework.** The PARiHS framework was useful in prospectively guiding the EPIC intervention implementation in Study 2 and was helpful in the interpretation of the key qualities of the evidence, context and facilitation process that could contribute to successful sucrose administration practices. However, one of the criticisms of the PARiHS framework is its limited use to prospectively guide intervention implementation (Helfrich et al., 2010).

The elements and sub-elements of PARiHS framework were helpful in highlighting the activities required for successful intervention implementation (Rycroft-Malone, 2010). The roles, skills, and attributes of the RPC members as internal facilitators and the researcher as an external facilitator were determined a priori by identifying eligibility criteria for their
involvement in the study. Data from the PEC and focus group sessions indicated that RPC members had strong leadership qualities, and the appropriate roles, skills and attributes that were representative of “high” facilitation. These characteristics of high facilitation were consistent with the credentials of the intervention providers described in the intervention fidelity framework (Bellg et al., 2004; Borrelli et al., 2005). RPC members applied various high quality sources of evidence (i.e., research, clinical expertise, local audit of pain practices) to identify their pain practice change. Based on the qualitative findings from the focus group sessions, the participating unit demonstrated qualities of a high receptive context, a supportive unit and organizational culture, and had established effective methods to evaluate the progress of sucrose use practices using audit and feedback strategies. Focus group participants provided insight into the importance of a receptive context where dedicated support was deemed essential to create a momentum for sustainability of the practice change. This conceptual framework on intervention fidelity reflected in the PEC complemented the PARiHS element of facilitation. Successful implementation can therefore be better understood when the fidelity of the intervention implementation process is monitored (Helfrich et al., 2010).
Figure 4. Treatment fidelity frameworks (Bellg et al., 2004; Borrelli et al., 2005; Carroll et al., 2007; Gearing et al., 2011)
The main objective of Study 2 was to examine the construct validity of the PEC by monitoring the fidelity of the EPIC intervention implementation. Therefore, emphasis was placed on how the RPC members as facilitators implemented KT strategies to promote sucrose practices in the NICU. The element of facilitation has a major role in the intervention implementation process (Dogherty et al., 2010; Kitson et al., 1998; Rycroft-Malone et al., 2002; Stetler et al., 2006). Qualitative findings from the focus group sessions revealed the complexity and multifaceted nature of the facilitation process. The additional internal facilitator roles and their task and holistic-based skills that emerged during the study provided new knowledge about the facilitation process, especially the importance of the leadership role and project management skills (Dogherty et al., 2010; Stetler et al., 2006).

Currently, questions remain as to how evidence, context, and facilitation interact, and whether these elements are equally weighted in terms of promoting evidence into practice (Kitson et al., 2008; Rycroft-Malone et al., 2010). These questions may be challenging to answer as the weighting and the level of interaction of the three elements are situation dependent (Rycroft-Malone, 2010). Kitson and colleagues (2008) recommended that future applications of the PARiHS framework should consider conducting a diagnostic evaluation of the evidence and context that could be used to help to identify the most suitable facilitation strategies. For each of the sub elements of evidence and context, Kitson et al. included a list of evaluative questions for intervention providers/facilitators that could be used to diagnose the main KT gaps or areas that would require additional attention. Helfrich et al. (2010) described the implementation process as being unpredictable. In the EPIC intervention implementation, facilitators included a designated external facilitator (i.e., the researcher) and internal facilitators (i.e., the RPC). During the course of the study, two staff nurses assisted the RPC with facilitation strategies.
Focus group participants described that some bedside staff also reminded physicians and nurse practitioners to order sucrose; therefore representing another level of facilitation. Thus, using the PARiHS framework to identify appropriate facilitation strategies could be challenging due to the complexity and unpredictable quality of the facilitation process.

Finally, the comprehensiveness of the elements of the PARiHS framework requires further development and clarity (Helfrich et al., 2010; Rycroft-Malone, 2010). Helfrich and colleagues (2010) identified areas of overlap among qualities of a receptive context, culture, and leadership. In Study 2, the qualities of the RPC members described under the element of context and the sub-element of leadership overlapped with the characteristics of facilitation. RPC members were viewed as both leaders and internal facilitators of the pain practice change. Dogherty and colleagues (2010) developed taxonomy of facilitation in terms of strategies and roles, and also included leadership and teamwork in their definition of facilitation. Moreover, Helfrich et al. commented that facilitation to date has been defined primarily as a role, where individuals with specific attributes and skills would facilitate the intervention implementation. Interestingly, the authors noted that the element of facilitation had not moved beyond the role to include the methods or strategies (i.e., KT strategies such as reminders, and audit and feedback) used to promote knowledge translation. This conceptualization of facilitation was more aligned with the PEC that was used to collect information regarding all KT strategies that were delivered and received during the EPIC intervention implementation. Therefore, based on Study 2 findings, expanding facilitation to include aspects of leadership, team work, and implementation/KT strategies provides evidence that the element of facilitation is gaining some consistent thinking and clarity. Future applications of the EPIC intervention should evaluate
these additional roles, skills and attributes that could contribute to conceptual clarity related to the element of facilitation.

**Implications for Research**

The overall objective of Studies 1 to 3 was to develop and test the psychometric properties (i.e., face, content and construct validity), and feasibility and clinical utility of the PEC using a multidimensional KT strategy. The PEC has beginning construct validity demonstrated by assessing the fidelity of the EPIC intervention implementation. In Study 2, data on the delivery of KT strategies and the enactment of sucrose ordering and documentation of administration were collected using the PEC. The study was conducted on one unit, and focused on one pain practice change implemented by one RPC which precluded meaningful statistical analysis to determine the relationships between the KT strategies used, and the pain practice outcomes (i.e., sucrose ordering and documentation of administration). As there has been a growing interest in using the EPIC intervention in other countries and patient populations (Program Manager for EPIC, personal communication, April 3, 2011), the EPIC intervention process and the PEC can be used beyond the NICU settings (Lee et al., 2009). Further research on the use of the PEC in different health care settings is required to support the construct validity of this checklist and strengthen the generalizability of the study results. The PEC is currently being used in a multi-centre study, TROPIC (Stevens et al., 2008). In a prospective cohort comparative design with repeated measures, 16 intervention units from eight university-affiliated paediatric hospitals in Canada recently used the PEC to document the fidelity of implementing the EPIC intervention to improve pediatric pain practices in a variety of hospital units (i.e., medical, surgical, and critical care [neonatal intensive care units and pediatric intensive care units]). From these data, a more detailed analysis is possible to evaluate relationships between
components of intervention fidelity (e.g., dose and usefulness of KT strategies delivered) and targeted pain practices, and patient outcomes (i.e., pain intensity) as a means to further validate the PEC. Revisions to the PEC could include additional items to assess (a) changes in the RPC membership, (b) frequency of meetings with facilitators and methods to ensure adherence to the intervention process (e.g., use of boosters), (c) other KT strategies such as the use of staff champions and teaching moments, and (d) health care professionals’ knowledge about the practice (e.g., sucrose guideline). As construct validation is an ongoing process, the PEC should continue to be evaluated to determine how the constructs/components of the checklist could be integrated to make inferences about the degree to which the EPIC intervention was implemented as planned (Streiner & Norman, 2008).

Finally, other than one poster that was aimed at parents, KT strategies focused mostly on health care professionals. Including parents in the process of sucrose implementation could have been enhanced through education and provision of information and materials regarding sucrose use aimed at parents, as parent involvement is an important aspect of family centred care (Gooding, et al., 2011). Parents have a key role, and desire to be involved in the management of their infants’ pain (Pillai Riddell & Chambers, 2007). For example, parents could advocate for their infant to receive sucrose if they were more aware of the benefits of sucrose for procedural pain. Two prospective observational studies on pain management in NICUs in France (Carbajal et al., 2008), and Canada (Johnston, Barrington, et al., 2011) reported on the importance of parental presence. Carbajal and colleagues (2008) found that parental presence was associated with improved use of preprocedural analgesia. Similarly, Johnston, Barrington et al. (2011) reported that parental presence predicted the use of both nonpharmacologic interventions and administration of sweet solutions (i.e., sucrose and glucose) for tissue damaging procedures. The
authors speculated that potential reasons for this finding could be that parental presence might have motivated health care professionals to pay more attention to their infants’ care. Another possibility is that parents might have requested pain management for their infant (Johnston, Barrington et al., 2011). These results highlight the importance of encouraging parents to participate in the management of their infants’ care, which could be accomplished by providing parent education and support regarding strategies to manage procedural pain (Johnston, Barrington et al., 2011). Future research on the EPIC intervention implementation should consider including and evaluating the effect of KT strategies aimed at parents and caregivers.

In Study 3, the feasibility and clinical utility of the PEC was studied with research nurses from the TROPIC study (Stevens et al., 2008). In the future, it would be important to assess how the RPC members themselves or staff who implement the EPIC intervention would rate the feasibility and clinical utility of using the PEC. Finally, further prospective research on evaluating the feasibility and clinical utility of the PEC in different clinical settings is required.

**Implications for Practice and Policy**

The PEC could provide useful information for clinical educators or managers who are responsible for introducing and evaluating clinical quality improvement initiatives such as changes in practice guidelines, policies, and procedures. As part of a continuous quality improvement process, the PEC could be used to monitor and evaluate the delivery of any practice change initiatives using the same EPIC Phases and KT strategies to ensure implementation fidelity. For example, if a new or revised practice guideline or policy were introduced into practice setting, individuals in leadership positions would require training on how to implement the guideline, or could include other health care professionals on how to use the guideline. The PEC could be used to monitor the number and type of health care
professionals who have been trained and evaluate the degree of usefulness of the training received. The KT strategies used to facilitate guideline use along with the dose, reach, and duration of the strategies could be documented using the PEC. Modifications made to the KT strategies would be based on sources of evidence collected from local data in the form of chart audits, health care professionals and parents on the unit on the usefulness of the strategies implemented along with any facilitators and barriers to the delivery of the strategies.

RPC members and health care professionals in Study 2 recognized and articulated within the focus groups that there were three key practice assumptions necessary to improve sucrose administration practices. These practice assumptions included leadership, education, and a timely audit and feedback process that would be acceptable to the staff within the units. Identifying appropriate leaders to facilitate and promote the practice change was an important first step to changing health care professionals’ sucrose administration practices. These leaders would be aware of the different sources/types of evidence that could be used as a foundation to support changes in practice. Additional leaders such as unit practice champions who demonstrate a vested interest and expertise in the practice change could assist in facilitating the change process (Milner, Estabrooks, & Humphrey, 2005). Personal rewards for these individuals could include increased knowledge and potential opportunities for professional advancement on the clinical ladder. Additionally, their involvement in these activities includes contributing to the knowledge base and expertise of the unit nursing staff, and overall for the profession, and advancing evidence based patient care. Direct compensation and provision of protected time are examples of professional rewards for their participation as unit champions. Strategies to facilitate behavioural changes include the development and education about changes in practice standards. For example, health care professionals in Study 2 revealed their uncertainty regarding
the administration of sucrose, thus highlighting the importance of first developing and providing appropriate education for those individuals who would be involved in implementing the practice change. Following educational outreach sessions, the use of constant reminders such as strategically placed educational posters, reminder stickers, and unit based champions were found to be effective KT strategies. These strategies promoted practice changes, and should be considered when implementing new policies and procedures. These KT activities could be integrated as competency requirements within the health care professionals’ performance review process in order to ensure the sustainability of these activities. Finally, the use of audit and feedback KT strategies should be integrated during the practice change process. Providing unit staff with timely feedback reinforces and raises health care professionals’ awareness of the practice change. Promoting buy-in of the practice change is supported through ongoing demonstration of its effectiveness using audit and feedback. Creating a momentum for sustainability of the practice change must be achieved by obtaining financial and human resources such as dedicated personnel (Davies et al., 2008). Similar processes and strategies to facilitate behavioural change have been used to disseminate other types of practice guidelines in clinical settings (Duff, Loftus-Hills, & Morrell, 2000).

Measurement of intervention fidelity is required in the evaluation of any change process. The PEC could be used to evaluate the success of guideline implementation. For example, the Registered Nurses Association of Ontario (RNAO) developed the Nursing Best Practice Guidelines Program (http://www.rnao.org/Page.asp?PageID=861&SiteNodeID=133) but did not include a detailed process evaluation measure to evaluate intervention fidelity. The PEC could be applied to assess the process of implementing these best practice guidelines. The RPC members would be replaced with practice leaders, and the content of the training would need to
be related to the specific practice guideline. Applying the PEC in activities related to promoting guideline use in a different context would strengthen the utility of the PEC.

**Implications for Knowledge Translation**

**Integrated KT.** An integrated KT approach to improving or changing practice involves ongoing, active collaboration between the researchers and the users of research during the research process (Graham & Tetroe, 2007). The PEC was useful in collecting information about the fidelity of the EPIC intervention implementation, as well as RPC member activities that reflected an integrated KT approach to changing practice. From the onset of Study 2, RPC members worked collaboratively within their group and with the researcher to identify the pain practice change, design KT strategies, evaluate the usefulness of the KT strategies on the enactment of sucrose administration practices, and disseminate feedback regarding the progress of the practice change. During Study 2, RPC members were committed to changing practice, included other team members to participate in the change process, and had gained support from the unit leadership team to promote and improve sucrose practices in the NICU. All of these factors have contributed to effective integrated KT (Gagnon, 2009). Future studies need to consider using integrated KT approach such as the EPIC intervention process. One of the advantages of this approach was that RPC members identified a pain practice aim that was relevant to their unit (Graham & Tetroe, 2007). Furthermore, the RPC members’ involvement in all steps of the EPIC intervention kept them engaged throughout the study.

**End of study KT.** End of study KT refers to appropriate methods used to disseminate the results of knowledge gained from research studies (CIHR, 2010; Graham & Tetroe, 2007).

**KT goal.** The end of KT goal for this study is to disseminate key findings regarding the fidelity of implementing a complex KT intervention, EPIC.
**Audience.** Key stakeholders would include health care professionals/clinicians, educators, researchers, quality improvement health care specialists working in the area of pediatrics and pain, decision makers within the organization, and professional health care organizations who are interested in evaluating the process of translating pain evidence such as guidelines into practice. Professional organizations or regulating bodies such as the Registered Nurses Association of Ontario (RNAO), and the Canadian Neonatal Network (CNN) are also audiences that will be targeted. The RNAO has developed Nursing Best Practice Guidelines, and the CNN has developed strategies to improve the use of policies and procedures in NICUs across Canada using the Evidence-based Practice for Improving Quality (EPIQ) intervention (Lee et al., 2009).

**KT strategies.** Study results will be presented locally at interdisciplinary hospital pain and research rounds, and nursing lunch and learn sessions. Information will also be shared more broadly at local and national/international conferences on pain, such as the Canadian Pain Society annual meetings, and the International Association for the Study of Pain (IASP); knowledge translation such as the Knowledge Utilization (KU) conference, and quality improvement initiatives. Other potential interactive KT forums could include presentations or main messages on pediatric pain websites, via the use of interactive webinars format or at a café scientifique where the focus is to disseminate results broadly to health care professionals and members of the community including, parents, and families (http://www.cihr-irsc.gc.ca/e/34951.html).

A one-page evidence summary of research results, three-page executive summary, 25-page detailed report, and a plain language brochure will be disseminated to key stakeholders including health care professionals, unit and organizational leaders. Finally, a toolkit will be
developed for health care professionals and researchers interested in monitoring the fidelity of implementing interventions. The toolkit will also include effective KT strategies that can be adapted for use in different clinical settings.

**Conclusions**

Changing health care professional pain practices is a complex process involving the use of different sources of information/evidence, and methods to facilitate these changes within practice contexts. Monitoring implementation fidelity is crucial in complex interventions as there are many factors that can influence the translation of evidence into practice. The PEC was developed and tested in a clinical setting to monitor the fidelity of the EPIC intervention implementation. Evidence obtained from systematic reviews, local practice audits, and clinical expertise emphasized the importance of managing procedural pain in infants with sucrose. As the EPIC intervention was primarily focused on the PARiHS element of facilitation, monitoring intervention fidelity strengthened the facilitation process. The implementation of the EPIC intervention included a number of complex and detailed steps, and the PEC was successful in monitoring whether these steps were implemented as planned. Data collected using the PEC therefore, provided detailed information that supported the high degree intervention fidelity of the EPIC intervention. Additionally, preliminary support exists for the feasibility and clinical utility of the PEC. The PEC was useful in assisting RPC members to identify evidence based KT strategies to improve sucrose administration practices during the EPIC intervention implementation. Future research will evaluate minor revisions made to the PEC, which includes additional items related to components of fidelity. The PEC is currently being applied to a variety of pediatric pain related practice changes (Stevens et al., 2008) using the EPIC intervention process. Additional research is required to evaluate the use of the PEC with a
variety of health care professional users in different clinical settings. Finally, as variability in sucrose practices was evident during the two Cycles of change, the PEC could be used to monitor whether pain practices are sustained over time in future applications of the EPIC intervention.
References


Baker, R., Camosso-Stefinovic, J., Gillies, C., Shaw, E. J., Cheater, F., Flottorp, S., & Robertson, N. (2010). Tailored interventions to overcome identified barriers to change: effects on


Haynes, R. B. (2002). What kind of evidence is it that Evidence-Based Medicine advocates want health care providers and consumers to pay attention to? *BMC Health Services Research, 2*(1), 1-7.


Appendices
### Appendix A: Review of Implementation Strategies of Pediatric Pain Guidelines

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Conceptual Framework/ Theory</th>
<th>Outcomes/Results/Comments</th>
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<tbody>
<tr>
<td>Duncan &amp; Otto (1995)</td>
<td>Descriptive Pilot study</td>
<td>Nurses and physicians in a pediatric population</td>
<td>Purpose: To implement Agency for Health Care Policy and Research (AHCPR) clinical pathway guidelines for acute pain assessment and management in children Multidisciplinary task force developed guidelines for acute pain management Nurses-informal self directed learning including readings from clinical practice guidelines quick reference guide for pain management, journal articles, videotape on guidelines, and formal 3 hour continuing education program Physicians-formal 7x 1 hour CME, educational bulletins from the clinical practice guidelines quick reference guide for clinicians; drug reference guides by pharmacist</td>
<td>Not specified</td>
<td>Patients on the pathway had consistent pain assessment, plan of management, shorter time of onset of pain to pain relief compared to not on pathway Experienced physician resistance to change No statistical analysis reported Type of facilitation: Mostly task focused; some holistic focus by soliciting input from nurses on current pain management practices</td>
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<td>Ellis et al. (2007)</td>
<td>Pretest-posttest</td>
<td>366 nurses, 8 physicians</td>
<td>Purpose: To evaluate a comprehensive program to improve pediatric pain practices in hospitalized children Multidisciplinary team developed 4 hour pain education workshop including instruction on new pain document measure; unit based champions as coaches to promote pain practices; unit advocates supported the change Education of staff included rounds, email, newsletters, information pegboards, feedback to and from nurses</td>
<td>Ottawa Model of Research Use (Logan &amp; Graham, 1998)</td>
<td>Significant improvement in nurses’ perceptions about the adequacy of their pain assessment (p&lt;.004), and management (p&lt;.017) practices No significant changes in nurses’ knowledge and beliefs about pain assessment and management Significant improvement in the use of pain measures (p=.005) and pain assessment narratives (p&lt;.01) Type of facilitation: Task and holistic focus; champions and advocate support the change</td>
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<td>Friedrichs, Young, Gallagher, Keller, &amp; Kimura (1995)</td>
<td>Descriptive post - intervention using 3 x PDSA cycles over a 2 yr period</td>
<td>Medical and nursing staff in 1 Neonatal Intensive Care Unit (NICU)</td>
<td>Purpose: To improve pain assessment and management in the NICU. Pain task force developed intervention with input from health care team 2 hour educational program Video on pain assessment and management guidelines in patient charts and weekly pain rounds</td>
<td>Not specified</td>
<td>Improvement of pain assessment and management documentation Type of facilitation: Task and holistic focused; soliciting practitioner feedback about pain management practices in the NICU</td>
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<td>Furdon, Eastman, Benjamin, &amp; Horgan (1998)</td>
<td>Descriptive Pre-post intervention</td>
<td>Nursing, medical documentation for 14 infants before and 15 infants after implementation of guidelines in the NICU</td>
<td>Purpose: To implement a pain assessment (using the Neonatal Infant Pain Scale (NIPS) and management protocol for post operative infants Development of a standardized pain management protocol for neonates, infants and toddlers developed by nursing staff, neonatal fellow and pharmacist followed by education of nursing and medical staff</td>
<td>Not specified</td>
<td>1 year after implementation of pain protocol: Compliance with using the NIPS was 70% All infants received continuous opioid infusions for 24-48 hours after an initial loading dose More infants received analgesics over the first 3 days post operatively Reduced reports of side effects related to morphine Infants returned to their operative day weight on the second post operative day Reduction in time to extubation, Decreased in length of stay Type of facilitation: Task focused</td>
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<tr>
<td>Gallo (2003)</td>
<td>Descriptive post intervention</td>
<td>125 labour and delivery nurses</td>
<td>Purpose: Implementation of the Neonatal Infant Pain Scale (NIPS) in an NICU. Implementation of the Neonatal Infant Pain Scale (NIPS) as an algorithm Education in phases: (a) 30</td>
<td>Not specified</td>
<td>1 year audit revealed improved adherence to using NIPS (increase from initial 27% to 65% use)</td>
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<td>Geyer et al. (2002)</td>
<td>Descriptive post intervention</td>
<td>29 newborn records reviewed for use of pharmacologic and non-pharmacologic pain interventions by nurses and physicians</td>
<td>minute presentation and video for advanced practice nurse core group (resource persons), and (b) over 30 day period, staff nurses received education from the advanced practiced nurse core group using in-services, bedside teaching, video</td>
<td>Not specified</td>
<td>6 months after protocol implementation, 29/29 100% infants received dorsal penile block, swaddled, offered sucrose with pacifier At least 1 dose of acetaminophen given to 84% of the infants Type of facilitation: Task focused</td>
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Type of facilitation: Task focused
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<tr>
<td>Howell, Foster, Hester, Vojir, &amp; Miller (1996)</td>
<td>Descriptive posttest design and process evaluation</td>
<td>All nursing personnel (N=39; 16 RN, 9 LPN, 6 nursing assistants)</td>
<td>Purpose: To evaluate the research utilization process for a pediatric pain assessment and management strategy 6 month pain management educational sessions: Knowledge: 5 x 30 minute formal pain assessment and management classes for all staff nurses and included ongoing education using posters, distraction kit, case-study handouts, literature, teaching video role modeling, consulting, reinforcement using Pain Experience History (PEH), poker chip tool (PCT), Pain Observation Scale (POS), Pain Flow Sheet (PFS) Unit based nurse as liaison and nurse educator available to support staff</td>
<td>Roger’s (1995) innovation-decision process model using knowledge, persuasion, decision, implementation, confirmation</td>
<td>Nurses reported increased knowledge and skills and understanding of pain Pain assessment and management aids rated as moderately helpful PEH had highest rating for assessment aids (M=3.3, SD =.7) Distraction materials (M=3.5, SD = 8) and analgesic medications (M=3.4, SD =.7) were highest rated pain aids Use of pain management forms increased (77%) Anecdotal results- staff continued to use the pain flow sheet, but staff RNs did not use tools as frequently as predicted</td>
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<td></td>
<td>Over 11 months 5 month follow-up</td>
<td>Core staff group assigned over 6 month period</td>
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<td>Type of facilitation: Task and holistic focused: focus group interview at end of intervention to determine how the research program changed practice</td>
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<td>Jordan-Marsh et al. (2004)</td>
<td>Descriptive pre-post intervention over 2 years</td>
<td>Interdisciplinary team of clinicians including nursing and hospital administrators 1 unit from university affiliated public hospital Nurses had access to and support from the director of nursing research as well as from a visiting nurse researcher/consultant whose expertise was in pediatric pain</td>
<td>Purpose: To improve acute pain assessment and management for hospitalized children Poker Chip Tool for pain assessment; morphine for acute postoperative pain Focus groups to determine health care professional needs regarding pain assessment and management Individual strategies at unit level: Extensive educational activities-clinical rounds, attitude survey, unit pharmacists as resident experts, self-guided education module, pain flow sheet, role modeling by clinical leaders System-based strategies: Grand rounds, newsletter, engagement of directors, unit-based QI and peer review Societal level: Conference presentations, publications. American Pain Society Quality Assurance Standards</td>
<td>Socioecologic approach to changing pain assessment Focused on the environmental and behavioural determinants of health and relationships with team members</td>
<td>Increase from baseline in pain intensity assessments (30% increase), and unit doses dispensed for acetaminophen with codeine (100% increase, p&lt;0.002) and morphine (455% increase, p = 0.0001) Significant reduction in distribution of meperidine (250% reduction, p = 0.0004) Changes x 2 years after the intervention. Type of facilitation: Task and holistic focused: Nurses actively participated in the research process such as participating on interdisciplinary pain rounds where intervention strategies were developed</td>
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<td>Joyce, Keck, &amp; Gerkensmeyer (1999)</td>
<td>Descriptive pre-post intervention</td>
<td>Post operative unit nurses pain documentation of 42 (20 pre and 22 post-operative) children for first 48 hrs after surgery (mean age 5.85-7.38 yrs)</td>
<td>Purpose: To evaluate the implementation of a pain flow sheet for pain assessment and management in post operative children Pain management flow sheet guideline for post operative pain management in children Formal in-service instruction followed by self-study education program</td>
<td>Roger’s Diffusion of Innovation Theory to explain why the intervention was not effective</td>
<td>Implementation of flow sheet did not significantly improve pain assessment and management in terms of pain related documentation, use of analgesics, parent satisfaction with pain management Increase in nonpharmacological interventions (p&lt;.05) Type of facilitation: Task focused</td>
</tr>
<tr>
<td>Johnston et al. (2007)</td>
<td>Cluster Randomized Trial</td>
<td>6 university affiliated pediatric hospitals in Canada 90 nurses</td>
<td>Purpose: To evaluate the effects of introducing one-to-one coaching to improve nursing pain assessment and management practices 30 minute coaching sessions every 2 weeks for a total of 10 coaching sessions with expert pain nurse based on audit and feedback of patients the nurse had cared for in previous 2 weeks Think aloud approach to increase knowledge and intention to change pain practices</td>
<td>Promoting Action on Research Implementation in Health Services (PARIHS) (Kitson et al., 1998)</td>
<td>Significant increase in nurses knowledge, documentation of pain assessments and use of non-pharmacologic pain interventions (11% improvement) in the coaching group (p&lt;.0001) No significant difference in administration of analgesics from baseline to post intervention in coaching group, but significant decrease in control group (p&lt;.001) Organizational context might have influenced pain assessment practices</td>
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<td>Knoblauch &amp; Wilson, (1999)</td>
<td>Descriptive pre-post intervention</td>
<td>Convenience sample of 52 nurses attending pain management in-service program. Documentation of pain management on 20 children pre and post-operatively for tonsillectomy and adenoidectomy.</td>
<td>Purpose: To examine the influence of a mandatory hospital in-service pediatric pain assessment and management program on analgesic administration in nurses. Pediatric pain measurement program on acute pain management in children. 3 hour in-service (lecture, media, reference guides, discussion) on pediatric pain management.</td>
<td>Not specified</td>
<td>as significant differences noted at baseline and post intervention. Type of facilitation: Task and holistic focused: coaching sessions allowed for reflection of pain practices. Increase length of time elapsed before the first dose of analgesic given after the pain management in-service than before the intervention (p&lt;.001). Type of facilitation: Task focused.</td>
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<td>Meunier-Sham &amp; Ryan (2003)</td>
<td>Descriptive post intervention</td>
<td>Nurses in the emergency department.</td>
<td>Purpose: To evaluate a nurse driven protocol for procedural PainFree management (i.e., pharmacologic and nonpharmacologic interventions). Multidisciplinary approach.</td>
<td>Not specified</td>
<td>Rate of documentation of pain free interventions increased by 70% (p&lt;.001) from initial rate of 16%. Type of facilitation: Mostly task focused with some...</td>
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<td>Pederson</td>
<td>Pre + post intervention + 2 month follow-up assessment</td>
<td>35 nurses from 5 units: critical care, bone marrow transplant, 3 acute care units</td>
<td>Purpose: To test effects of a 2 hour educational program about using 5 nonpharmacologic pain management strategies (breathing, relaxation, distraction, imagery, changing perception of painful stimuli) on nurses’ knowledge, comfort, attitude and use of these strategies Educational program presented by social worker, director of Child Family Life program, clinical nurse specialist, nursing instructor Group experience using imagery, video, group discussion, group practice in pairs using case studies</td>
<td>Theory of planned behaviour (Ajzen, 1991) used to measure nurses’ intention to guide children’s imagery</td>
<td>Significant increase in nurses knowledge, comfort, use of the 5 pain relieving techniques (p&lt;.05) No significant changes in nurses’ attitude to use guided imagery post-intervention Type of facilitation: Task and holistic focused: interventions included discussions on how to tailor strategies to participants</td>
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<td>Study</td>
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<td>Sheridan et al. (1997)</td>
<td>Descriptive post intervention</td>
<td>Nurses and physician documentation for 125 children with acute burns</td>
<td>Purpose: To develop and evaluate a guideline for pain assessment and anxiety management for acutely burned ventilated, non ventilated children; chronic acute care patients and reconstructive surgical patients Guideline distributed to all staff; pain and anxiety control addressed during daily rounds</td>
<td>Not specified</td>
<td>Guideline was effective across ages and patient care categories Type of facilitation: Task focused</td>
</tr>
<tr>
<td>Simons &amp; MacDonald (2006)</td>
<td>Action research: post intervention</td>
<td>23 nurses surveyed at 6 months and 20 nurses at 12 months post implementation</td>
<td>Purpose: To implement validated pediatric pain measures in a pediatric hospital Assessed use of 3 validated pain tools (FLACC, Wong-Baker Faces tool, VAS) Pain control Service ran monthly study days, and time spent teaching nurses on how to use the tools</td>
<td>Not specified</td>
<td>Nurses used pain measures on 40% of children at 12 months compared to 23% at 6 months Discrepancies between what nurses reported and actual use of tools Type of facilitation: Task and holistic focused: nurse input on pain assessment tools</td>
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| Thompson (2005)             | Descriptive post intervention         | Nurses from a 34 bed NICU evaluation over 1 month                            | Purpose: To implement sucrose protocol  
Unit in-services, presentations during staff meetings, pain management lectures to new graduate interns; labels placed on nursing kardex to identify eligible patients; reminders to staff who administered sucrose to continue to use sucrose | Not specified               | Fourfold increase in sucrose use.  
Type of facilitation: Task focused                                                      |
| Treadwell, Franck, & Vichinsky (2002) | Quasi-experimental pre-post-intervention | Pediatric hematology/oncology unit Convenience sample of 36 children and 68 staff at time 1 and 49 children and 82 staff at time 2 | Purpose: To evaluate implementation of pain assessment guideline  
Postoperative Pain scores using: CHEOPS (12-36 months); Faces scale (3-6 years); Faces or numerical rating scale (0-10 years); Word graphic scale (6-7 years); Adolescent Pediatric Pain Tool (8 years and older)  
Posters, staff education by nurse specialist and psychologist through didactic, discussion, role plays of challenges to pain assessment | Not specified               | Patients, family members, and staff reported improved pain assessment, increased staff responsiveness to patients’ pain, and satisfaction with pain assessment measures between time 1 and time 2  
Increased compliance with guidelines (p<.01)  
Type of facilitation: Task and holistic focused: health professionals asked how pain management could be improved on their units |
# Appendix B

## A Review of Multifaceted CQI Strategies in the NICU

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<th>Study</th>
<th>Focus</th>
<th>Potentially better practices</th>
<th>Results</th>
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<tr>
<td>Carteaux, et al. (2003)</td>
<td>Reducing incidence rates for intraventricular hemorrhage and brain injury</td>
<td>Collaborated with benchmark NICUs and evaluated the literature to develop potentially best practices. Information in the form of posters, graphs, flow charts, laminated cards, copies of guidelines and protocols, resource tools located on a website viewed as improving compliance with the change. Use of newsletters, pizza meetings, use of websites to ensure that staff remained updated with the progress of the practice change</td>
<td>Results of implementing the potentially best practices varied. Type of facilitation: Task and holistic focused. Highlighted the importance of communication and collaboration with other sites, identifying an effective leader to facilitate change, including a multidisciplinary team approach to implementing strategies, offering hands on group and one to one demonstrations and in-services on an ongoing basis.</td>
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<td>Kilbride, Powers et al. (2003)</td>
<td>Reducing nosocomial infections in the NICU</td>
<td>Developed strategies based on literature reviews and better performing benchmarked sites. Developed summary statements on potentially better practices in handwashing, nosocomial sepsis evaluation and central venous catheter management. Information disseminated to clinicians using regular communication including email, in-services, regular staff meetings, newsletters, pamphlets, posters, videos, audit and feedback, and open discussions.</td>
<td>Implementation of these strategies over a two year period led to reductions in the incidence of nosocomial infections (24.6% to 16.4%). Type of facilitation: Task and holistic focused. Collaborative approach to change involving many staff facilitated participation and commitment to change.</td>
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<td>Kuzma-O'Reilly, et al. (2003)</td>
<td>Improving nutrition practices in the NICU</td>
<td>Used core group consisting of a multidisciplinary team of health professionals. Identified 8 potentially better practices through the participation in benchmarking activities.</td>
<td>Participating NICUs showed improvements in nutritional support and reductions in length of stay.</td>
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<tr>
<td>Study</td>
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<td>Potentially better practices</td>
<td>Results</td>
</tr>
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<td>------------------------</td>
<td>--------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Burch et al.</td>
<td>Reducing chronic lung disease</td>
<td>Benchmarked sites and developed database to evaluate process and patient outcomes Implemented 9 potentially better practices 7 strategies used: 1) provision of clear information about the change (e.g., use of algorithm); 2) feedback to improve compliance with guidelines; 3) educational programs, posters, written instructions at bedside, meetings with individual nurses; 4) multidisciplinary collaboration and communication; 5) imitation of other sites’ techniques for change; 6) compromising on strategies; and 7) measuring process indicators and outcomes</td>
<td>No significant changes in both mortality rates and CLD rates Type of facilitation: Task and holistic focused Developed culture of accountability which facilitated implementation of practice changes Experienced, dedicated leader to ensure successful change process</td>
</tr>
<tr>
<td>Sharek et al.</td>
<td></td>
<td>literature and by benchmarking practices from centres of excellence</td>
<td>Type of facilitation: Task and holistic focused Process was effective using a multidisciplinary approach used with expertise of a neonatal nutritionist</td>
</tr>
<tr>
<td>Payne, LaCorte, Karna et al.</td>
<td>Reducing bronchopulmonary dysplasia (BPD)</td>
<td>Summaries developed for potentially better practices based on evidence and expert opinion. Use of resource kits, one-to-one discussions, group meetings, revision to standing orders to manage BPD, educational sessions, use of opinion leaders, performance feedback, celebration of successes</td>
<td>BPD reduced Significant reduction in ROP, IVH, supplemental oxygen at discharge Type of facilitation: Task and holistic focused Participants developed trust in one another and shared successes and failures in implementing changes in practice</td>
</tr>
</tbody>
</table>
## Appendix C

### Intervention Fidelity Measures

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>Measure</th>
<th>Psychometric Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive behavioural Intervention for Relapse Prevention</td>
<td>RPT-FS (Alvarez-Jimenez et al., 2008)</td>
<td>Reliability established</td>
</tr>
<tr>
<td>Assertive Community Treatment</td>
<td>Dartmouth Assertive Community Treatment Scale</td>
<td>Reliability, validity</td>
</tr>
<tr>
<td></td>
<td>(Bond &amp; Salyers, 2004; Winter &amp; Calsyn, 2000)</td>
<td>established</td>
</tr>
<tr>
<td>Integrated Dual Disorders Treatment</td>
<td>Integrated Dual Disorders Treatment Fidelity Scale</td>
<td>Reliability, validity</td>
</tr>
<tr>
<td></td>
<td>(Chandler, 2009; Wilson &amp; Crisanti, 2009)</td>
<td>established</td>
</tr>
<tr>
<td>Wrap Around Intervention for Children with Behavioural Health Needs</td>
<td>Wraparound Fidelity Index (Bruns, Burchard, Suter, 2004; Bruns, Suter, &amp; Leverenz-Brady, 2008)</td>
<td>Reliability, validity</td>
</tr>
<tr>
<td></td>
<td>Leverenz-Brady, &amp; Force,</td>
<td>established</td>
</tr>
<tr>
<td>Type of intervention</td>
<td>Measure</td>
<td>Psychometric Properties</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Schoolwide Positive Behavioral Interventions and Supports</td>
<td>IPI (Bradshaw, Debnam, Koth, &amp; Leaf, 2009)</td>
<td>Reliability, validity established</td>
</tr>
<tr>
<td>Individual Placement and Support</td>
<td>IPS Fidelity Scale (Bond et al., 2002; McGrew &amp; Griss, 2005)</td>
<td>Reliability, validity established</td>
</tr>
<tr>
<td>Supported Employment Services for People with Severe Mental Illness</td>
<td>QSEIS (Bond et al., 2002; McGrew &amp; Griss, 2005; Campbell et al., 2007)</td>
<td>Reliability, validity established</td>
</tr>
<tr>
<td>Case Management for Adolescent Substance Abuse</td>
<td>Case Management Quality Inventory (Noel, 2006)</td>
<td>Not specified</td>
</tr>
<tr>
<td>3CM for Depression Management</td>
<td>3CM Fidelity Measure (Oxman et al., 2006)</td>
<td>Validity established</td>
</tr>
<tr>
<td>Project Towards No Drug Abuse (TND)</td>
<td>Fidelity observation instrument/index (Rohrbach, Dent, Skara, Sun, &amp; Sussman, 2007)</td>
<td>Reliability established</td>
</tr>
<tr>
<td>Type of intervention</td>
<td>Measure</td>
<td>Psychometric Properties</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Illness Management Recovery Program</td>
<td>Illness Management and Recovery Fidelity Scale (McHugo et al., 2007; Salyers, Rollins, McGuire, &amp; Gearhart, 2009)</td>
<td>Reliability established</td>
</tr>
<tr>
<td>SPIRIT Psychoeducational Intervention</td>
<td>SPIRIT treatment fidelity assessment tool (Song, Happ &amp; Sandalowski, 2010)</td>
<td>Reliability established</td>
</tr>
<tr>
<td>Coronary Heart Failure Nurse Practitioner Case Management Program</td>
<td>FOI ratings (Keith, Hopp, Subramanian, Witalia, &amp; Lowery, 2010)</td>
<td>Validity established</td>
</tr>
</tbody>
</table>

*Note.* FOI = Fidelity of Implementation; IPI = Implementation Phases Inventory; IPS = Individual Placement and Support; QSEIS = The Quality of Supported Employment Implementation Scale; RPT-FS = Relapse Prevention Therapy Fidelity Scale; SPIRIT = Sharing the Patient’s Illness Representations to Increase Trust; 3CM = 3-Component Model.
Appendix D

Notice of Study for Health Care Professionals and Parents

TO: NICU STAFF

A Process Evaluation of the Evidence Based Practice, Identification and Change (EPIC) Intervention to Improve Neonatal Pain Practices

PURPOSE

The EPIC intervention consists of strategies used to increase the use of pain guidelines in clinical practice. The purpose of this study is to assess the process of the implementing the EPIC strategies and to see how these strategies influence pain practices in the NICU.

HOW WILL THE STUDY AFFECT YOU?

A Research Practice Council (RPC) made up of 3-4 staff will help health professionals implement pain guidelines in the NICU. The Research Nurse will be reviewing patient charts for information on how pain is assessed and managed in the NICU 3 times: Once before the EPIC intervention, once during the intervention to assess the practice change, and once after the EPIC intervention. At the end of the intervention, you may be asked to participate in a focus group about your experiences with the EPIC intervention. Participation in this study is voluntary.

WHEN WILL THE STUDY TAKE PLACE?

The Preparation Phase of this study is occurring in the NICU starting X and the implementation or change phase of the EPIC intervention will take place from X to X.

WHAT WILL THE STUDY ACCOMPLISH?

The study information will help us learn more about the best ways to change pain practices in the NICU by monitoring the process of implementing the EPIC intervention.

FOR MORE INFORMATION CONTACT:

Janet Yamada RN, MSc

(Phone number and email address)
TO: NICU PARENTS

A Process Evaluation of the Evidence Based Practice, Identification and Change (EPIC) Intervention to Improve Neonatal Pain Practices

PURPOSE

The purpose of this study is to look at how health professionals treat pain in babies in the NICU.

HOW WILL THE STUDY AFFECT YOU?

A small group of health professionals will be helping NICU staff to use different methods of treating pain. A research nurse will review charts over 1 to 2 days during (Date inserted) to see how pain in babies is treated. Names and personal information from infant charts are confidential and would be identified by a code number only. As a parent, you are free to ask the research nurse not to review your baby’s chart for this study. If you choose not to participate in this study you and your baby will continue to have quality care.

WHEN WILL THE STUDY TAKE PLACE?

The study will occur in the NICU during the months of X to X

WHAT WILL THE STUDY ACCOMPLISH?

Study information will help us learn more about the best ways to change pain practices in the NICU. If you are interested in our findings, please let Janet Yamada know and she will arrange to send you a summary of the results.
Dear Participant:

We are interested in evaluating the Evidence Based Practice Identification and Change (EPIC) intervention (Lee, et al., 2002), now referred to as Evidence Based Practice for Improving Quality (EPIQ), in terms of the process of implementing the components of the strategies used to change neonatal pain practices. This process evaluation of EPIC is part of the CIHR Team Grant in Children’s Pain (PI: Dr. Bonnie Stevens) and my PhD dissertation. The EPIC intervention, involves a complex process and the components of this intervention are not clearly articulated in the literature. Examining the EPIC process is important as there is variability in how groups have applied EPIC strategies into practice. Knowledge of the process of implementing the EPIC intervention will assist in its implementation and in measuring clinical outcomes. Currently, there are no process evaluation measures that have been used to evaluate the EPIC intervention strategies. To accomplish this task, we have created a process evaluation checklist (PEC) that will be used to examine the step-by-step activities required to execute pain practice strategies.

Since you are familiar with the EPIC intervention and the NICU environment/culture, you have been chosen to evaluate the PEC for its content. We are looking at establishing content validity for this measure. Content validity determines whether the items in a measure include appropriate information and content reflective of all of the domains comprising the concept. Our goal in developing this measure is to be able to provide some guidance and standardization of knowledge translation strategies on a broader basis in pediatric centres across Canada.

Please find attached the PEC for your review. The description of the EPIC Intervention (contains an outline of activities for Phase 1 and 2 of the EPIC Intervention) and scoring instructions are described in the attached Appendix.

Thank you for taking the time to complete this evaluation for us. As this process evaluation measure is part of my PhD thesis, please note that this measure is copyrighted and therefore confidential and not available for distribution beyond this study. Once we have tested this measure in a single NICU, we hope to use the PEC in other participating EPIC sites and will be pleased to share the final version with you.

Sincerely,

Janet Yamada RN, MSc (PhD Student)
Trainee, CIHR Team in Children’s Pain

The Process Evaluation Checklist (PEC) is based on the two Phases of the EPIC intervention: Phase 1- Preparation Phase, and Phase 2- Identification of Change Phase of EPIC. Items in this checklist are drawn from the steps in the EPIC process (please refer to Appendix). In Phase 2, knowledge translation strategies that will be used to deliver pain practice changes include
reminders, educational interventions and audit and feedback.

We are asking you to assist us by providing your expert opinions about the importance/relevance of items in the PEC in reflecting all phases and steps of EPIC. The information that you provide will help us to ensure that variables/items will accurately and comprehensively measure key information about the delivery of the components of the EPIC intervention.

**Potential Inconvenience:**
This exercise should take you no longer than 30-45 minutes.

**Confidentiality:**
All information collected during this evaluation will be kept confidential by using a code number on all information. The individual who emailed you this evaluation is not familiar with this study and will not link your identity with any responses. Any external reporting (such as publications) will keep personal information confidential and will only be reported in aggregate form.

**Participation:**
Completing and returning this evaluation is voluntary and implies your consent to participate.

**Sponsorship:**
The sponsor of this research is the Canadian Institutes of Health Research (CIHR).

The Research Ethics Board has approved this evaluation.

**PLEASE SAVE YOUR COMPLETED EVALUATION AND RETURN IT BY EMAIL BY X Date TO: (neutral individual)**

If you have any questions about this evaluation, please contact:
Janet Yamada RN, MSc or at (phone number)

Thank you for taking the time to assist us in this very important project.
APPENDIX

Description of the EPIC Intervention
A description of the EPIC intervention is given below. A Research Practice Council (RPC), which you know as the “EPIC Team”, are the group of health professionals who will use strategies such as reminders, to change health professional pain practices. Each of the items in the checklist were developed using the activities related to Phase 1 and 2 activities of the EPIC intervention.

Phase 1 - Preparation Phase of the EPIC Intervention (3 months)

<table>
<thead>
<tr>
<th>Phase 1: Activities</th>
<th>Description of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of baseline data</td>
<td>Pain assessment and management data and unit profile information will be collected to determine current pain practices in the NICU.</td>
</tr>
<tr>
<td>Establishing the Research Practice Council (RPC)</td>
<td>The RPC will include 3-4 members (e.g. physician, nurse) and will lead the implementation of the EPIC intervention.</td>
</tr>
<tr>
<td>Training</td>
<td>The RPC will attend a 2-3 hour training session on critical appraisal of the pain assessment and management literature (e.g., systematic reviews on pain practices), quality improvement methods, effective knowledge translation strategies.</td>
</tr>
<tr>
<td>Identifying potentially useful practices</td>
<td>A list of potentially useful practices (e.g. sucrose) and knowledge translation strategies (e.g. reminders) will be developed by the RPC to address the identified pain practice change.</td>
</tr>
<tr>
<td>Reviewing existing evidence</td>
<td>The RPC will review published evidence on selected pain management practices from the literature including completed critical appraisals or reviews. RCT’s (not included in the reviews) may also be reviewed.</td>
</tr>
<tr>
<td>Identifying critical practice changes</td>
<td>From the literature and baseline pain practice data, the RPC will compare their list of potentially useful pain practice changes with current NICU pain guidelines and identify a practice change.</td>
</tr>
</tbody>
</table>

Phase 2 - Identification and Change Phase of EPIC (8 months)

<table>
<thead>
<tr>
<th>Phase 2: Activities</th>
<th>Description of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning a test of practice change.</td>
<td>Once the RPC has identified a pain practice change, they will develop a plan to test the change. This plan will include communication and training sessions about the practice change using selected knowledge translation strategies. Training will be provided by the Research Nurse to familiarize unit staff with practice changes, protocols, or guidelines.</td>
</tr>
<tr>
<td>Implementing the change.</td>
<td>The specific pain practice change will be implemented by the RPC using rapid cycles.</td>
</tr>
</tbody>
</table>
| Evaluating the | Monitoring of the practice change will occur through two 3 month rapid }
change. cycles. Results from each of the rapid cycles allow for feedback to the staff, reinforce the change and allow for further tailoring of intervention strategies.

**Instructions**
For each Phase (i.e. Phase 1 and 2) of EPIC, please rate each of the items according to how important/relevant its content is in representing the steps in the EPIC intervention.

**Rating 1-4**
In each category, rate each item in terms of:
- How **IMPORTANT** the item content is in the EPIC process, on a scale from 1 to 4 where:
  - 1 means that the item is not important
  - 2 means that the item is somewhat important
  - 3 means that the item is quite important
  - 4 means that the item is very important

Please consider as you rate the items: Does the checklist measure:
1) Fidelity- The extent to which EPIC intervention strategies were delivered as planned.
2) Feasibility- How easy was it to implement the EPIC intervention strategies.
3) Usefulness- How helpful were the KT strategies in changing practices (e.g. pain practices).

When providing your ratings, please consider whether each item/variable is clear and uses appropriate language. Also, please note whether the items/variables are listed in a logical order. Please include your comments in the Comments section provided.
### Phase 1: Preparation Phase Data

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>IMPORTANCE RATING 1-4</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Identify Research Practice Council (RPC)</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>What is the professional status of the RPC team members?</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>Describe:</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>a) the professional backgrounds of team members (by checking all that apply below)</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>b) the number of participants (by writing the number beside each profession listed)</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>c) how they were chosen (e.g., appointed, volunteered) by responding in the space provided below.</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>Professional background</td>
<td># Participants</td>
<td>How Chosen</td>
</tr>
<tr>
<td>Physicians- Staff</td>
<td></td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Physicians-Fellow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses – Staff RN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses – Neonatal Nurse Practitioner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses – Clinical Nurse Specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses- Educator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses- Clinical Leader</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses – Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupational Therapist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiotherapist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Therapist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Improvement Specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. Training for RPC on the EPIC Process

How useful was the training in understanding each of the following: Write the number corresponding to your response, using a 5 point scale where 1= not at all useful, and 5= extremely useful.

<table>
<thead>
<tr>
<th>1. Review of baseline data.</th>
<th>1 2 3 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Review of the literature on pain assessment in infants.</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>VARIABLE</td>
<td>IMPORTANCE RATING 1-4</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>3. Review of the literature on pharmacologic interventions to improve neonatal pain practices.</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>4. Review of the literature on nonpharmacologic interventions to improve neonatal pain practices.</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>5. Quality improvement processes including the use of rapid cycle methodology.</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>6. Review of effective knowledge translation strategies to implement pain practice change(s) (e.g. educational interventions, audit and feedback, and reminders).</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Other comments?</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>What facilitated attendance at the training (e.g. supported by manager).</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>What hindered attendance at the training (e.g. no time off).</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td><strong>3. Identify potentially useful practice changes based on RPC consensus.</strong></td>
<td></td>
</tr>
<tr>
<td>Over the duration of the study, what were the potentially useful practice changes identified for your unit? (please specify-e.g., to increase use of sucrose in NICU).</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>How were these practice changes chosen (choose all that apply)?</td>
<td></td>
</tr>
<tr>
<td>Systematic review of the literature.</td>
<td></td>
</tr>
<tr>
<td>RPC expert opinion.</td>
<td></td>
</tr>
<tr>
<td>Baseline data from Canadian Pediatric Pain Research (CPPR) database.</td>
<td></td>
</tr>
<tr>
<td>Other (specify)</td>
<td></td>
</tr>
<tr>
<td>How effective do you think these practice changes were in improving pain practices?</td>
<td></td>
</tr>
<tr>
<td>Write specific practice change and the number corresponding to your perception of its effectiveness, using a 5 point scale where 1= not at all effective, and 5= extremely effective.</td>
<td></td>
</tr>
<tr>
<td>Practice change(specify)_________________________ Score ______</td>
<td></td>
</tr>
</tbody>
</table>
Phase 2: Selected Practice Change Strategies: Reminders (to be completed by RPC member for each new strategy implemented)

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>IMPORTANCE RATING 1-4</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy: Reminders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reminders: Any intervention, manual or computerized program, that prompts the health care provider to perform a clinical action. For example, concurrent reports are targeted at providers at the time of an encounter to remind them of desired actions for individual patients.</td>
<td>1 2 3 4</td>
<td></td>
</tr>
<tr>
<td>Target Audience:</td>
<td># Targeted</td>
<td></td>
</tr>
<tr>
<td>MD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff RN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APN (Advanced Practice Nurse)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educator</td>
<td></td>
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<tr>
<td>OT</td>
<td></td>
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<tr>
<td>PT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Components:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check the type and format of material used (electronic or hardcopy). For the location, list where the material was situated and the date when the information was distributed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of material</td>
<td>Electronic</td>
<td>Hardcopy</td>
</tr>
<tr>
<td>Poster</td>
<td>√</td>
<td>e.g. hallway</td>
</tr>
<tr>
<td>Memo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handout</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify (e.g. in-person reminders)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Evaluation of Strategies Used**

On a scale of 1-5 where 1 is not useful and 5 is extremely useful:

a) If you used any of the strategies below, indicate how useful you think the strategy was to enhance practice change (please circle the appropriate number)

b) What facilitated or hindered the delivery of the reminders? Please write your response in the space provided.

<table>
<thead>
<tr>
<th>List of Reminders</th>
<th>Not useful</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1a)</strong> Poster electronic</td>
<td>Facilitated</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>1b)</strong> Facilitated</td>
<td>Hindereden</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>2a)</strong> Poster hard copy</td>
<td>Facilitated</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>2b)</strong> Facilitated</td>
<td>Hindereden</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>3a)</strong> Memo electronic</td>
<td>Facilitated</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>3b)</strong> Facilitated</td>
<td>Hindereden</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>4a)</strong> Memo hard copy</td>
<td>Facilitated</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>4b)</strong> Facilitated</td>
<td>Hindereden</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td><strong>5a)</strong> Handout electronic</td>
<td>Facilitated</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<tr>
<td><strong>5b)</strong> Facilitated</td>
<td>Hindereden</td>
<td>1</td>
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</tbody>
</table>
Appendix F

Process Evaluation Checklist (PEC)


Phase 1 of EPIC Intervention: Preparation Phase Data

Date: __________ (dd/mmm/yyyy)

Study Site: ______________ Study Group: ______________ RCP member code: ____________

To be completed by all Facilitators (RPC committee members)

<table>
<thead>
<tr>
<th>EPIC Steps</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Identify Research Practice Council (RPC)</td>
<td>Professional background</td>
</tr>
<tr>
<td></td>
<td>□ Physicians- Staff</td>
</tr>
<tr>
<td></td>
<td>□ Physicians- Fellow</td>
</tr>
<tr>
<td></td>
<td>□ Nurses – Staff RN</td>
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<tr>
<td></td>
<td>□ Nurses – NNP/NP</td>
</tr>
<tr>
<td></td>
<td>□ Nurses – CNS</td>
</tr>
<tr>
<td></td>
<td>□ Nurses- Educator</td>
</tr>
<tr>
<td></td>
<td>□ Nurses- Clinical Leader</td>
</tr>
<tr>
<td></td>
<td>□ Nurses – Manager</td>
</tr>
<tr>
<td></td>
<td>□ Occupational Therapist</td>
</tr>
<tr>
<td></td>
<td>□ Pharmacist</td>
</tr>
<tr>
<td></td>
<td>□ Physical therapist</td>
</tr>
<tr>
<td></td>
<td>□ Psychologist</td>
</tr>
</tbody>
</table>

# of participants

□

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CIHR Team in Children’s Pain
2. Training for RPC on EPIC process

How useful was the training in understanding each of the following: Write the number corresponding to your response, using a 5 point scale where 1= not at all useful, and 5= extremely useful.

1. Review of baseline data. _____
2. Review of the literature on pain assessment _____
3. Review of the literature on pharmacologic interventions to improve pain practices _____
4. Review of the literature on nonpharmacologic interventions to improve pain practices _____
5. Quality improvement processes including the use of rapid cycle methodology. _____
6. Review of effective knowledge translation strategies to implement pain practice change(s) (e.g., educational interventions, audit and feedback, and reminders). _____

What facilitated attendance at the training (e.g. supported by manager) ____________________________
What hindered attendance at the training (e.g. no time off) ________________________________

3. Identify potentially useful practice changes based on RPC consensus

Over the duration of the study, what were the potentially useful practice changes identified for your unit? (please specify-e.g., to increase use of sucrose in NICU)

1. ____________________________________________
2. ____________________________________________
3. ____________________________________________
4. ____________________________________________
5. ____________________________________________

How were these practice changes chosen (choose all that apply)?
□ Systematic review of the literature
□ RPC expert opinion
□ Baseline data from Canadian Pediatric Pain Research (CPPR) database
□ Other (specify)___________________________________

How effective do you think these practice changes were in improving pain practices? Write specific practice change and the number corresponding to your perception of its effectiveness, using a 5 point scale where 1= not at all effective, and 5= extremely effective.

Practice change(specify)_________________ Score ______
Practice change (specify)_________________ Score ______
Practice change(specify)_________________ Score ______
Phase 2 of EPIC Intervention: Selected Practice Change Strategy: **Reminders**

**Study Site:** __________  **Study Group:** __________  **RCP member code:** ____________  **Rapid Cycle #** __________

**Date** __________ (dd/mmm/yyyy)

Pain Practice Selected for Change (e.g. sucrose for procedural pain) _______________________________________________________

**Definition**
*Reminders: Any intervention, manual or computerized program, that prompts the health care provider to perform a clinical action. For example, concurrent reports are targeted at providers at the time of an encounter to remind them of desired actions for individual patients (EPOC, 2002).*

**Audience:** □ MD  □ Staff RN  □ APN  □ Educator  □ OT  □ PT  □ RT  □ Pharm  □ RD

**#Targeted** ____________ ____________ ____________ ____________ ____________ ____________ ____________ ____________

**Intervention Components:**
Check the type and format of material used (electronic or hardcopy). For the location, list where the material was situated and the date when the information was distributed.

<table>
<thead>
<tr>
<th>Type of material</th>
<th>Electronic</th>
<th>Hardcopy</th>
<th>Location</th>
<th>When (Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poster</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handout</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify (e.g., in person reminders)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Evaluation of Strategies Used

On a scale of 1-5 where 1 is not useful and 5 is extremely useful:
  a) If you used any of the strategies below, Indicate how useful you think the strategy was to enhance practice change (please circle the appropriate number)
  b) What facilitated or hindered the delivery of the reminders? Please write your response in the space provided.

<table>
<thead>
<tr>
<th>List of Strategies</th>
<th>Not Useful</th>
<th>Extremely Useful</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a) Poster electronic</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>1b) Facilitated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hindered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a) Poster hard copy</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>2b) Facilitated</td>
<td></td>
<td></td>
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<tr>
<td>Hindered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a) Memo electronic</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>3b) Facilitated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hindered</td>
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<tr>
<td>4a) Memo hard copy</td>
<td>1</td>
<td>2</td>
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<tr>
<td>4b) Facilitated</td>
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<tr>
<td>Hindered</td>
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</tr>
<tr>
<td>5a) Handout electronic</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5b) Facilitated</td>
<td></td>
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<tr>
<td>Hindered</td>
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<tr>
<td>6a) Handout hard copy</td>
<td>1</td>
<td>2</td>
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<td>6b) Facilitated</td>
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<tr>
<td>Hindered</td>
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<tr>
<td>7a) Other</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>7b) Facilitated</td>
<td></td>
<td></td>
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<tr>
<td>Hindered</td>
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</tbody>
</table>
Appendix G

CIHR Team in Children’s Pain Canadian Pediatric Pain Research Database

Components:

1) Child socio-demographic data collection form (e.g., gender, diagnosis)

2) Unit profile form (e.g., unit staff information)

3) Child painful procedure data collection form

Were the following painful procedures used within the past 24 hours? (Indicate yes or no, the number of times used and whether an intervention was used for all procedures).

<table>
<thead>
<tr>
<th>Example</th>
<th>Painful procedure used?</th>
<th>Intervention used with this procedure?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capillary sampling</td>
<td>Yes  No</td>
<td>Times Yes No  Pharm Phys Psych</td>
</tr>
</tbody>
</table>

4) Child pain assessment profile: Were the following pain assessment tools used within the past 24 hours? (If yes, please indicate the number of times this pain assessment tool was used over the past 24 hour period).

<table>
<thead>
<tr>
<th>Were any pain assessment tools used over the past 24 hours?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

5) Child pharmacological interventions profile: Record each medication this patient received in the past 24 hours with the respective dosing information.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Total Doses Received</th>
<th>Solution Amount (mL)</th>
<th>Infusion Rate (mL/hr)</th>
<th>Infusion Duration (hh:mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

6) Child physical interventions profile: Were any physical interventions performed over the past 24 hours? (If yes, please indicate the number of times this physical intervention was used over the past 24 hour period).
7) Child psychological interventions profile: Were any psychological interventions performed over the past 24 hours? (If yes, please indicate number of times this psychological intervention was used over the past 24 hour period).

<table>
<thead>
<tr>
<th>Example</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were any psychological interventions performed over the past 24 hours?</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Example</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music Therapy, Auditory Stimulation</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
Appendix H

Rapid Cycle Data Collection Form for Giving and Documenting Sucrose in first 24 hours of Admission

Rapid Cycle # _______________________
Unit Code: _______________________
Date: dd/mmm/yyyy __

Chart Abstraction Form

<table>
<thead>
<tr>
<th>Pt ID</th>
<th>Date (dd/mmm/yyyy)</th>
<th>Admission Date (dd/mmm/yyyy)</th>
<th>Sucrose order in chart on admission (Y/N)</th>
<th>Sucrose order in chart in first 24 hrs by F/R/NP (Y/N)</th>
<th>If not in chart in first 24 hrs, then what date was it first ordered</th>
<th>Documentation of # times sucrose was documented on the MAR In first 24hrs (Y/N)</th>
<th>Reminder Sticker on the MAR (Y/N)</th>
<th>Reminder Sticker on admission order sheet (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
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Appendix I

Unit Activity Log

Study Site: Study Group:

To be completed by the Research Nurse.

This Log will document knowledge translation and/or pain initiatives being employed by the unit and/or hospital throughout the study period. Please note when the initiative was introduced, who was responsible for implementing the initiative, what exactly the initiative entailed, and how the initiative progressed (e.g., compliance by staff, effectiveness of initiative, facilitators and barriers etc.).

<table>
<thead>
<tr>
<th>Date Initiative Implemented</th>
<th>Staff Involved in Implementation</th>
<th>Brief Description of Initiative</th>
<th>Comments on Implementation of Initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Appendix J

RPC and Health Care Professional Interview Guides

Introduction:

Thank you for taking the time to participate in this group session. The purpose of this session is to gather a better understanding of your experience with the EPIC intervention process.

What we would like to do in this session is get feedback from you as to what you found helpful and not helpful about the EPIC intervention. Also we like to get your ideas on what you think helped facilitate or hindered the EPIC intervention, and any suggestions you have for improvement.

The focus session will last approximately 60 minutes

The focus group session will be audio-taped. The audio-files and transcripts from the focus groups will be stored in a secure locked location. Only members of the research team will have access to the data.

It is your choice to take part in the study. You can stop or leave the room at any time. You can refuse to answer questions or discuss any subject in the focus group if you do not want to. Your performance evaluation will not be affected in any way by whether you take part in the focus group.

We ask that you review the research study consent (that has been handed to you at the beginning) and if you agree to participate, please sign the consent form. There are two separate places to sign – one for agreeing to participate in the group session and the other for agreeing to audiotaping.

Consent:
If the individual has not already done so provide the consent form for them to read and sign.

Interview questions:

Questions for the RPC

1) What was your role on the RPC?
2) To what extent did your work on the RPC affect your practice? In what way?

3) What did you think of the RPC? In terms of its functions/role, membership, ability to initiate practices changes, or any other aspects? How was it like to work as a group? Probe: How did you come to agreement/resolve conflict?

4) How were decisions made about the potentially best practice(s) and knowledge translation strategies to implement in the unit? How was this done?
5) What sources of evidence were used to support the practice change (e.g., systematic reviews, clinical experience, patient feedback, baseline data from CPPR database).

In terms of the EPIC process:

6) What did you think facilitated the use of pain guidelines or new information on pain practices within the NICU?

7) What do you think hindered the use of guidelines or new information related to practice in the NICU?

8) What was the biggest challenge in changing practice (e.g., to increase the use of pain guidelines in this unit)?

9) What do you think about the role of the RPC as change agents in implementing change?

10) Over the course of the study, which pain and KT interventions were most successfully implemented in your unit? What contributed to this success?

11) Over the course of the study, which KT strategies were least successfully implemented in your unit? What contributed to this limited success?

12) Is there anything else that you would like to tell me or recommend?

Thank you for your time in contributing to this research project.
Focus Group Interview Guide with Health Professionals

**Introduction:**

Thank you for taking the time to participate in this group session. The purpose of this session is to gain a better understanding of your experience with the process of using sucrose for procedural pain in the NICU. This process has been part of a thesis study developed and implemented by Janet Yamada, PhD student at the Lawrence S. Bloomberg Faculty of Nursing at U of T. As part of the Translating Research on Pain in Children study, the purpose of Janet’s study over the past 12 months was to uncover the steps that were involved in implementing sucrose to improve neonatal pain management. In this study, a baseline audit on the use of sucrose in the NICU revealed that sucrose was given (signed for in MAR) 10% of the time. A research practice council consisting of 4 health professionals on your unit focused on improving the ordering of sucrose. The second change was to improve documentation of sucrose on the Medication Administration Record (MAR). Different KT strategies to improve sucrose management were organized by the research practice council.

What we would like to do in this session is get feedback from you as to what you found helpful and not helpful about the strategies used to promote sucrose use over the past 12 months. Also, we would like to get your ideas on what you think helped facilitate or hindered the use of these strategies.

The focus session will last approximately 60 minutes.

The focus group session will be audio-taped. The audio-files and transcripts from the focus groups will be stored in a secure locked location. Only members of the research team will have access to the data.

It is your choice to take part in the study. You can stop or leave the room at any time. You can refuse to answer questions or discuss any subject in the focus group if you do not want to. However, we cannot erase your comments from the audio-tape as it includes the responses of all participants. Your performance evaluation will not be affected in any way by whether you take part in the focus group.

We ask that you review the research study consent (that has been handed to you at the beginning) and if you agree to participate, please sign the consent form. There are two separate places to sign – one for agreeing to participate in the group session and the other for agreeing to the audiotaping.

**Consent:**

If the individual has not already done so provide the consent form for them to read and sign.
Interview questions: Health Care Professional

Questions for Health Professionals

1) What types of strategies did you see happening or were you exposed to in the NICU in terms of how to improve the use of sucrose to manage painful procedures in infants?

   Probes:
   For example, did you see or were you involved in:
   Education around ordering sucrose
   Education around giving and documenting sucrose (if yes, what kind of education- poster, 1:1 bedside teaching, education days, staff meeting)
   Educational materials- posters, handouts
   Reminders- stickers on the admission order sheet reminding to order sucrose; stickers on the MAR reminding to give and sign for sucrose.
   Feedback on how the unit was doing in terms of ordering sucrose and giving sucrose in the form of emails, newsletter, presentation

2) Do you think any of these strategies were useful ways to change practices?

3) Over the course of the study (i.e., the past 12 months), which strategies were most successfully implemented in the unit? What contributed to this success?

4) Have you noticed any differences in sucrose administration in the unit?

5) To what extent did your practice change in terms of giving sucrose? In what way?
   Probes: Was your practice change related to any of the strategies that you were exposed to in the unit (see above).

6) What or who did you think helped the use of sucrose in the NICU?

7) Over the course of the study, which strategies do you think were the least successfully implemented in the NICU? What contributed to this limited success?

8) What do you think about the role of a practice council as change agents in implementing change in the NICU?

9) Is there anything else that you would like to tell me or recommend?

Thank you for your time in contributing to this research project.
Appendix K

Process Evaluation Checklist (PEC) Feasibility and Clinical Utility Measure

Instructions: Over the past year, the Process Evaluation Checklist (PEC) has been used to track all of the KT strategies used to implement a practice change on your unit. It is important to establish whether the PEC is a clinically useful tool for use in the EPIC intervention. As you have been involved in the EPIC intervention process and KT strategies used to change practice, we would very much appreciate if you could review the PEC and rate its feasibility and clinical utility by answering the 6 questions below.

1. The instructions for using the Process Evaluation Checklist (PEC) are easy to understand and follow (please check one box).

<table>
<thead>
<tr>
<th>Not at all easy to understand</th>
<th>Somewhat easy to understand</th>
<th>Easy to understand</th>
<th>Very easy to understand</th>
<th>Extremely easy to understand</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
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</tbody>
</table>

2. The structure for the 5 PEC surveys (Preparation Phase, Educational Materials, Educational Outreach, Reminders, Audit and Feedback) of the PEC is easy to understand and follow (please check one box).

<table>
<thead>
<tr>
<th>Not at all easy to understand and follow</th>
<th>Somewhat easy to understand and follow</th>
<th>Easy to understand and follow</th>
<th>Very easy to understand and follow</th>
<th>Extremely easy to understand and follow</th>
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</table>

3. The online format for the 5 PEC surveys (Preparation Phase, Educational Materials, Educational Outreach, Reminders, Audit and Feedback) of the PEC is easy to complete (please check one box).

<table>
<thead>
<tr>
<th>Not at all easy to complete</th>
<th>Somewhat easy to complete</th>
<th>Easy to complete</th>
<th>Very easy to complete</th>
<th>Extremely easy to complete</th>
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</tbody>
</table>

4. The length of the PEC is appropriate for use when evaluating the EPIC process (please check one box).

<table>
<thead>
<tr>
<th>Not at all Appropriate</th>
<th>Somewhat Appropriate</th>
<th>Appropriate</th>
<th>Very Appropriate</th>
<th>Extremely Appropriate</th>
</tr>
</thead>
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</tbody>
</table>
5. The method of scoring used in the PEC is easy to understand and follow (please check one box).

<table>
<thead>
<tr>
<th>Not at all easy to understand and follow</th>
<th>Somewhat easy to understand and follow</th>
<th>Easy to understand and follow</th>
<th>Very easy to understand and follow</th>
<th>Extremely easy to understand and follow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

6. Information obtained from the PEC tool can be easily interpreted (please check one box).

<table>
<thead>
<tr>
<th>Not at all easy to interpret</th>
<th>Somewhat easy to interpret</th>
<th>Easy to interpret</th>
<th>Very easy to interpret</th>
<th>Extremely easy to interpret</th>
</tr>
</thead>
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</table>

7. Information obtained from the PEC tool can be used to guide and plan practice change interventions (e.g., knowledge translation (KT) strategies) (please check one box).

<table>
<thead>
<tr>
<th>Not at all useful to guide strategies</th>
<th>Somewhat useful to guide strategies</th>
<th>Useful to guide strategies</th>
<th>Very useful to guide strategies</th>
<th>Extremely useful to guide strategies</th>
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8. The PEC would be easy to incorporate into my practice setting (please check one box).

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<th>Somewhat easy to use in practice</th>
<th>Easy to use in practice</th>
<th>Very easy to use in practice</th>
<th>Extremely easy to use in practice</th>
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Other Comments:
Appendix L

Consents for RPC and Health Care Professionals

Research Practice Council Member Consent Form

Title of Research Project:
A Process Evaluation of Evidence Based Practice, Identification and Change (EPIC)
Consent for Research Practice Council (RPC)

Investigator(s):
PhD Supervisor, PhD Committee, PhD Student

Purpose of the Research:
The purpose of this study is to evaluate the process of implementing the EPIC intervention. The specific aims are to develop and validate a process evaluation measure so that we can assess the extent to which the EPIC intervention was implemented as planned (fidelity). We are also interested in the Research Practice Council’s (RPC) perceptions of the usefulness of the EPIC intervention components, and barriers and facilitators of the EPIC intervention process.

Description of the Research:
As a member of the Research Practice Council (RPC), your role will be to plan and lead the implementation of EPIC strategies with the support of the Research Nurse (Doctoral Student). You will be participating in the following activities during the 2 Phases of the EPIC Intervention:

Phase 1: (3 month Preparation Phase)
1) A 2 to 3 hour training session to learn about research evidence on potentially better pain practices, to review current pain practices in the NICU and methods related to continuous quality improvement.
2) Identifying pain practice changes that will be implemented in the NICU.

Phase 2: (8-9 month Implementation and Change Phase)
1) Planning and implementing pain a practice change(s) over two 3-month rapid cycles of change (on average, 30 minutes/week).
2) Evaluating the practice change and providing feedback about the change to NICU staff.

You will meet with the Research Nurse (Doctoral Student) on a regular basis (i.e., biweekly) to complete the Process Evaluation Checklist (PEC) and to tailor the EPIC intervention process for the duration of the EPIC intervention.
The process of implementing the EPIC intervention will also be evaluated in a focus group at the end of the EPIC Intervention. Opinions will be sought from the health professionals who participate as members of the RPC. The focus groups will last approximately 60 minutes. The RPC will be asked to discuss their experience with implementation of the EPIC intervention in terms of the processes that were involved in delivering the intervention. Information about the barriers and facilitators of these processes used to change pain practices will also be collected. A research team member will lead and audio-record all focus group sessions.

**Potential Harms:**
We know of no harm that taking part in this study could cause you.

**Potential Discomforts or Inconvenience:**
The only inconvenience to your participation in this study will be the time commitment required to participate in the EPIC intervention process as a member of the RPC. There is also a possibility of inconvenience due to the time spent answering questions and/or participating in the focus group. To minimize this inconvenience, focus group meetings will be arranged at a time convenient to you, and will take as little time as possible.

**Potential Benefits:**

**To individual subjects:**
You will not benefit directly from participation in this research study. However, you may indirectly increase your knowledge of pain management within the NICU, and increase your leadership skills as a result of participation in this study.

**To society:**
Your participation in this study will help us to develop a process evaluation measure that can be used for future assessments of the implementation of the EPIC intervention. Health professionals may benefit from the results of this study as it may help them to use the latest research more. This may help to improve the care that health professionals give to infants in an NICU.

**Confidentiality:**
We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

Hospital Clinical Research Monitors, employees of the funder [Canadian Institutes of Health Research (CIHR)], or the regulator of the study may see the record of the focus group. The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by
Hospital policy. Published study results will not reveal your identity. During the focus group meeting we will remind everyone that the information shared is private and should not be repeated outside the group but we cannot be sure that information about you will be kept private. People in focus groups may share information about you with others outside the group.

**Reimbursement**
Participation in this study will not result in any expenses to you, and we will provide you with some compensation (a gift certificate in the amount of $200) in recognition of your time and effort as a member of the RPC.

**Participation:**
It is your choice to take part in this study. You can stop at any time. Your employment status will not be affected in any way by whether you take part in this study.
New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

**Sponsorship:**
The sponsor of this research is the Canadian Institutes of Health Research (CIHR).

**Conflict of Interest:**
No member of the research team has a commercial or financial interest in this study.

**Consent:**
By signing this form, I agree that:
1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my employment status.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my focus group discussion will be kept private. You will give no one information about me, unless the law requires you to.
6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7a) I agree, or consent, to take part in this study.
7b) In addition to participating in this part of the study, I also consent to participate in the optional focus group described within this consent form

□ Yes □ No

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<tr>
<th>Printed Name of Subject</th>
<th>Subject’s signature &amp; date</th>
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<tr>
<td>Printed Name of person who explained consent</td>
<td>Signature of Person who explained consent &amp; date</td>
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</table>
Health Care Professional Consent Form

Title of Research Project:
A Process Evaluation of Evidence Based Practice, Identification and Change (EPIC) Intervention to Improve Neonatal Pain Practices
Consent for Focus Group for Health Professionals

Investigator(s):
PhD Supervisor, PhD Committee, PhD Student

Purpose of the Research:
The purpose of this research is to obtain perceptions of health professionals who participated in the EPIC intervention about the usefulness of the EPIC intervention components and the barriers and facilitators of the EPIC intervention process.

Description of the Research:
The process of implementing the EPIC intervention will be evaluated in this study, and opinions will be sought from the health professionals who participated in the EPIC intervention process. When the research nurse wishes to talk to you, she/he will ask you for a verbal consent. If she/he asks you to participate in a focus group, she/he will ask you to sign a written consent, including consent for audiotaping.

The focus groups will last approximately 60 minutes. You will be asked to discuss your experience with implementation of the EPIC intervention in terms of the processes that were involved in delivering the intervention. Information about the barriers and facilitators of the processes used to change pain practices will also be collected. A research team member will lead and audio-record all focus group sessions.

Potential Harms:
We know of no harm that taking part in this study could cause you.

Potential Discomforts or Inconvenience:
There is a possibility of inconvenience due to the time spent participating in the focus group. To minimize this inconvenience, focus group meetings will be arranged at a time convenient to you, and will take as little time as possible.

Potential Benefits:
To individual subjects:
You will not benefit directly from participation in this research study. However, you may indirectly increase your knowledge of pain management within the NICU and increase your leadership skills as a result of participation in this study.
To society:
Health professionals may benefit from the results of this study as it may help them to use the latest research more. This may help to improve the care that health professionals give to infants in an NICU.

Confidentiality:
We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the law makes us do this. For example, the law requires us to give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

Hospital Clinical Research Office Monitor, employees of the company funding the study (Canadian Institutes of Health Research [CIHR]), or the regulator of the study may see the record of the focus group.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study, the data will be kept as long as required and then destroyed as required by Hospital policy. Published study results will not reveal your identity. During the focus group we will remind everyone that the information shared is private and should not be repeated outside the group. But we cannot be sure that information about you will be kept private. People in focus groups might share information about you with others outside the group.

Participation:
It is your choice to take part in this study. Your employment status will not be affected in any way by whether you take part in this study.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study.

Sponsorship:
The sponsor of this research is the Canadian Institute of Health Research (CIHR).

Conflict of Interest:
No member of the research team has a commercial or financial interest in this study.
**Consent:**

By signing this form, I agree that:

1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my employment status.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my focus group discussion will be kept private. You will give no one information about me, unless the law requires you to.
6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7) I agree, or consent, to take part in this study.

________________________________                  ____________________  
Printed Name of Subject                                           Subject’s signature & date

________________________________     __________________________________  
Printed Name of person who explained consent     Signature of Person who explained consent and date

If you have any questions about this study, please call Janet Yamada at (phone number)

If you have questions about your rights as a subject in a study or injuries during the study, please call the Research Ethics Manager at (phone number)
Video/audio taping & photography consent form.

**Title of Research Project:**

A Process Evaluation of Evidence Based Practice, Identification and Change (EPIC) Intervention to Improve Neonatal Pain Practices

Focus Group for Research Practice Council and Health Professionals

**Investigator(s):**

Yamada, RN, MSc, PhD Student Eaton Chair in Paediatric Nursing Research, PhD Thesis Committee members

**Description of Research**

The purpose of conducting focus groups with members of the Research Practice Council (RPC) and health professionals who participated in the EPIC intervention is to obtain their perceptions about the usefulness of the EPIC intervention components, and barriers and facilitators of the EPIC intervention process.

**Confidentiality:**

The audiotapes produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe the hospital monitor, or employees of the company sponsoring the study or the regulator (Canadian Institutes of Health Research [CIHR]) will have access to them. Following completion of the study the audiotapes will be kept as long as required in the Hospital “Records and Retention and Destruction” policy. They will then be destroyed according to this same policy.

**Consent:**

By signing this form,

1) I also agree to be audiotaped during this study. These audiotapes will be used to review the focus group discussions.

2) I understand that I have the right to refuse to take part in this study. I also have the right to withdraw from this part of the study at any time. e.g., before or even after the audiotapes are made. My decision will not affect my employment status.

3) I am free now, and in the future, to ask questions about the audiotaping.

4) I have been told that my record will be kept private. You will give no one information about me unless the law requires you to.

5) I understand that no information (including these audiotapes) will be given to anyone or be published without first asking my permission.

6) I have read and understood pages 1 to 2 of this consent form. I agree, or consent, to be audiotaped for this study.
In addition, I agree or consent for my audiotape(s) to be used for:

1. Other studies on the same topic
2. Teaching and demonstration (at hospital).
3. Teaching and demonstration at meetings (outside hospital)
4. Not to be used for anything else.

In agreeing to the use of my audiotape(s) for other purposes, I have been offered a chance to view/hear the audiotape(s). I also have the right to withdraw my permission for other uses of the audiotape(s) at any time.
Appendix M

RPC and Health Care Professional Questionnaire

A Process Evaluation of Evidence Based Practice Identification and Change (EPIC) Intervention to Improve Neonatal Pain Practices: RPC Member and Health Care Professional Questionnaire

Please answer the following questions in the space provided.

**Type of health professional:**

- [ ] Staff Nurse
- [ ] Advanced Practice Nurse
- [ ] Nurse Educator
- [ ] Nurse Manager
- [ ] Staff Physician
- [ ] Fellow
- [ ] Resident
- [ ] Intern
- [ ] Occupational Therapist
- [ ] Physiotherapist
- [ ] Pharmacist
- [ ] Respiratory Therapist
- [ ] Other (please specify below):

__________________________

**Years of ‘neonate-specific’ health professional experience at this institution:**

[ ]
Appendix N
Coding Framework for RPC and Health Care Professionals

Coding Framework for RPC Member Focus Group

1. Reasons for joining RPC
2. Benefits to RPC membership
3. Benefits to NICU
4. Role of RPC members
5. Reasons for success of RPC members
6. Understanding responsibilities of RPC role (training)
7. Sources of evidence to support sucrose/choosing practice change (i.e., research evidence, clinical expertise, baseline practice audit)
8. Facilitators of practice change process
   Barriers to practice change
9. Barriers to implementing KT strategies
10. Effective KT strategies (educational materials, outreach, reminders, audit and feedback).
11. Factors that contributed to sustainability of practice changes

Coding Framework for Health Care Professional Focus Group

1. Types of KT strategies observed in unit (educational materials, outreach, reminders, audit and feedback).
2. Effective KT strategies
3. Less effective KT strategies
4. Factors facilitating practice change
5. Barriers to practice change
6. Factors influencing sustainability of the practice change
7. Barriers to sustainability