Development of a Clinical Practice Guideline For Managing Sedation in Intubated Patients in the Pediatric Intensive Care Unit

By

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Abstract

Evidenced based practice (EBP) is a systematic approach to managing health care that utilizes contemporaneous research as the basis for clinical decisions. Research utilization or 'knowledge transfer' is the mechanism for transferring the evidence from research studies to the clinical setting for application. This practicum project, the development of a clinical practice guideline (CPG) for managing sedation in the intubated patient, provides an opportunity for demonstrating EBP and knowledge transfer in the Pediatric Intensive Care Unite (PICU).

A prior review of the patient database determined sedation practices in the PICU were inconsistent and contributed to the occurrence of unplanned extubations, or premature removal of endotracheal tubes. Inadequate sedation places the patient at risk for this life-threatening event, and complications such as pain, psychological distress, and asynchrony of the ventilator (Grap, Blecha, & Munro, 2002). The development of the sedation CPG, is intended to standardize sedation practices in the PICU. The guideline incorporates three components: a sedation assessment tool, a goal-directed drug protocol, and strategies for weaning sedatives while monitoring for signs of withdrawal. A descriptive evaluation of the sedation CPG demonstrated unequivocal support for the potential adoption of the guideline by PICU respondents. Barriers and facilitating factors to implementing the guideline as well as suggestions for revising the CPG were identified. The Ottawa Model of Research Use (OMRU) provided the framework for the development of the CPG and guided recommendations for future implementation and evaluation.

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Development of a Clinical Practice Guideline For Managing Sedation in Intubated Patients in the Pediatric Intensive Care Unit

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I dedicate this project to the memory of my father, Lawrence Halipchuk, who passed away before completion of my program.

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Chapter 1: Introduction

The Problem

Endotracheal tubes (ETTs) and mechanical ventilation are commonly used in the pediatric intensive care unit (PICU), and although life-saving, may be a great source of stress to the patient. Pain and anxiety have been associated with these therapies resulting in the potential for ventilator asynchrony or dislodgement of the ETT and compromised oxygenation and ventilation (Grap, Blecha, & Munro, 2002; Wielenga, De Vos, de Leeuw & De Hann, 2004). Pharmacological agents are used to prevent the negative consequences associated with ETT's and mechanical ventilation. Sedation and analgesics helps alleviate anxiety and pain, facilitate mechanical ventilation, and reduce unplanned extubations (Hoffman-Hogg, Bobek, Mion, Legere, Banjac, VanKerkhove & Arroliga, 2001; Popernack, Thomas, & Lucking 2004). Sedation practices in the PICU however, have recently been under scrutiny and deemed problematic by the Patient Care Team. A review of the PICU patient database completed in the fall of 2004 (Bonin, unpublished data, 2004) found sedation issues to be a contributing factor in ten unplanned extubations. These occurred in seven patients with three patients experiencing two unplanned extubations. Only half the patients were receiving a continuous infusion of sedation and had their level of sedation measured to ensure adequacy four hours prior to the event. Fortunately no deaths occurred as a result, although one infant suffered an episode of bradycardia and hypoxia that required compressions and the administration of epinephrine. Recommendations from the

review included the development of a sedation guideline, which was previously lacking in the PICU.

Purpose of Practicum Project

The purpose of this practicum project is to develop a clinical practice guideline (CPG) for managing sedation in the patient requiring an endotracheal tube or mechanical ventilation in the PICU. This will permit a standardized approach to managing sedation with the objectives of improving patient safety, communication between the health care team members regarding desired sedation goals, and nursing autonomy in the delivery of medications to maintain the established sedation goal. Proposed outcome measures include a reduction in unplanned extubations, increased patient comfort, reduced or maintained total ventilator days, reduced or maintained length of stay in PICU and increased staff satisfaction with sedation practices.

Background

Frequency of the Problem.

The PICU database was reviewed from April 2003 to March 2004 (12 month period) to determine the total number of patient admissions, ventilator days, and the incidence of unplanned extubations. During this period there were 453 patients admitted to the PICU for a total of 1,710 patient days. Sixty-one percent of these days (1,044 days) had patients requiring an endotracheal tube and mechanical ventilation. There were 10 unplanned extuabtions in 7 patients for a rate of 1.04 per 100 intubated days (Bonin, unpublished data, 2004). This rate is comparable to literature reports that range between no unplanned extubations to 2.5 extubations per 100 intubated days

(Popernack et al., 2004). One study involving adults, reported a rate of 19 per 100 intubated days, citing the main reason as the failure to use any sedation (Yeh, Lee, Ho, Chiang, & Lin, 2003). This appears to emphasize the importance and influence of sedation on maintaining ETT placement.

Significance of the Problem.

Unplanned extubation, or accidental displacement of the ETT, increases the risk of morbidity and mortality. The literature associates inadequate sedation with several complications including pain and distress, with inadequate sedation increasing the potential for unplanned extubations. Complications and medication issues will be discussed with the recommendation of sedation guidelines for managing these problems.

Complications.

Research indicates endotracheal tubes (ETT) and mechanical ventilation are associated with negative outcomes despite the life-saving intention of these therapies. Endotracheal tubes and mechanical ventilation have been associated with great stress related to the use of restraints, the loss of verbal communication, perceived loss of control, sleep disorders, pain, discomfort, and ventilator asynchrony, and unplanned extubations, (Grap et al., 2002). Research in the neonatal population reports the stress from ETT suctioning and ventilator asynchrony (fighting the ventilator) is associated with an increased length of stay and ventilator days, growth retardation, and chronic lung damage (Wielenga et al., 2004). Research in intubated adult patients has found ETTs to be associated with elevated heart rates and blood pressures secondary to

increased catecholamine levels caused by stress (Grap et al. 2002). Although negative experiences such as pain and anxiety have been associated with the ETT and mechanical ventilation, the greatest concern remains to be unplanned extubations.

Accidental displacement of the ETT poses serious risks to the patient. Complications of an unplanned extubation include dypnea, bronchospasm, airway edema from traumatic tube reinsertion, secondary pneumonia, and death if the tube cannot be reinserted (Chevron, Menard, Richard, Girault, Leroy & Bonmarchand, 1998; Yeh et al., 2003; Sadowski, Dechert, Bandy, Juno, Bhatt-Mehta, Custer, Moler & Bratton, 2004). Sadowski and colleagues (2004) reviewed the effects of 164 unplanned extubations in 2,192 pediatric critical care patients. Investigators determined mean ventilator days and length of stay in the unit, doubled from 3 to 6 days and 4 to 8 days respectively. This prolongation in mechanical ventilation places the patient at increased risk for experiencing ventilator-acquired pneumonia. A review by Chevron and colleagues (1998) determined 39% of the adult patients experiencing an unplanned extubation (n = 23) died as a result of ETT displacement and attempts at re-intubation. The seriousness of unplanned extubations reported in the literature is reflected in an event in the Winnipeg PICU. As a result of an unplanned extubation, one infant experienced severe hypoxia and bradycardia that required chest compressions and one dose of epinephrine to manage the event. This event and the evidence above demonstrate the significance of ETT displacement and the potential life-threatening complications.

Medication Issues.

Sedation is often utilized to manage and prevent the negative consequences associated with the ETT and mechanical ventilation (Bizek, 1995). However, research indicates many patients may not receive the medication available to them (Bizek, 1995). One study found less than 32% of adult patients received medications that were available to them, citing weaning the ventilator as one reason for withholding medications (Bizek, 1995). This results in a state where the patient is inadequately sedated and increases the potential for unplanned extubations (Yeh et al., 2003; Sadowski et al., 2004).

Researchers reviewed unplanned extubations in an adult intensive care unit (ICU) and found 85% of the patients who self-extubated did not receive any sedation prior to the event. Seventy-one percent of these patients reported pain as being the primary reason for removing their ETT (Yeh et al., 2003). When reviewing 164 cases of pediatric unplanned extubations, Sadowski and colleagues (2004) found 76% of the events were caused by the patient, 46% occurred during ventilator weaning, and 38% of patients were described as agitated prior to the event. Chevron and colleagues (1998) compared 36 adult cases experiencing unplanned extubations to 74 controls. Investigators determined the patients suffering ETT dislodgement were more frequently agitated and required restraints, both indications of inadequate sedation. Although the majority of patients did not require reintubation, of those who did (n=23), nine patients died compared to one patient in the control group. It was noted that total ventilator

days and length of stay in the ICU were also significantly higher in the patients requiring reintubation (Chevron et al., 1998).

In the review of the unplanned extubations in the PICU in which 7 patients experienced 10 unplanned extubations, five of the patients received no sedation two hours prior to the event. Despite the recommendation for assessing adequacy of sedation every four hours, there was only documentation of this in five of the ten unplanned extubations, four hours prior to the event. Only one patient was reported as being agitated prior to the event. However, adequacy of sedation, or any degree of agitation, is unknown in many of the cases (Bonin, unpublished data, 2004). Although difficult to prove in the PICU population, there appears to be a correlation between sedation and unplanned extubations.

Pharmacological agents, intended to alleviate the negative consequences of ETT placement and mechanical ventilation, may also be associated with complications. Under-sedation, manifested as anxiety, agitation, increased heart rate and blood pressure can lead to pain and discomfort, increased risk of myocardial ischemia, hypertension, arrhythmias, ventilator asynchrony, and unplanned extubations (Kruskamp 2003). Over-sedation is manifested by reduced respiratory rate, hypotension and a decreased level of consciousness, which may in turn, lead to difficulties in assessing neurological status and pain, cardiac compromise, missed diagnosis of abnormalities, worsening of withdrawal symptoms and prolonged ventilation and ICU days from delayed emergence (Crain, Slonim & Pollack, 2002; Kruskamp, 2003). The risks associated with under and over-sedation emphasizes the

need for astute assessment and clear guidelines for medication administration, something that is currently lacking in the PICU.

Sedation guidelines.

The literature recommends sedation regimes and assessment tools as mechanisms for improving patient safety and the efficiency of sedation (Playfor, 2000; Carnevale & Ducharme, 1997). Sedation protocols in the form of clinical practice guidelines could improve patient safety by reducing the risk of over-sedation, provide quicker response to indications of under-sedation, reduce the incidence of unplanned extubations, and improve staff satisfaction with sedation management (Alexander, Carnevale, & Razack, 2002; Popernack et al., 2004; Bennett, 2003).

The PICU in the Children's Hospital in Winnipeg currently lacks a guideline to direct their sedation practices making their approach to managing sedation problematic. Anecdotal reports by several nurses in the PICU identified sedation assessment, sedation plans, and drug administration, as issues that required attention. Corroborating the findings of the patient database review, nurses indicated the COMFORT Sedation Assessment Scale is used inconsistently. They reported the heart rate and blood pressure components of the COMFORT Scale are difficult to score when the child is febrile or receiving inotropes. Nurses also reported the variation in personal preference when ordering sedatives among Physicians created confusion regarding the overall goal of sedation. Thirdly, several nurses were concerned over the apparent indiscriminate use of medications. They indicated that on occasion, certain nurses

administered sedatives to meet the nurse's goal of limiting patient movement, and not according to the patient's needs.

Summary of the Problem

A review of the PICU database indicates endotracheal tubes and mechanical ventilation are common therapies used in the PICU. The literature associates ETT placement and mechanical ventilation with negative complications increasing the risk of patient morbidity and mortality. Although sedation is used to alleviate the negative complication, studies indicate patients may not receive the sedation that is available to them. The resultant inadequate sedation increases the risk of unplanned extubations and death. The literature recommends a sedation guideline to reduce the complications associated with ETT placement and mechanical ventilation and prevent the risks related to inadequate sedation. The lack of a sedation guideline in the Winnipeg PICU has led to inconsistent sedation practices and contributed to episodes of unplanned extubations, with one patient requiring life-saving measures. This emphasizes the need for a standardized approach to managing sedation in the PICU, which in turn, will improve patient safety.

Chapter Two: Review of the Literature

Search strategy

A systematic approach to the literature search was conducted utilizing the CINAHL, Medline, EMBASE and Cochrane Database of Systematic Reviews electronic search engines. Key search terms included: sedation, endotracheal tube, mechanical ventilation, pediatrics, neonates, protocols, clinical practice guidelines, and systematic reviews. Selected articles focused on sedation issues in the neonatal and pediatric populations requiring an endotracheal tube and mechanical ventilation in the intensive care setting. A small subset of studies involving adult patients was accepted to compliment the findings from studies based on the pediatric population. This chapter discusses the literature relevant to the development of the sedation CPG and includes sedation practices, sedation assessment tools, sedation protocols and recommendations for weaning sedatives.

Review of the literature

Sedation Practices.

Despite the current emphasis on evidenced based practice, at present there is no "gold standard" for managing sedation in the critically ill pediatric patient. More than a decade ago, researchers found a systematic approach to managing sedation was lacking in the majority of PICU's. Fortunately, studies that are more recent are showing improvements in sedation practices. A survey of sedation practices conducted in Canada and the United States (US) in 1993 (n=34, 76% response rate) reported 6% of PICU's followed written sedation guidelines and relied upon subjective opinion for

assessing adequacy of sedation (Marx, Rosenberg, Ambuel, Hamlett, & Blumer, 1993). By 2002, the utilization of written sedation guidelines in PICU's across the US had increased to 13%. (n = 145, 51% response rate). At this time, 20% of the PICUs reported using the COMFORT Scale for assessing the efficacy of sedation (Rhoney & Murray, 2002). Last year, investigators found 66% of respondents in the US now employ a written sedation guideline in their PICU (n=35, 59% response rate). Eighty-six percent of these units used a sedation assessment tool with the most common (48%) being the COMFORT Scale (Twite, Rashid, Zuk & Friesen, 2004). Overall, the literature demonstrates a positive trend in the usage of sedation guidelines, emphasizing the growing movement towards evidenced based practice.

Sedation Assessment Tools.

The literature highly recommends the use of a sedation scale to avoid complications associated with under and over-sedation (Alexander et al., 2002; Kruskamp, 2003; Bennett, 2003). Over-sedation may result in coma, paralytic ileus, hypotension and respiratory depression, while under-sedation may cause anxiety, fear, pain, tachycardia, hypertension, and may lead to unplanned extubation and ventilator asynchrony (Fuhrman & Zimmerman, 1999; Alexander et al., 2002; Kruskamp, 2003). Assessment allows for the titration of medication that is appropriate to meet the sedation goals and prevent physical dependence and withdrawal (Bennett, 2003). "Utilization of a validated, reliable and objective method for measuring behavioural and physiologic distress in children would allow systematic documentation of sedative response on an individual basis and allow patient-specific alteration in the therapeutic

regime" (Marx, et al., 1993, p.375). Infants and children, however, pose a greater challenge in assessing sedation needs. Assessment tools developed for the adult population are of little value in pediatrics. Tools such as the Ramsay Scale require the patient to be communicative and cooperative (De Jonghe, Cook, Appere-De-Vecchi, Guyatt, Meade, & Outine, 2000). In the pediatric patient, an assessment tool must consider the absence of verbal cues, few obvious pain indicators, and be independent of the child's ability to cooperate (Foster, 2001).

A search of the literature for sedation assessment tools yielded seven articles pertaining to infants and children. In addition, a systematic review conducted by De Jonghe and colleagues (2000) found 25 adult and pediatric sedation scoring tools. Investigators reported only one tool, the COMFORT Scale, has been validated for assessing ongoing sedation needs in the pediatric ICU patient.

An article by Bennett (2003) describes the Nottingham Pediatric Intensive Care Pain and Sedation Score for Ventilated Children. This tool measures response to suctioning in terms of breathing/coughing, activity, facial expression, sleep/wake state, and blood pressure/heart rate. However, its use is limited to intubated and ventilated patient. It also includes heart rate and blood pressure, two determinants that are affected by factors other than distress, making the tool problematic.

A more recent review of sedation scales conducted by Ista and colleagues (2005) identified five scales determined to be valid and reliable for assessing sedation adequacy in the pediatric population. Included is the Hartwig Sedation Scale, Neonatal Pain and Sedation Scale (N-PASS), University of Michigan Sedation Scale, Vancouver Sedative

Recovery Scale, and the COMFORT Scale (Appendix A) (Ista, van Dijk, Tibboel & de Hoog, 2005).

The Hartwig scale is based upon five behavioural criteria that measures the response to ETT suctioning, limiting its use to patients who are intubated (Ista et al., 2005). This scale requires the child to be stimulated and is not useful for ongoing assessment when undisturbed. The N-PASS assesses pain and sedation but is limited to the neonatal population (Hummel, Puchalski, Creech, & Weiss, 2003). The University of Michigan sedation scale assesses LOC and agitation but is limited to procedural sedation in children (Voepel-Lewis, Malviya, Burke, & Tait, 2004). The Vancouver Scale measures LOC during emergence from anesthetic following open-heart surgery in children. Similar to the Michigan scale, it is limited to procedural sedation (Macnab, Levine, Glick, Phillips, Susak, & Elliot, 1994).

COMFORT Scale.

The COMFORT scale appears to be the most practical scale for assessing adequacy of sedation in the pediatric setting. Developed in 1992 by Ambuel and colleagues, the COMFORT scale measures the level of distress in critically ill, ventilated infants and children (Marx et al, 1994) (Appendix B). It is useful for ventilated or non-ventilated patients. The assessment is observational and does not require the patient to be disturbed. Comparing the criteria to the age-appropriate behaviour of the patient makes the tool age-independent and useful in children of all ages (Marx, Smith, Lowrie, Hamlett, Ambuel, Yamshata, & Blumer, 1994). The scale assesses six behavioural determinants: alertness, calmness/agitation, movement, facial tension, muscle tone,

and respiratory response to mechanical ventilation or crying in the non-intubated patient. Heart rate and blood pressure compose the two physiological determinants (Marx et al., 1994; van Dijk, Peters, van Deventer, & Tibboel, 2005).

In 1994, Marx and colleagues validated the COMFORT Scale for assessing distress and attempted to determine the target range that reflected adequate sedation. By comparing COMFORT scores to expert opinion, investigators identified a range of 17-26 was congruent with adequate sedation (Marx et al., 1994).

In 1996 van Dijk and colleagues extended the use of the COMFORT Scale by conducting a randomized controlled study (n=158) and validating it for assessing postoperative pain in infants and children ≤ 3 years of age. A category ranging from 'no crying' to 'screaming' was added to the tool as an alternative to the response to mechanical ventilation, for children who are not intubated (van Dijk et al., 2005).

Investigators attempted to validate the COMFORT Scale in pediatric ICU patients (n=20) who required paralysis. Utilizing an observational design, they compared COMFORT scores to physician opinion, but found the scale to be unreliable and invalid in this population (Razmus, Clarke, & Naufel, 2003).

The COMFORT Scale was extended to premature infants in the Neonatal Intensive Care when investigators compared 30 COMFORT scores to expert opinion in 19 ventilated premature infants (mean age 30 weeks), validating it for assessing distress and adequacy of sedation (Wielenga, De Vos, de Leeuw, & De Hann, 2004).

The literature has recently acknowledged the difficulties with the COMFORT Scale. The heart rate and blood pressure determinants can be influenced by factors

other than distress, such as fever and the use of intropes. This has led to an item analysis by two research studies assessing the components of the scale for reliability and their contribution to the total COMFORT score. Investigators have determined the heart rate and blood pressure add little to the overall score and that 97% of the total score is explained by the six behavioural measurements alone (Carnevale & Razack, 2002; Ista et al., 2005). This has resulted in the development of a modified COMFORT scale known as the COMFORT Behavior Scale, or COMFORT-B Scale, by van Dijk and colleagues in New Zealand.

The COMFORT-B Scale is comprised of the six behavioural determinants from the original COMFORT Scale. Scores range between 6 and 30, representing no distress, to a high degree of stress, respectively (Appendix C) (Carnevale & Razack, 2002; van Dijk et al., 2005). One study to date has attempted to determine the target scores reflecting ideal sedation. Ista and colleagues conducted an observational study on 78 patients in a PICU comparing COMFORT-B scores to expert opinion by the nurses. Investigators determined a range of 11-22 appeared to demonstrate adequate sedation but recommended the addition of a nurse's opinion scale to enhance reliability (Ista et al., 2005).

In consideration of the most recent evidence, it appears the COMFORT-B scale is the most practical and suitable scale for assessing sedation in the PICU. Studies by Carnevale, Ista and colleagues, report the determinants adequately measure distress and pain in pediatric patients. The deletion of the heart rate and blood pressure components make it easier to use. It can be used in intubated and non-intubated

patients, and does not require the child to be disturbed. It is appropriate for infants and children of all ages, and may be used at intervals for ongoing assessment of sedation needs.

Sedation Protocols.

Sedation protocols are beginning to appear in the literature as a means of standardizing the approach to sedating the patient requiring intubation and mechanical ventilation. "Protocol-directed sedation by nurses allows for more rapid clinical decision-making at the bedside by eliminating the need for physician orders and thereby reducing the time needed to implement sedation changes" (Thomas, 2000, commentary). Nurses are directed to titrate medications within a defined range to maintain the established goal, thus, increasing their autonomy (Alexander et al., 2002). A literature search focusing on sedation protocols yielded four studies based on the adult population and three articles related to pediatric sedation guidelines. Articles included the following:

- One random controlled trial (RCT) comparing a nurse-led sedation protocol (n = 162) to traditional methods (n = 159) in an adult ICU (Brook, Ahrens, Schaiff, Prentice, Sherman, Shannon, & Kollef, 1999).
- One systematic review of adult sedation practices attempting to determine the most optimal drug regime (Izurieta & Rabatin, 2002).
- One chart audit/survey study in an adult ICU evaluating a sedation protocol (Greiner & Greiner, 2004).
- One general review articles related to adult sedation guidelines (Bizek, 1995).

- Two pediatric studies evaluating sedation protocols:
    1. Popernack, Thomas, & Lucking, (2004), prospective observational study
    2. Alexander, Carnevale & Saleem, (2002), chart audit /survey
- One general review articles related to pediatric sedation guidelines (Bennet, 2003).

Brooks and colleagues conducted a RCT comparing a nurse-led sedation protocol (n = 162) to traditional methods (n = 159) in adult ICU patients requiring intubation and mechanical ventilation. Patients managed with the sedation protocol demonstrated a significant reduction in mean ventilator days (3.7 days from 5.2 days), ICU days (5.7 from 7.5 days), hospital days (14 days from 20 days), fewer tracheostomies (6% from 13%), and a total cost savings of $349,920 during the review period (Brook, et al., 1999). Limitations of the study however, precluded the ability to discern the differences in practice that resulted in the positive findings. Adherence to the protocol and the effect on the unplanned extubations were not evaluated, and the impact of comfort measures was not considered. Despite the inability to generalize the findings of this study to the pediatric ICU population, the data appears promising and directs future research in the field of sedation management.

A systematic review of sedation protocols in the adult ICU patient conducted by Izurieta and Rabatin (2002) determined there were too few RCTs available to develop a sedation protocol. This was the only systematic review found in the literature emphasizing the limitations of the literature and the realization that current research is inadequate in the adult population, and completely lacking in the pediatric population.

Greiner and Greiner (2004) evaluated a sedation protocol in an adult medical intensive care unit utilizing chart audits and nursing surveys (60% response rate) to evaluate a sedation guideline. It was hypothesized that the sedation protocol would increase nurse's knowledge of EBP, improve documentation of sedation assessment, and provide a standardized approach to managing sedation (Greiner & Greiner, 2004). Investigators determined the sedation protocol led to a significant reduction in average ICU length of stay (11.4 to 9.1 days), average ventilator days (10.3 to 8.1 days), average hospital costs per patient ($42,000 to $26,000) and improved documentation of sedation assessment. Despite the inability to generalize the findings to the pediatric population it provides evidence that a sedation guideline improves patient care and resource utilization.

Bizek (1995) discusses the implementation of a sedation protocol in an adult ICU at the Detroit University Hospital. The author reviews general sedation concepts and makes recommendations for optimizing sedation administration. Recommendations include using a sedation assessment tool and written sedation guideline. Drug dosing should be consistent and continuous infusions used to avoid the pitfalls associated with intermittent drug administration. This article is useful for developing an understanding of the issues surrounding sedation administration and provides clear suggestions for optimizing sedation practices.

Alexander and colleagues (2002) evaluated a pediatric sedation guideline in the PICU at the Montreal Children's utilizing and chart audit and survey design. A review of ten patient charts attempted to determine the level of sedation using the COMFORT

Scale while following the sedation guideline. A survey of PICU team members (n = 53, response rate 72%) evaluated the level of satisfaction with the sedation protocol. The evaluation found patients received more sedatives while following the guideline, evident by the reduced incidence of under-sedation. Cases of under-sedation that occurred despite the guideline may be attributed to the lower target range of the COMFORT scale. Their sedation practices targeted a score of 14-18, lower than the 17-26 recommended by the literature. There were no reports of over-sedation of the patients following the sedation guideline. The survey demonstrated overall satisfaction with the sedation protocol and agreement by staff that sedation practices were more efficient and led to improved patient comfort (Alexander et al., 2002). Weaknesses of the study include a small sample size (n = 10), reports of a higher than average severity of illness in the population studied, and the retrospective nature of the evaluation. Despite these limitations, the findings add to the small body of evidence that supports sedation guidelines and the association with improved patient care.

Bennett (2003) describes the process of developing a sedation protocol for pediatric critically ill patients at the Queen's Medical Centre in Nottingham. The author has devised a sedation guideline that includes a sedation and comfort assessment tool, drug management protocol, structured weaning protocol, and withdrawal assessment tool. Bennett claims the guideline has improved overall practice and reduced the episodes of physical dependence and withdrawal (Bennett, 2003). Failing to evaluate the guideline however, leaves the reliability and validity of the tools uncertain.

Penn State Sedation Protocol.

Popernack and colleagues (2004) developed a sedation protocol for the pediatric ICU population after determining sedation practices were inconsistent in the PICU and confusion exists regarding sedation goals. Goals of the protocol include reducing unplanned extubations, improving the communication regarding the desired sedation goal, and promoting nursing autonomy when carrying out the individualized care plan. The protocol places patients into levels ranging 1 through 6, each with specific patient behaviors and nursing actions for administering medications in order to maintain the desired level of patient activity (Appendix D). Initiated upon intubation of the patient, the desired sedation goal is ordered in the patient chart. Utilizing a prospective observational design, the investigators evaluated the protocol by comparing rates of unplanned extubations five years before, and four years after, the implementation of the sedation protocol. Unplanned extubations were significantly reduced from 0.63 per 100 intubated patient days to a range of 0 – 0.19 / 100 intubated patient days after the sedation protocol was implemented (Popernack et al., 2004). The investigators felt the positive change was related to the protocol, maintaining that patient demographics and length of stay remained unchanged, and no other major changes in practice occurred (Popernack, 2004). Despite the impact of the guideline on communication and nursing autonomy was not evaluated, investigators believed these had improved. Therefore, it can be implied, that a sedation protocol improves patient safety, communication between practitioners, and allows for autonomy by nursing in maintaining the established sedation goal. This protocol was selected by the PICU Patient Care Team

for inclusion in the sedation CPG to provide a goal-directed approach to administering sedatives. Guided by a multidisciplinary team, this tool allows for an individualized approach appropriate to the patients disease process and organ function.

Weaning Protocols.

Withdrawal is defined as unpleasant or life-threatening physiologic changes that occur after severe reduction or cessation of sedatives following prolonged or regular use (Mosby, 2002). Clinical manifestations include neurological excitability, gastrointestinal dysfunction and autonomic dysfunction (Yaster, Berde & Billet, 1995) (Appendix E). It is suggested that sudden or rapid reduction in opioid administration results in exaggerated opioid receptor antagonism rapidly altering a patient's central nervous function (Carnevale & Ducharme, 1997). Similarly, benzodiazepine withdrawal occurs after the receptors mediating GABBA release are depleted of neurotransmitter (Carnevale & Ducharme, 1997). Withdrawal occurs after tolerance and dependence are established requiring increasing drug doses to obtain the same effect (Yaster et al., 1995). Withdrawal often occurs at a time when caregivers expect improvement and can be quite distressing to families (Hughes & Choonara, 1998). Symptoms usually occur within a few hours of changing the sedation (Playfor, 2000), peak around 72 hours (Yaster et al, 1995), and may last several weeks according to case reports (Carnevale & Ducharme, 1997).

There is currently no reliable and validated tool in the literature for assessing and scoring withdrawal symptoms during weaning of sedation in the pediatric ICU patient. For this reason, it was appropriate to include a list of signs and symptoms of withdrawal

when weaning sedatives such as opioids and benzodiazepines in the sedation CPG. This list complements the sedation weaning protocol and assists the practitioner in determining an individualized weaning schedule by monitoring for withdrawal symptoms and altering the weaning plan if required.

Several methods have been described in the literature as a means to reduce the incidence of withdrawal, including slow tapering of drug dosages, substituting one class of sedatives for another, and introducing a long-acting sedative such as lorazapam (Playfor, 2000). An ideal rate of tapering or 'weaning' sedation is gradual enough to prevent withdrawal but quick enough to avoid unnecessary prolongation of mechanical ventilation (Carnevale & Ducharme, 1997). Six articles with recommendations specific to weaning sedation in the pediatric ICU patient were found in the literature (Appendix F). A compilation of the recommendations includes reducing the initial dose by 13-50% for infusions running less than one week, with subsequent reductions made daily by 20%. Infusions running longer than one week should be reduced initially by 8-20% followed by reductions of 10-20% every 12-24 hours as tolerated (Ducharme et al., 2005; Bennet, 2003; Grehn 1998; Arnand & Ingraham, 1996; Yaster et al., 1995). The variation in suggested dose reduction and frequency of changes are accounted by the individual response to weaning. Weaning plans are adjusted to accommodate changes in patient status and tolerance to weaning. Patients must be monitored for signs of withdrawal every 4-8 hours for a minimum of 24-48 hours, or for as long as the weaning schedule mandates (Carnevale & Durharme, 1997; Arnand & Ingraham, 1996).

Considering the minor variations for weaning sedation recommended in the literature, a schedule was selected for the sedation CPG that reflected the most common approach. Weaning was divided into low to moderate dosages for less than a week, and high doses for greater than a week, as directed by the evidence. The majority of studies indicated reducing the dosages by 25-50% initially for the first group would be sufficient to prevent withdrawal with subsequent doses reduced by 20%. With long-term use it was decided a conservative approach of reducing the dose by 10-20% every 12 to 24 hours would be appropriate. It is emphasized the sedation guideline provides a starting place for weaning with patient response as the key factor to guiding the process.

Summary of the literature

There is a paucity of strong evidence in the literature for managing sedation in the pediatric population in the PICU. When clinical issues are technically, economically, or ethically difficult to address with randomized trials, the best available evidence may be predominately based on expert opinion (Hayward, Wilson, Tunis, Bass, Guyatt, 1995). Of the evidence that is available, the literature suggests sedation guidelines improve patient care and resource utilization. Sedation assessment tools allow for timely management of sedation needs and reduce the occurrence of withdrawal. Pediatric sedation protocols appear to be associated with significant reductions in unplanned extubations, episodes of under-sedation, and improved staff satisfaction with sedation practices. Evidence from studies on the adult population appear promising and include a reduction in ventilation days, ICU days, hospital days, total costs per case,

reduced need for tracheostomy, and improved documentation. Weaning protocols recommend reducing the dosage of sedation incrementally and as tolerated by the patient. It is clear there is sufficient evidence to develop a CPG for managing sedation in the defined population with the literature supporting guidelines as a method of improving patient safety.

Chapter Three: Methodology

The methodology employed in this project can be described as the development and evaluation of the sedation CPG. The sedation guideline will allow for a standardized approach to managing sedation in the intubated PICU patient. The evaluation will provide the information necessary to determine the feasibility of implementing the CPG in the PICU. This chapter will discuss the development of the sedation CPG and the approach utilized to formally evaluate the guideline. This includes a description of the components of the CPG, identification of the target setting and populations, evaluation design, format and purpose. The Ottawa Model of Research Use will be discussed as it provides the conceptual framework for guiding this project. Dissemination of the results, ethical considerations, recruitment strategy, data analysis and underlying assumptions of the project will also be presented.

Target Setting & Population:

This practicum project was conducted in the PICU of the Winnipeg Children's Hospital. This facility provides healthcare to infants and children aged six weeks to 17 years within the province of Manitoba, North-Western Ontario, and Nunavut. The target population for this project is composed of two cohorts. The first level refers to the patients that will be impacted by the implementation of the proposed change in practice (van Bokhoven, Kok, & van der Weijden, 2003). This sedation guideline is intended to impact the infants and children in the PICU requiring an endotracheal tube (intubation) and mechanical ventilation. The second cohort of the target population refers to the potential adopters of the proposed guideline and those who will decide upon formal

adoption (van Bokhoven, et al., 2003). The multi-disciplinary members of the PICU are the potential adopters of the CPG with the Patient Care Team responsible for the decision to formally adopt the CPG.

Project Model

The Ottawa Model of Research Use (OMRU) was selected to guide this practicum project (Appendix G). This planned change model is useful for directing the implementation of a quality care innovation, such as clinical practice guideline (CPG) (Graham, & Logan, 2004). This model incorporates the theory of knowledge transfer and research utilization, a process that systematically transfers research research-based knowledge into practice (Graham, 2004). Most appealing is the similarity of the OMRU to the nursing process. Both frameworks emphasize the need for assessment, implementing interventions with simultaneous monitoring, and evaluating the intervention using predetermined outcome measures. Composed of three stages, the first stage of the OMRU identifies barriers to implementing a change in practice by assessing the practice environment, potential adopters and evidenced-based innovation. Stage two guides the implementation and adoption of the intervention and includes strategies to promote uptake of the change in practice. Stage three involves the evaluation of the proposed outcomes impacting the patient, practitioner and system (Graham, 2004). The elements within this model are dynamic, interconnected, and are heavily influenced by the health care environment (Graham, & Logan, 2004). This project focuses on stage one of the OMRU, with stages three and four guiding recommendations for implementing and evaluating the sedation CPG in the future.

Underlying Assumptions

- The environment of the PICU is supportive of, and values, evidenced based practice and clinical practice guidelines.
- The PICU Patient Care Team understands the levelling of evidence and the strength of recommendations.
- The allotted time is sufficient to complete this project.
- The PICU team members have the knowledge and skill to utilize the COMFORT Scale.
- The PICU team members have a basic understanding of sedatives, withdrawal and weaning sedation.
- Respondents of the questionnaire are representing their true attitudes, beliefs and feelings.

I. Development of the Clinical Practice Guideline

Clinical practice guidelines (CPGs) are "systematically developed statements to assist the practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Sackett, Straus, Richardson, Rosenberg & Haynes, 2000, p. 170). These guidelines have become a universal tool for improving the quality of care by operationalizing the implementation of evidenced based practice. Benefits of CPGs include reduced morbidity, mortality, and improved resource utilization with associated cost-containment. CPGs also allow for the evaluation of practitioners and services by comparing performance to measurable criteria outlined in a guideline (Miller & Kearney, 2003).

CPG development involves the identification of a clinical problem, a search and synthesis of the evidence, and the creation of recommendations that guide the clinical decision-making process (Geyman, Deyo & Ramsey, 2000). CPGs are based upon the most current evidence with the awareness that guidelines change over time as knowledge advances. It is generally accepted that findings from RCTs, identified as the highest level of evidence, are preferred for developing CPGs. Limitations in available research however, force practitioners to base CPGs upon a combination of expert opinion and lower level research studies (Miller & Kearney, 2004). This is reflected in the development of the sedation CPG and the need to utilize various forms of evidence.

Identification of the clinical problem.

In review, the problem of inconsistent sedation practices in the PICU led to the recommendation for the development of a CPG for the purpose of standardizing the approach to managing sedation. The PICU Patient Care Team supported this recommendation and emphasized the primary goal of improving patient safety.

Development of the Clinical Innovation.

A review of the literature surrounding sedation practices in the PICU population determined a validated evidenced based CPG for managing sedation was non-existent. Consequently, several individual components were selected from the literature based on recommendations for including a tool to assess adequacy of sedation, goal-directed sedation administration, and suggestions for weaning sedation while monitoring for signs of withdrawal. Based upon these recommendations, the revised COMFORT Behavior Scale, Penn State Sedation Protocol, and a weaning guideline were selected for

inclusion in the sedation CPG (Appendix H). This process was based upon a fundamental tenet of knowledge management to prevent 're-inventing the wheel' and the utilization of resources already identified as best practice (Newell, Edelman, Scarbrough, Swan, & Bresnen, 2003). Although may CPGs address specific medications in their recommendations, this was not considered for the sedation CPG. This was based upon the decision of the PICU Patient Care Team to individualize sedation practices specific to the patient's disease process and organ function.

The COMFORT Behavior Scale.

A sedation assessment tool is essential for avoiding complications associated with inadequate sedation and provides objective means for titrating medications to meet sedation needs (Bennett, 2003). Due to the influence of factors other than distress on the HR and BP components of the scale, recent evidence demonstrates these determinants can be safely removed (Carnevale & Razack, 2002; Ista et al., 2005). For this reason, the revised COMFORT Behavior Scale (COMFORT-B Scale) was chosen for inclusion in the sedation CPG (Appendix C). The COMFORT-B Scale has been proven reliable and valid for assessing sedation in infants and school-aged children, and for assessing postoperative pain in children less than three years of age (Ista et al., 2005; Wielengal et al., 2004; van Dijk, de Boer, Koot, Tibboel, Passchier, & Duivenvoorden, 2000). Due to the limitation in available research confirming the reliability of the proposed target range (11-22), a nurse's opinion score (NOS) was included as an adjunct assessment tool. The NOS score ranges from 1 – 3 reflecting inadequate sedation to over-sedation respectively (Ista et al., 2005).

The Penn State Sedation Protocol.

As a strategy for optimizing sedation administration, protocols are proactive in nature and allow for the anticipation of sedation needs (Bizek, 1995) and a timely response for meeting these needs. Research has demonstrated positive outcomes associated with the use of a pediatric sedation guideline. Popernack and colleagues (2004) have demonstrated a reduction in the rate of unplanned extubations. Alexander and colleagues (2002) have demonstrated a reduced incidence of severe under-sedation, and improved staff satisfaction with sedation practices. Based upon the desire to individualize sedation practices, the Penn State protocol was selected for inclusion in the sedation CPG (Appendix D). This model was designed with the following concepts or goals in mind:

- Goal-directed sedative administration.
- Promotion of nursing autonomy in carrying out the individualized sedation plan.
- Facilitation of communication between team members regarding the desired goal of sedation.

Patients are assigned one of six levels that describe the desired patient behaviour and associated nursing action to maintain the behavior. The levels indicate the desired goal of sedation related to patient behaviour and the amount of ventilator support required (Popernack et al., 2004). The sedation level, or goal of sedation, is determined upon intubation, reviewed daily during rounds, and revised as changes in patient status mandate it. This protocol is beneficial for it is patient-focuses and emphasizes a

multidisciplinary team approach to managing sedation in consideration of the patient's status and needs.

Weaning Protocol.

Several mechanisms have been described in the literature as a means to prevent withdrawal during weaning of sedation. This includes slow tapering of drug dosages, substituting one class of sedatives for another, and changing continuous infusions to intermittent dosing and then oral routes before discontinuing sedation (Playfor, 2000). Several weaning strategies have been documented in the literature, with slight variation in the frequency and degree of dose reduction (Appendix F). An ideal rate of tapering or 'weaning' sedation is gradual enough to prevent withdrawal but quick enough to avoid unnecessary prolongation of mechanical ventilation (Carnevale & Ducharme, 1997). A compilation of the recommendations from the literature suggests reducing the initial dose by 13-50% for infusions running less than one week, with subsequent reductions made daily by 20%. Infusions running longer than one week should be reduced initially by 8-20% followed by reductions of 10-20% every 12-24 hours as tolerated (Ducharme et al., 2005; Bennet, 2003; Grehn 1998; Arnand & Ingraham, 1996; Yaster et al., 1995). The weaning strategy selected for inclusion of the sedation CPG reflected the most common recommendation found in the literature (Appendix I). As there is currently no validated tool for assessing signs of withdrawal a list of symptoms associated with the withdrawal of benzodiazepines and opioids was included in the sedation CPG to assist the practitioner in the assessment of withdrawal (Appendix E).

Despite the paucity of literature in the pediatric population guiding sedation practices, it is clear the addition of a sedation guideline positively impacts the patient and assists the practitioner to improve the quality of care provided. The development of the sedation CPG, includes the COMFORT-B scale for assessing adequacy of sedation, the Penn State Sedation Protocol for providing goal-directed sedation, and a weaning protocol to prevent or manage withdrawal. This guideline demonstrates the utilization of the most current evidence and considers the needs of the individual patient and values of the Winnipeg PICU.

II. Evaluation of the Sedation Guideline

Stage one of the OMRU involves the assessment of the practice environment, potential adopters, and the clinical innovation (Graham, Logan, 2004). This was accomplished through informal communication and formal evaluation of the CPG by a convenience sample of PICU team members. The formal evaluation of the CPG would provide the information necessary to determine the feasibility of implementing the guideline in the PICU. Formative evaluations are a type of descriptive, developmental evaluation, an approach that is useful for describing consumer satisfaction and providing key stakeholders a basis for quality improvement considerations (Ovretveit, 2002). This method is particularly useful in the early developmental stages of a new service to describe the intervention and provide users a more informed judgement on the value of the innovation (Ovretveit, 2002).

Purpose of the Formative Evaluation.

The purpose of the formative evaluation includes the following:

1. Determine the feasibility of implementing the sedation guideline into the PICU culture and setting.
2. Obtain suggestions to improve the guideline and customize it to the beliefs and values of the PICU.
3. Identify barriers to implementing the guideline.
4. Identify suggestions to facilitate implementation and adoption of the sedation guideline.

Evaluation Format.

A questionnaire format was chosen to evaluate the sedation CPG. This design is appropriate when data is required regarding knowledge, values, beliefs, feelings and attitudes (LoBiondo-Wood & Haber, 2002). The questionnaire was composed of two sections, the first having a table with goal statements and a Likert Scale, the second having open-ended questions for collecting qualitative information (Appendix J). The content was chosen to reflect the information found in the literature review regarding sedation guideline. The Likert Scale was chosen to measure the degree the participants agreed with the proposed goals of the CPG. It is a ranking scale that is an ordinal level of measurement that is commonly used for this purpose (Jamieson, 2004). Qualitative data included suggested revisions to the CPG, and barriers to implementation, with strategies to manage these barriers. Space was allotted for miscellaneous comments or questions, and a check-off box to indicate their overall support for the CPG. Open-

ended questions were more appropriate in this case to allow the reader to respond in their own words (LoBiondo-Wood & Haber, 2002).

Data Analysis.

The responses obtained from the five-point Likert Scale were analyzed using descriptive statistics. Although calculating mode or median would have been more appropriate for this ordinal type of ranking (Jamieson, 2004), the small sample size precluded this type of analysis. Content analysis of the narrative responses identified several themes relating to suggested revisions of the guideline, barriers to implementation with suggestions to facilitate implementation, and miscellaneous questions the respondents posed to the evaluator.

Dissemination of Results.

The findings of the evaluation were reviewed, compiled and a report made available to the PICU staff members two weeks after the closure of the data collection period (Appendix K). This report, along with a revised guideline and plan for implementation and evaluation, would be presented to the PICU Patient Care Team in the fall of 2005 for consideration.

Ethical Considerations.

Ethical approval was obtained by the Education / Nursing Ethics Board from the University of Manitoba (Appendix L). A form was used to obtain consent from the participants of the discussion groups prior to commencement of the session (Appendix M). Informed consent is required to ensure the participants have adequate information regarding the evaluation process, are capable of comprehending the information and

have the free will to voluntarily agree or decline participation (Polit & Hungler, 1995). A statement of confidentiality will be attached to clarify confidentiality rules of the discussion. Ovretveit (2002) indicates a written statement given to the participants is recommended to maintain trust and cooperation by describing the evaluation process and confidentiality rules for the discussion and whom the report will be made available to.

Recruitment Strategy.

The method of convenience sampling was employed for the review of the sedation CPG. Attending Physicians, nurses, Respiratory Therapists, Pharmacists, Physiotherapists, and Occupational Therapists were considered eligible for inclusion in the evaluation. Social work, Unit Clerks and Unit Assistants were excluded from the project, as they are not directly involved in the medical care of the patients. Considering the heterogeneity of the PICU and the multi-disciplinary team approach, the distribution to all disciplines allowed for a broader representation of the sample and ability to generalize the findings (Polit & Hungler, 1995). Packages consisting of a cover letter, the consent form, the guideline and a questionnaire were made available in the PICU multi-disciplinary room, the pharmacy, the Physiotherapy/Occupational Therapy department and Respiratory Therapy lounge for staff unable to be reached in person.

Participation in the evaluation was presented to the PICU team using four methods, emphasizing the voluntary nature of the project. Staff members were notified of the project and their participation requested utilizing the hospital e-mail system, a

poster in the staff lounge and several personal presentations. Group presentations were not feasible due to the physical layout of the unit and the inability of nurses to leave the bedside for patient safety reasons. Personal presentations were particularly helpful in the current study and they have been found to increase the return rate and allow for explanation and clarification of the project (Polit & Hungler, 1995).

Chapter 4: Findings of the Formative Evaluation

This chapter illustrates the findings of the evaluation of the sedation CPG conducted in the PICU. The purpose of the evaluation was three-fold: determine the feasibility of implementing the sedation CPG into the PICU culture, obtain suggestions to improve the CPG, and identify barriers to implementation and associated management strategies.

Evaluation of the Clinical Practice Guideline

Seventy-seven evaluation packages were distributed to all PICU disciplines in attempts to obtain a representative sample. Team members were asked to review the sedation CPG and complete the questionnaire seen in appendix F. In accordance with Board of Ethics requirements, participation was voluntary, requiring the employment of a convenience sample. Nineteen evaluation forms were received for a response rate of 24.7%. Content analysis of the qualitative data demonstrated the presentation of themes. Table one demonstrates the level of agreement the respondents held regarding the proposed goals of the CPG utilizing a five-point Likert scale. Responses were tabulated based on frequency and percentages to provide a descriptive analysis. Likert scales are an ordinal measure and have a rank order, but the intervals cannot be presumed equal. Calculating the mean and standard deviation would be inappropriate for the numbers reflect verbal statements. In this case using frequency and percentages for each category is appropriate (Jamieson, 2004). This is reflective of the purpose of a formative evaluation and the desire to validate the goals of an innovation and improve the innovation where necessary (LoBiondo-Wood & Haber, 2004).

Table 1. Level of agreement with objectives of the CPG

Question	Strongly Agree	Agree	Undecided*	Disagree	Strongly Disagree
The CPG will improve patient safety.	5 26.3%	8 42.1%	6 31.6%		
The CPG will facilitate communication between team members regarding the desired sedation goal for patients.	5 26.3%	12 63.2%	2 10.5%		
The CPG will standardize the approach to managing sedation.	4 21.1%	10 52.6%	5 26.3%		
The CPG will increase nursing autonomy in the delivery of medications to maintain the established sedation gaol.	4 21.1%	10 52.6%	5 26.3%		
The CPG will increase overall team satisfaction with sedation practices.	2 10.5%	5 26.3%	11 57.9%	1 5.3%	
The CPG is easy to read and understand.	6 31.6%	9 47.4%	2 10.5%	2 10.5%	
The CPG is in a format pleasing to the eye.	6 31.6%	8 42.1%	2 10.5%	3 15.8%	
The CPG contains all the information required for me to follow the recommendations made in the CPG.	3 15.8%	8 42.1%	3 15.8%	5 26.3%	

The majority of participants agreed or strongly agreed, the sedation guideline would improve patient safety (68.4%), allow for improved communication regarding the desired sedation goal (89.5%), standardize sedation practices (73.7%), and increase nursing autonomy for drug administration (73.7%). More than half (63.2%) did not agree, or felt uncertain, the guideline would improve overall team satisfaction with sedation practices. The majority of respondents agreed the guideline was easy to read (79%) and it was printed in a format that was pleasant to the eye (73.7%). Just over half (57.9%) felt the guideline contained all the information necessary to implement the guideline while 26.3% felt content was lacking in some regard.

Suggested Revisions.

Suggested revisions from the evaluation to improve the CPG focused on changes in format or content. Suggestions for changes in format included the following:

- streamlining the guideline & simplifying the "how to use" section.
- emphasizing the guideline portion.
- creating an abbreviated version for each.

Suggested changes to the content of the CPG included:

- the addition of recommendations for managing and monitoring over-sedation
- defining terms (high/moderate/low drug doses, physician, "a few hours" and age groups)
- differentiating between sedation for anxiety and analgesia for pain
- monitoring for withdrawal greater than 24 hours

- adding the sedation opinion score of the Respiratory Therapist when weaning ventilator in conjunction with the NOS.
- clarifying descriptions of patient behavior in the Penn State Protocol
- developing a list of specific medications and dosage ranges for each Penn State sedation level.
- deleting physical dependence for it may not be avoidable
- defining monitoring recommendations after administration of PRN medications and infusion changes
- deleting chloral hydrate for managing withdrawal and recommending only a benzodiazepine.
- deleting the Oxford Level of Evidence because it was too confusing.
- developing high/moderate/low ranges for the COMFORT-B scores
- recording signs of withdrawal and untoward events on the flowsheet not the patient chart.
- deleting the nurse's opinion score (NOS).

Barriers to Implementation.

The identification of barriers is crucial to the successful implementation of a clinical innovation in order to identify issues that could negatively impact adoption (Graham & Logan, 2004). Potential barriers identified in the CPG evaluation presented as four themes surrounding education, communication, collaborative approach, and personal resistance.

1. Education.

Issues related to education surrounded the lack of education by PICU staff including Residents, and staff on the general wards. Specific comments include the following:

- There is a lack of education regarding the Penn State Sedation Protocol and training would be required in order to implement this tool.
- The levels from the Penn State protocol could be interpreted differently.
- The guideline has too many tools (NOS, COMFORT-B score, Penn State sedation level).
- The Residents rotate through the unit on a monthly basis and need to be educated about the guideline.
- The recommendations for monitoring signs of withdrawal could be problematic once the patient was transferred out of PICU. Monitoring may not continue due to the lack of training on the general wards.
- A fourth issue referred to nursing experience and how impacts medication administration. There was concern that inexperienced nurses would administer excessive doses of sedation in attempts to minimize patient movement, basing administration on their comfort level and not on patient need.
- The guideline doesn't direct the administration of specific medications.
- Physicians may change the orders according to personal preferences after the plan had been established.

2. Communication

Three issues regarding communication between team members were identified as potential barriers to implementing the CPG. It is inferred; this poor communication would lead to problems following the sedation CPG. Examples of this includes:

- The perception that no one 'cares' about the COMFORT scores because it is not often discussed in rounds, thus, giving the impression that sedation assessment is not important.
- Failure of nurses to report in daily rounds, the total amount of medication used. These practices may lead to uncertainty that the sedation plan is effective and safe. This uncertainty, combined with
- The fear that changes in the plans may not be relayed to all team members.
- The fear that a collaborative approach may not be emphasized.

3. Collaborative Approach.

Concerns relating to a collaborative approach related to the fear that all disciplines would not agree to the sedation CPG. This infers that the failure of utilizing a team approach would create a barrier to effective implementation. Examples of this include:

- It was emphasized respiratory therapy must be informed of all changes in patient status, especially as they relate to the ETT and mechanical ventilation.
- Respiratory Therapy wanted a RT opinion score in conjunction with the Nurses opinion score regarding sedation adequacy, especially when weaning the ventilator.

- Need for 'buy in' by all disciplines.
- A consensus is needed from all Physicians regarding specific drugs for each level of the Penn State Sedation Protocol.

4. Personal Resistance.

Respondents raised concerns that certain Physicians and Nurses may resist accepting and using the guideline for personal reasons. Examples of these concerns include:

- Certain nurses might reject the guideline because they do not want the autonomy the guideline proposes.
- Certain nurses would choose not to follow the established sedation goal and over-sedate to ease their workload.
- Resistance may occur from the perception that the guideline increases their workload.
- Concern that certain Physicians would be reluctant to relinquish control over sedation practices and refuse to follow the guideline.

Facilitators of Implementation.

Recommendations to manage the barriers to implementing the sedation include the following:

- a comprehensive education plan that includes the Residents and a plan to re-educate 4-6 months after implementation.
- Commitment to follow the guideline from all disciplines and individual team members.

- Placement of an abbreviated version of the guideline at each bedside for easy access.
- Reinforcement of the guideline during rounds on a daily basis.
- Development of a check-off sheet to record sedation levels for each patient during rounds as a reminder to use the CPG.
- Effective communication and sharing of sedation plans and changes in patient status with all disciplines.
- A consensus by Physicians and Pharmacists regarding the use of specific medications for each level defined in the Penn State protocol.
- A trial period to demonstrate the value of the guideline and the achievement of proposed goals.

Miscellaneous Questions.

Participants of the evaluation used the narrative space designated for 'other' comments to provide information other than what was requested by the researcher. Open-ended questions such as this are useful for allowing the participant to respond in their own words and when the researcher does not know all the potential responses (LoBiondo-Wood & Haber, 2004). The information provided in this section would be useful when designing the educational plan and meeting the needs of the team members. Questions surrounded four topics that included scoring tools for assessing sedation, levelling of evidence, medications, and evaluation of the guideline.

Assessment/Scoring tools.

1. Do we need all three tools? (NOS, COMFORT B score and Penn State sedation level).
2. Is there a plan to include a tool for scoring withdrawal?
3. How many signs constitute withdrawal?
4. Is there a plan to include the Neonatal Abstinence Score?

Level of Evidence.

1. How does the level of evidence apply to the guideline?

Medications.

1. How will we manage drug dosages that are higher than what is recommended in the Pediatric drug guideline?
2. What if a new Resident orders too wide a range for a drug infusion?
3. Who recommends the medications?

Evaluation.

1. How long will the data collection period be?
2. Will the nurse's level of understanding be evaluated?
3. What will be done with the NOS data?

Other Comments.

Overall the miscellaneous comments were positive and generally praised the guideline and the work done by the developer. One respondent anticipated that a benefit of the CPG would be the ability to respond to patient's sedation needs more quickly. It was felt the CPG would allow nurses more freedom and uniformity in caring

for this population and reduce the number of accidental extubations and fluctuations seen in sedation practices.

Summary of the Findings

The formative evaluation of the sedation CPG provided sufficient information to determine that it is feasible to implement the guideline into the PICU with the majority of respondents supportive of the project. Respondents indicated the CPG would improve patient safety and communication, standardize sedation practices, and promote nursing autonomy. Content analysis of the narrative responses demonstrated themes regarding barriers to implementation and management strategies to promote uptake of the clinical innovation. Revisions were identified to improve the CPG. The interpretation of these findings with reference to the OMRU will be discussed in the proceeding chapter of this project.

Chapter 5: Discussion

This chapter will discuss the findings of the descriptive evaluation of the sedation CPG in accordance with the Ottawa Model of Research Use (OMRU) and the processes recommended for CPG development. A dissemination plan for the findings, limitations of the literature and evaluation design will then be discussed.

Utilization of the Findings: Application of the OMRU

This project focused on the first stage of the OMRU (Appendix G) and includes the assessment of the practice environment, potential adopters, and the sedation CPG. The findings of the evaluation provided the information necessary to accomplish this first stage of CPG development. Graham (2004) states the practice setting, potential adopters, and the attributes of the CPG influence the uptake of research. Assessment of these factors allow for the identification of barriers and facilitators that will impact the integration of the CPG into clinical practice (Graham & Logan, 2003).

Profile of the Practice Environment

The practice environment has been identified in the literature as the most important factor in promoting best nursing practice (Graham & Logan, 2003). This environment is dynamic and directly influences the implementation of a clinical practice guideline through potential barriers and supporting factors (Hogan & Logan, 2004). The environment must be supportive of knowledge transfer and promoting best practice initiatives for a change to be successful (Graham & Logan, 2003). The practice environment includes the administrative structure and decision-making authority, culture, patient population and economic factors.

Structure.

Structure pertains to the decision-making structure and process for the development of regulations and policies (Graham & Logan, 2004). The PICU is an eight-bed unit governed by a multidisciplinary team. This team is composed of the following: a Chief Medical Director, an Attending Physician, the Manager of Patient Care, the PICU Nurse Practitioner, a Clinical Resource Nurse, a Clinical Educator, a General Duty Nurse, a Pharmacist, a Respiratory Therapist, and a Social Worker for the PICU. Decisions regarding practice changes are under the direction of this team as they represent the various disciplines in the PICU. A proposal of the sedation guideline was presented to the team and approval received for development of the sedation CPG. This revealed that team members perceived the seriousness of the effect inconsistent sedation practices placed upon patient comfort and the ability to facilitate therapies such as ETT placement and mechanical ventilation. Thus, this project was deemed of great value for the improvement of patient care and safety.

Culture.

Culture of the environment relates to the belief systems, local politics and personalities, leadership, and the endorsement of change by local champions (Graham, 2004). An assessment of the social environment or culture of the PICU proved to be positive with the identification of few barriers. This organization has a strong history of quality improvement initiatives and of supporting evidenced based practice. The Nurse Practitioner in the PICU has implemented two evidenced based guidelines in the PICU, and has provided education to further the EBP movement. The PICU is currently

involved in a collaborative, multi-centre, quality improvement initiative across Canada for the purpose of improving patient care. The successful implementation of previous CPG's in the PICU and the multiple projects currently underway confirmed the culture was supportive of clinical innovations such as the sedation CPG. This was supported by the CPG evaluation where 78% of respondents expressed their overall support for the implementation of the sedation CPG. Although slightly more than half (58%) of respondents were uncertain the CPG would improve team satisfaction with sedation practices, almost 90% believed it would improve communication regarding the desired sedation goals, and 74% agreed it would increase nursing autonomy for maintaining these goals. It is apparent the respondents support the CPG and anticipate positive outcomes, but the uncertainty of improving satisfaction in sedation practices exists.

Barriers to the implementation of the CPG identified by the evaluation included issues surrounding education, multidisciplinary collaboration, communication, personal resistance and evaluation. The evaluation findings emphasized the need for a collaborative approach and education to enhance communication, understanding of the guideline, and improve acceptance of the CPG. It was believed a trial period and data collection to prove the achievement of goals of the CPG would facilitate the acceptance and adoption of the guideline. After reviewing the barriers, it appeared they could be managed through a comprehensive education plan combined with support by leaders in the PICU.

Patient Factors.

An assessment of the patient factors of the practice environment determined the infants and children requiring an endotracheal tube and mechanical ventilation would most benefit from a sedation guideline. As discussed earlier, a review of the sedation practices in the PICU determined a lack of uniformity and inadequate sedation contributed to unplanned extubations. As a result, this placed patients at risk for life-threatening events such as hypoxia and bradycardia secondary to unplanned extubations. This risk appeared substantial in that a majority of patient days (61%) demonstrated patients requiring an endotracheal tube and mechanical ventilation. This project proposed the sedation CPG would improve patient safety by standardizing the approach to sedation. The evaluation demonstrated overall corroboration with these anticipated outcomes. Seventy-four percent of respondents agreed the guideline would standardize sedation practices and 68% anticipated improvements in patient safety.

Economic Factors.

Economic factors to consider when implementing a change in practice include remuneration, resources and equipment (Graham & Logan, 2004). An informal economic assessment of the environment revealed a cost of $1,142 dollars per patient day in the PICU. Further expenses are dependent upon on the severity of illness and diagnostics or therapeutics that are required. It was proposed the sedation CPG might provide a financial savings in that unplanned extubations have been associated with an increase in ventilator days and ICU days (8 days versus 4 days) in pediatric patients (n = 2,192) (Sadowski et al., 2004). Extrapolation of this data concludes unplanned

extubations have the potential to increase total health costs by $4,568 per patient, amounting to $45,680 for the ten unplanned that occurred during the review period in the PICU. Studies also indicate an overall cost savings attributed to the implementation of a sedation protocol. Popernack and colleagues (2004) claim their sedation guideline reduced their unplanned extubation rate to zero at one point during their data collection period. Studies on adult patients have associated a reduction in ICU and hospital days and costs per case with a sedation guideline (Brook et al., 1999; Greiner & Greiner, 2004). Although one must accept studies based upon adult cautiously the data appears promising. Despite limited studies, the evidence does support the potential for cost savings through improved resource utilization.

No major costs were anticipated in the development and implementation of the sedation CPG. The PICU presently has supportive resources in place including a Clinical Educator, Nurse Practitioner, Administrative Assistant, and key nursing staff interested in participating in quality improvement initiatives. The main developer of the sedation guideline was a student Nurse Practitioner training in the PICU whose time was not financially supported by the PICU. Anticipated costs of the guideline include the cost of paper to produce copies of the guideline for each of eight bedsides and the time required to educate and evaluate the guideline after implementation.

Potential Adopters

Assessment of the potential adopters, or target users of the CPG is required to determine attitudes, knowledge, skills, and motivation for the proposed change (Graham & Logan, 2004). The potential adopters for the sedation guideline include nurses,

Attending Physicians, Respiratory Therapists, Pharmacists, Physiotherapists and Occupational Therapists that are employed in the PICU. Additional adopters, considered to be opinion leaders, support frontline staff and include the Manager of Patient Care, Nurse Practitioner and Clinical Educator.

An informal interview was performed to investigate the attitudes of several PICU team members regarding sedation practices and the potential support for a sedation guideline. More detailed information was obtained through the formal evaluation of the CPG. Nursing indicated there was the perception that the various Attending Physicians and Pharmacists demonstrated personal styles and preferences that resulted in sedation practices that were confusing and inconsistent. Several nurses indicated the sedation assessment tool currently used, the COMFORT Scale, was difficult to use for heart rate and blood pressure could be affected by factors other than distress. Several staff members expressed their motivation toward a change in practice surrounding sedation management. This informal data collection was considered crucial for "soliciting support from consumers is pivotal to fostering research uptake and use by clinicians" (Graham & Logan, 2003, p. 20). The formal CPG evaluation supported this preliminary acceptance of the sedation CPG with the majority of respondents (78%) agreeing to the project. Support by the PICU NP was demonstrated by her ongoing involvement in the development of the CPG. This was key to the success of the project for engaging leaders to champion a project facilitates research uptake and use by the adopters (Graham & Logan, 2003).

It was presumed that the majority of PICU team members had the knowledge and skills that would be required to adopt a CPG for managing sedation. The PICU Nurse Practitioner had previously educated staff on the concepts of EBP, CPG's and sedation assessment utilizing the COMFORT Scale. Their knowledge of EBP and the clinical application of CPGs had been demonstrated by the successful implementation of two guidelines in the PICU in the past. These factors were considered as major supports that would facilitate the implementation and adoption of the sedation CPG.

The Clinical Innovation

Several factors associated with the CPG have been identified in the literature to affect the adoption of an innovation. Attributes of a CPG deemed important include relative advantages, complexity, compatibility, ability to trial the change, and the demonstration of observable benefits (Landrum, 1998; Graham & Logan, 2003).

The potential benefits of a sedation CPG have been discussed earlier, and include improved patient care. Sedation assessment tools, goal-directed sedation practices, and weaning protocols appear to be associated with positive outcomes in the literature that impact the patient, practitioner and system (Popernack et al., 2004; Bennett, 2003; Brook et al., 1999; Greiner & Greiner, 2004). Benefits of the guideline should be emphasized in the education plan for the greater the perceived advantages of a change the greater possibility it will be adopted. Failure to convince the potential users of the merit and value of a proposed change will result in the decision to abandon an innovation (Landrum, 1998).

"Complexity refers to the degree to which target adopters perceives an innovation as difficult to understand and use" (Landrum, 1998, p. 197). The more complex the change in practice is perceived to be, the more time it will take for users to adopt the practice. Despite the majority of respondents indicating the CPG is easy to read and understand (n = 15, 79%), one respondent indicated the Oxford levelling of evidence was confusing and should be deleted. Another respondent preferred a simplified and abbreviated version of the guideline for quicker information retrieval at the bedside. This emphasizes the need for the guideline to be presented in a format that is suitable to the target population, a factor that facilitates the uptake of a change in practice (Miller & Kearney, 2003). The evaluation confirmed changes were necessary to facilitate adoption with only 58% of respondents felt the guideline contained all the information necessary for implementation. This was clarified in the narrative section where specific revisions to format and content were made as discussed earlier.

Compatibility refers to the degree a potential adopter feels the innovation is consistent with their own values and beliefs (Landrum, 1998). It appeared, through informal evaluation that patient safety was of great importance to staff members. This was complimented by 68% of respondents in the evaluation agreed the CPG would improve patient safety.

The ability to try a clinical innovation on a smaller scale prior to full implementation is known to facilitate the adoption of a change in practice (Landrum, 1998). A pilot of the innovation would also facilitate the establishment of credibility (Buonocore, 2004) and discover issues not identified in the assessment of barriers.

These concepts were reflected in the evaluation by respondents suggesting a trial of the guideline on a small sample of patients. This may indicate members of the PICU would welcome the opportunity to pilot the sedation CPG. The sedation guideline utilizes an individualized approach for each patient, thus facilitating the ability to pilot the change in practice.

'Observability' refers to the degree adopters can observe the outcomes or benefits of an innovation (Landrum 1998). The more obvious the benefits, the more quickly a change in practice will be adopted. Adherence to the sedation guideline would be obvious on a daily basis as team members emphasized the importance of adequate sedation and goals during rounds. The degree of staff satisfaction with the CPG would also be evident during these rounds. Data collection during a pilot of the CPG would provide further information regarding the values of the guideline. The rate of unplanned extubations, documentation of sedation assessment and length of stay are just a few examples.

Dissemination of Findings

The findings of the CPG evaluation were compiled into a report and sent to all members of the PICU through the hospital e-mail system and by posting reports in the multidisciplinary room in the PICU (Appendix K). This report, the revised CPG, and a plan for a pilot and evaluation of the CPG will be presented to the PICU Patient Care Team in September 2005 for future consideration.

Limitations

Research Availability.

There is a paucity of research studies conducted in the PICU setting for managing sedation in the intubated patient. The limited number of available studies impinges on the inclination to implement a change in practice. This is rarely appropriate when recommended change is based on a single study (LoBiondo-Wood & Haber, 2002). Too few studies, combined with evidence that is based upon a lower level of evidence, makes it difficult to develop a CPG. A common hierarchy places RCT's and high quality systematic reviews at the top reflecting the highest level of evidence (Sackett, Strauss, Richardson, Rosenberg, & Haynes, 2000). This model however, places constraints on problems that cannot be quantified or rigorously scientifically tested (Miller & Kearney, 2003). This may be the reason that recommendations for sedating pediatric ICU patients are based upon surveys, case reports, observational studies utilizing small samples, and 'expert' judgement. This is consistent however, with a literature review that suggests a majority of guidelines are produced from literature reviews and expert opinion (Miller & Kearney, 2003).

Despite the limitations in the available literature, the articles selected provide a degree of evidence that is acceptable. In fact, the medical literature is still dominated by case studies, observational studies, and uncontrolled trials (Geyman, Deyo, & Ramsey, 2000). What should be emphasized is not the value of a study according to the evidence hierarchy, but to the degree to which it answers a clinical question and has clinical relevancy (McSherry, Simmons, & Abbott, 2002). Studies based on adult

populations, although promising, prohibit the ability to generalize data and recommendations to the pediatric population (Polit & Hungler, 1995). The relevant studies selected for the sedation CPG were conducted on infants and children who were intubated in a PICU setting. Study samples are similar to some degree to the population in the Winnipeg PICU. The studies were relevant to the author's intention of standardizing sedation practices and adequately answered this clinical question.

The Evaluation.

A review of the CPG evaluation demonstrated several limitations surrounding the sampling strategy, sample size, and questionnaire. This leads to the potential for biases, inaccurate results, and the risk of drawing erroneous conclusions. Utilizing a non-probability sampling strategy, such as the convenience sample employed in the CPG evaluation, a sample is produced that is less representative of the target population (LoBiondo-Wood & Haber, 2002). Convenience sampling is self-selective meaning only those who feel strongly about a subject will choose to participate (Lo-Biondo-Wood & Haber, 2002). Despite all members of the PICU having the opportunity to participate, a convenience sample does not ensure adequate representation from all disciplines. A quota-sampling design would have ensured sufficient representation by choosing a proportion of each discipline in the sample (Loiselle & Profetto-McGrath, 2004). Failure to collect demographic data that would identify the disciplines compounded this issue.

Limitations in response rates are affected by response and non-response biases. A response rate of 25% from the CPG evaluation makes interpretation of the data difficult and must be accepted with caution. A response rate of 65%, considered to be

high, would have been sufficient to negate the impact of the non-response bias (Polit & Beck, 2004). Non-response bias occurs because one cannot determine the differences between those who chose to participate and those who declined (Loiselle & Profetto-McGrath,2004). Thus, unable to describe the non-responders, sufficient representation of the PICU members cannot be guaranteed and the inability to generalize the results to the entire PICU population. It can only be speculated as to why many PICU members chose not to participate. Summer vacations, illness, a rotating schedule and the complexity of the evaluation may be reasons for not participating. The guideline is ten pages and requires fair time and concentration to review and complete the questionnaire. This forced interested participants to attempt completing the package at home, which could easily have been forgotten in many cases. A few PICU staff members indicated they intended to participate but could not complete the task while working in the PICU due to the busy nature of the unit.

Determining the validity and reliability of an instrument is imperative to every evaluation. Validity refers to an instrument's ability to accurately measure what it is intended to measure, while reliability allows the same results to be yielded upon repeated testing (Lo-Biondo-Wood & Haber, 2002). Failure to ensure validity and reliability leads to questionable results and inaccurate generalizations. Content and face validity of the questionnaire was achieved by having the PICU Nurse Practitioner review the questionnaire. Having an expert in the field review the survey ensures the questions reflect the contextual aspects of the topic or they at least appear to measure the concepts (Polit & Hungler, 1995). The limitation of the questionnaire lies in the

failure to test the reliability of the section of the tool that utilizes the Likert scale and measures level of agreement to the proposed goals of the CPG. Employing a test-retest strategy, the questionnaire could have been administered to a small sample twice and the scores compared (Polit & Hungler, 1995). Or a second version of the questionnaire could have been developed to administer on the second round to ensure parallel reliability (LoBiondo-Wood & Haber, 2004). Despite attempts at ensuring validity, the failure to achieve reliability limits the generalizabilty of the results of the evaluation.

Although questionnaires are easy to employ it is difficult to ensure the respondents accurately portray their true feelings. This design is prone to biases that make interpretation of the results difficult. 'Social desirability' relates to participants responding in a way that makes them look favourable (LoBiondo-Wood & Haber, 2002). 'Extreme responders' tend to represent their opinions in extremes regardless of their true feelings. 'Nay-sayers' tend to disagree independently of the question. An 'acquiescence response set' reflects the participants agreement with the statements regardless of the content (Polit & Hungler, 1995). Although the accuracy of the responses cannot be guaranteed, it must be assumed respondents are representing their true feelings.

The limitations described above should not devalue the sedation CPG but raise awareness of them; "acknowledgement of limitations is highly appropriate: it is fine to have them, but they must be acknowledged" (Hamer & Collinson, 1999, p. 38). Despite these limitations, the literature and evaluation of the sedation CPG provides a basis for future contributions to improving the quality of care in the PICU.

Significance of the Project

I feel this project is a great opportunity for demonstrating evidenced based practice and operationalizing the process of knowledge transfer. The guideline is based on the most current research, and as a quality improvement initiative, emphasizes improved quality of care. The guideline attempts to meet the needs of the patient for improving sedation practices by promoting safety and comfort, and the need for standardizing sedation practices for the team members. I also believe this project directs future research in the field of pediatric sedation management for the purpose of enhancing the existing body of knowledge.

Summary

This chapter discusses the evaluation of the sedation CPG and the application of the OMRU. Stage one of the OMRU involved the assessment of there domains: the practice environment to identify barriers to implementing the innovation, the potential adopters in regards to skills and knowledge, and the CPG for appropriateness. Informal communication with team members and formal evaluation utilizing a questionnaire determined the practice environment promotes EBP and is very supportive of the sedation CPG. Barriers and facilitating strategies to implementing the CPG surrounded education, multidisciplinary collaboration, communication, resistance and evaluation of the CPG. It is assumed the team members have the skills and knowledge necessary to implement the sedation CPG, and only require information specific to the Penn State Sedation Protocol. Suggestions for improving the content and format of the CPG were discussed. The limitations of the available literature and evaluation of the CPG are

acknowledged and the recommendations made in the CPG are to be accepted with caution until further research is available.

Chapter 7: Recommendations

The purpose of this practicum project was to develop a clinical practice guideline (CPG) for managing sedation for the population defined earlier. A descriptive evaluation of the CPG was conducted according to stage one of the OMRU. The findings of the evaluation identified barriers and facilitators for the implementation and evaluation of the CPG. Utilizing the findings of the evaluation, this chapter will discuss stages two and three of the OMRU, recommendations for implementing and evaluating the CPG. Components of the recommendations include the following:

1. Revise the CPG and develop an abbreviated version.
2. Identify educational strategies that accommodate the barriers and facilitators identified in the evaluation.
3. Develop an implementation plan for a pilot project.
4. Identify an evaluation plan to accompany the pilot project.

Revision of the Clinical Practice Guideline

Suggestions for revisions obtained in the evaluation of the CPG provide the basis for revising the guideline. These revisions allow for the modification of an innovation deemed 'best practice' to suit each situation where it is applied in consideration that *best* is not necessary *best* for everyone (Newell, Scarbrough, Swan, & Bresnen, 2003). Suggested revisions will be considered and those deemed feasible will be integrated into the second draft of the CPG. An abbreviated version of the CPG will also be developed for each bedside to allow for quick retrieval of information.

Educational Strategies

The OMRU provides the framework for stage two of developing and implementing a clinical innovation (Appendix H). Components of stage two encompass barrier management, transfer strategies, and the adoption and use of the CPG (Graham & Logan, 2003).

Effective implementation strategies include consideration of barriers and strategies to manage these barriers. Barriers identified in the CPB evaluation centred on a lack of education regarding the components of the CPG, the fear ineffective communication would inhibit adoption and promotion of the CPG, the lack of a multidisciplinary or collaborative approach for managing sedation, and resistance to adopt the CPG for personal reasons. These barriers can be managed effectively by tailoring the education process specific to the needs of the potential users through transfer strategies.

Implementation involves the *dissemination* of information, or transferring the knowledge to the target users, and *utilization*, ensuring the purpose or impact of the innovation is known (RUSH, n.d.). Prior to incorporating research into practice, the users must be convinced the innovation is beneficial (Bennett, 2003). Transfer strategies aim to ensure each potential adopter is aware of the CPG, comprehends the required change in practice, and has the skills and knowledge, to exhibit the new behaviour (Graham& Logan, 2004). Despite insufficient evidence to recommend the best method for knowledge transfer the literature suggests a multi-faceted approach is most effective (Richens, 2004; Miller & Kearney, 2003). Methods such as targeted

seminars, educational outreach, patient-specific prompts, and the involvement of leaders, have been recommended (Miller & Kearney, 2003). Specifically, group interactive educational sessions have been shown to be more effective than didactic methods (Richens, 2004; Miller & Kearney, 2003). Other effective strategies recommended to facilitate the implementation of a CPG include the following:

- Building collaborative relationships among leaders and users.
- Employ opinion leaders (eg. PICU Patient Care Team) as change agents to lead the change in practice.
- Employ 'link nurses' for local support and facilitate the change in practice at the ward level (Clinical Resource Nurses, Nurse Practitioner, Clinical Educator).
- Use data and evidence to persuade and inform potential users.
- Integrate the change into 'everyday' practice.

(Richen, 2004; Miller & Kearney, 2003).

The education plan for the sedation CPG would first discuss the development process of the CPG with an explanation of the limitations as discussed earlier. The COMFORT-B sedation scale would be reviewed with reference made to the COMFORT scale currently used in the PICU. Instruction would be provided regarding the Penn State sedation protocol and weaning protocol in reference to the signs and symptoms of withdrawal. Utilizing a case study demonstration, the CPG would be discussed in a group setting emphasizing a collaborative, and multi-disciplinary approach.

Adoption and Use

According to the OMRU, the second stage of implementing a change in practice is the adoption and use of the innovation (Graham & Logan, 2004). Adoption entails monitoring to "determine the extent to which the innovation has been diffused throughout the potential adopter group and affected the process of care" (Graham & Logan, 2004, p. 98). This phase provides information to determine whether the interventions have been sufficient to promote the desired change. During the adoption stage decisions regarding the constitution of adoption are formalized, the measurements to be collected and the time frame for data collection.

The literature indicates a change that is gradual is more easily accepted than a change that occurs quickly (Landrum, 1998). For this reason a pilot of the sedation CPG is recommended to facilitate the adoption of the innovation (Buonocore, 2004). A pilot refers to the implementation of a change on a smaller scale to allow for the identification of problems prior to full implementation. A pilot may also test the time schedule for implementation and obtain an impression of the target user's acceptability of the CPG (van Bokhoven, et al., 2003). Employment of a clinical audit is recommended during the pilot to provide the users with feedback regarding adherence to the CPG and the benefits of the innovation. Clinical audits have been shown to be effective adjuncts in the implementation of CPG's for it provides incentive and motivation to continue the proposed change in practice (Richens, et al., 2004).

Evaluation

The third stage, the evaluation of the CPG, is the final stage of the OMRU. It is employed to determine whether the strategies utilized to promote the adoption of the innovation have been of any value (Graham & Logan, 2004). During this stage, decisions are made regarding the anticipated outcomes that impact the system, practitioner and patient, and a plan developed to outline data collection and time frame (Graham & Logan, 2004). The proposed outcomes for the sedation CPG include a reduction in the rate of unplanned extubations, increased patient comfort, reduced or maintained total ventilator days, reduced or maintained length of stay in PICU, and increased staff satisfaction with sedation practices.

A descriptive evaluation using observational and chart review methods for data collection is suggested for the pilot of the sedation CPG. This formative type of developmental evaluation allows the intentions of the innovation to be clarified, actual practice to be compared to intended practice, and feedback provided to the users (Ovretveit, 2002). Observations during daily rounds would provide information regarding adherence to the CPG guideline and utilization of a collaborative approach in determining the sedation goals. Reviewing the patient charts would provide information to describe sedation weaning strategies, signs of withdrawal, and management techniques. A questionnaire could be employed to describe the experience of the users and the acceptance of the CPG. An audit evaluation design using chart review methods for data collection would be appropriate to determine the utilization of the COMFORT-B sedation scale and Penn State sedation protocol. The documentation of sedation scores

would be collected from the PICU patient flowsheets, and the ordering of sedation levels from the physician's order sheets. A Before-After design could be used to determine the effect of the CPG on the rate of unplanned extubations, and the mean number of ventilator days, ICU days and hospital days. This design judges the value of an intervention by comparing a measurement determinant before and after the implementation of a change in practice (Ovretveit, 2002). Several evaluation methods could be employed to determine the appropriateness and acceptability of the CPG by the targeted users and measure the effectiveness of the CPG on patient care. These evaluation proposals would be presented to the PICU Patient Care Team for consideration.

Implementation Plan

Upon completion of the evaluation of the pilot, decisions would be made to formally adopt and implement the CPG on a full scale, modify the CPG again, or abandon the proposed change (Buonocore, 2004). The implementation of stages two and three of the OMRU, the intervention and adoption, and evaluation of the CPG, would be organized in collaboration with the PICU Patient Care Team. The findings of the CPG evaluation will provide the foundation as the basis for their decision to implement the proposed pilot and evaluation plan as discussed in this project.

Summary of Recommendations

This section discusses the second and third stages of CPG development and implementation according to the OMRU. Implementation of a CPG involves intervention strategies to facilitate transfer of the research into clinical practice and adoption of the

proposed change. Evaluation provides the information necessary to determine the effectiveness of the intervention strategies and the value of the innovation. Several interventions strategies were discussed to promote uptake of the CPG and various evaluation designs to measure adherence to the CPG and impact on patient care. The implementation and evaluation plans will be presented to the PICU Patient Care Team for future consideration.

Project Summary

The impetus for this practicum project lies in the emphasis on evidenced based practice in health care today. Research utilization, 'knowledge transfer', directs the transfer of evidence from research studies to the clinical setting. This project demonstrates the opportunity for improving patient safety and operationalizing evidenced based practice in the PICU (Miller & Kearney, 2003). A prior review identified inconsistent sedation practices in the PICU that contributed to unplanned extubations. Inadequate sedation and unplanned extubations have been associated with serious complications and life-threatening events. A validated evidenced based guideline for managing sedation was lacking in the PICU contributing to inconsistent sedation practices. A review of the literature determined sedation guidelines improve patient care and resource utilization. The literature provided sufficient evidence to develop a CPG for managing sedation that consisted of three components. The COMFORT Behavior Scale allows for the determination of sedation adequacy. The Penn State Sedation Protocol is a goal-directed tool for describing patient behavior and nursing actions for maintaining the established sedation goal according to six levels. Organized

strategies for weaning sedatives while monitoring for signs of withdrawal allow for an approach individualized to the patient degree of tolerance. The Ottawa Model of Research Use (OMRU) guided the development of this project and the recommendations for implementing and evaluating the CPG by the PICU team in the future. This project demonstrates a patient safety initiative that meets the needs of the patients for improving safety and comfort, and of the PICU team members by providing a standardized approach to managing sedation.

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Appendix A

Pediatric Sedation Scales

Name	Consciousness	Agitation	Ventilation	Pain	Psychological	Other
COMFORT Scale	X	X	X	X	X	Muscle tone
Hartwig Sedation Scale	X	X	X	X		Response to ETT suctioning
CH of Wisconsin Sedation Scale	X	X				
Neonatal Pain, Agitation & Sedation Scale	X	X		X	X	
University of Michigan Sedation Scale	X	X				
Vancouver Sedative Recovery Scale	X					

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Appendix B
COMFORT Scale

Table I. COMFORT Scale

	No. of Patients		No. of Patients
Alertness		Calmness/agitation	
Deeply asleep	1	Calm	1
Lightly asleep	2	Slightly anxious	2
Drowsy	3	Anxious	3
Fully awake and alert	4	Very anxious	4
Hyperalert	5	Panicky	5
Respiratory response		Physical movement	
No coughing, no spontaneous respiration	1	No movement	1
Spontaneous effort with little response to ventilator	2	Occasional, slight movement	2
Occasional cough or resistance to ventilator	3	Frequent, slight movement	3
Breathes against ventilator or coughs regularly	4	Vigorous movement limited to extremities	4
Fights ventilator, coughs, or chokes	5	Vigorous movement including head and torso	5
Blood pressure		Heart rate	
Blood pressure below baseline	1	Heart rate below baseline	1
Blood pressure consistently at baseline	2	Heart rate consistently at baseline	2
Infrequent elevations ≥15% above baseline	3	Infrequent elevations ≥15% above baseline	3
Frequent elevations ≥15% above baseline	4	Frequent elevations ≥15% above baseline	4
Sustained elevations ≥15% above baseline	5	Sustained elevations ≥15% above baseline	5
Muscle tone		Facial tension	
Muscles totally relaxed, no muscle tone	1	Facial muscles totally relaxed	1
Reduced muscle tone	2	Facial muscle tone normal, no tension evident	2
Normal muscle tone	3	Tension evident in some facial muscles	3
Increased muscle tone, flexion of fingers and toes	4	Tension evident throughout facial muscles	4
Extreme muscle rigidity, flexion of fingers and toes	5	Facial muscles contorted and grimacing	5

Tobias, J., & Berkenbosch, J. (2000). Tolerance during sedation in a pediatric ICU patient: Effects on the BIS monitor. *Journal of Clinical Anesthesia, 13*, 122-124.

Total score: 8 (very deeply sedated) – 40 (no sedation)

Appendix C
COMFORT Behavior Scale (COMFORT-B Scale)

Alertness	**1**	Deeply asleep (eyes closed, no response to changes in environment)
	2	Lightly asleep (eyes mostly closed, occasional responses)
	3	Drowsy (child closes eyes frequently, less responsive to environment)
	4	Awake and alert (child responsive to environment)
	5	Awake and hyperalert (exaggerated response to stimuli)
Calmness-Agitation	**1**	Calm (child appears comfortable)
	2	Slightly anxious (child shows mild anxiety)
	3	Anxious (child appears agitated but remains in control)
	4	Very anxious (child appears very agitated, barely in control)
	5	Panicky (child appears severely distressed and out of control)
Respiratory Response	**1**	No spontaneous respirations, no coughing
	2	Spontaneous respirations with little response to ventilator
	3	Some resistance to ventilator
	4	Active breathing against ventilator or regular coughing
	5	Fighting against ventilator/coughing/choking
Physical Movement	**1**	No movement
	2	Occasional (3 or fewer) slight movements
	3	Frequent (more than 3) slight movements
	4	Vigorous movements limited to extremities
	5	Vigorous movements including torso and head
Muscle Tone	**1**	Muscles totally relaxed, no tone
	2	Reduced muscle tone, less resistance than normal
	3	Normal muscle tone
	4	Increased muscle tone and flexion of limbs/hands
	5	Extreme muscle rigidity and flexion of limbs/hands
Facial Tension	**1**	Facial muscles totally relaxed
	2	Normal facial tone
	3	Periodic tension of facial muscles (not sustained)
	4	Tension of facial muscles (sustained)
	5	Facial muscles grimacing
Total COMFORT B score		

(Adapted from van Dijk, Peters, van Deventer & Tibboel, 2005, Wielenga, De Vos, de Leeuw & De Hann, 2004)

Appendix D
Penn State Children's Hospital Sedation Protocol

Sedation Level	Goal Patient Behavior	Nursing Action
1	Awake & interactive with environment.	PRN anxiolytics / analgesics.
2	Sleep, arouses to light stimulation, becomes excited with nursing care & suctioning, moves spontaneously, turns head, consistently breaths over ventilator rate.	PRN anxiolytics / analgesics, with or without continuous infusions of anxiolytics / analgesics, paralytics only if PRN sedatives fail.
3	Asleep most of the time, arouses to pain, coughs with suctioning, and breathes above ventilator, little spontaneous movement or head turning.	PRN anxiolytics / analgesics, with or without continuous infusions of anxiolytics / analgesics, paralytics only if PRN sedatives fail.
4	Asleep all the time, arouses to pain, coughs with suctioning, returns to sleep immediately, very little spontaneous movement, no head turning.	Continuous anxiolytics / analgesics, PRN anxiolytics / analgesics for breakthrough agitation, paralytics only if PRN sedatives fail.
5	Asleep all the time, minimal response to suctioning, no respiratory effort, very brief /few episodes of spontaneous movement	Continuous anxiolytics / analgesics, PRN anxiolytics / analgesics for breakthrough agitation, liberal use of paralytics if PRN sedatives fail.
6	Asleep, continuous paralysis.	Continuous anxiolytics / analgesics, continuous paralytics, PRN anxiolytics / analgesics titrated to vital signs. Observe for minor movements between supplemental doses.

(Popernack, Thomas & Lucking, 2004).

Appendix E
Signs & Symptoms of Withdrawal

Signs and Symptoms of Withdrawal from Opioids and Benzodiazepines

- Signs and symptoms of withdrawal affect the autonomic, neurological and gastrointestinal systems.
- Symptoms may become evident 1-24 hours after discontinuing medications.
- Symptoms may persist for up to 6-8 weeks.

Signs of withdrawal from opioids

- Irritability/agitation
- ↑ wakefulness
- poor organization of sleep states
- hyperactive deep tendon reflexes
- ↑ muscle tone
- high pitched cry/inconsolable
- Convulsions
- Tremors
- Twitching/jittery
- Pyrexia
- Diaphoresis
- Nasal stuffiness
- Mottling
- Gagging
- Poor feeding
- Uncoordinated suck
- Nausea/vomiting
- Diarrhea
- Tachycardia
- Tachypnea
- Skin excoriation / trashing

Signs of withdrawal from benzodiazepines

- anxiety (mild to severe)
- confusion
- insomnia
- perceptual disorders
- depression
- agitation
- visual hallucinations
- facial grimacing
- ataxia
- myoclonus
- retrograde amnesia
- anterograde amnesia
- dyskinetic movements
- poor visual tracking

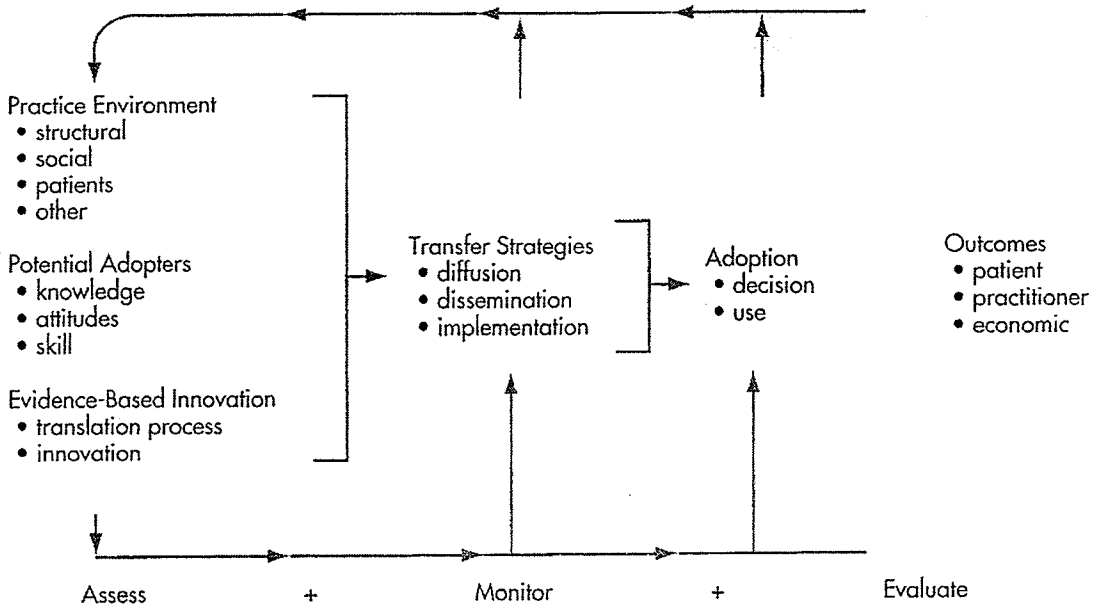
(Grehn, 1998; Carnevale & Ducharme, 1997; Bennett, 2003, Anand & Ingraham, 1996).

Appendix F: Recommendations for Weaning Sedation

Investigators	Medication	Initial dose reduction	Subsequent dose reductions	Frequency	Duration	Misc.
Yaster, Berde, & Billet, 1995 (PICU)	Opioids & Benzo's	10-20%	10-20%	Q24H	7-10 days	Change infusion to intermittent then ↑ interval then D/C when OD.
Anand & Ingraham, 1996 (PICU)	Low-moderate doses of opioids	20-40%	10-20%	Q6-8 H	3-4 days	Change infusion to intermittent, then ↑ interval, & change to oral. D/C when dose is 0.05-0.1mg/kg/day (≤4 yrs) or 0.01-0.02mg/kg/day (≥5yrs).
	High dose opioids	20-40%	10%	Q12-24H	2-3 weeks	
Grehn, 1998 (PICU)	Short term opioids	25-50%	25-50%	Q24H	Taper over number of days equal to number of days child received sedation.	
Bennet 2003 (PICU)	Low-moderate dose, ≤ 1wk, Opioids & Benzo's	25-50%	20%	Q 6-8 hours	72 hours	Change IV to oral, use adjunctive drugs, change infusion to intermittent, alternate agents.
	High dose, ≥ 1wk, Opioids & Benzo's	10-20%	10-20%	Q12-24H	Several days	
Franck, Naughton, & Winter, 2004 (PICU)	5-13 days Opioids & Benzo's	20%	20%	Q24H	N/A	N/A
	≥ 14 days Opioids & Benzo's	10%	10%	Q24H	N/A	
Ducharme, Carnevale, Clermont, & Shea 2005 (PICU)	Opioids & Benzo's: 1-3 days	20%	20%	Q24H	N/A	Limitations: Sedation assessment tool not proven reliable or valid. Small sample size: (n=1 - 11 per group).
	4-5 days	13-20%	13-20%	Q24H	N/A	
	6-7 days	13%	13%	Q24H	7 days	
	8-14 days	8-13%	8-13%	Q24H	N/A	
	15-21 days	≤8%	≤8%	Q24H	N/A	
	≥ 21 days	2-4%	2-4%	Q24H	Several weeks	

Appendix G

The Ottawa Model of Research Use (OMRU)



(As adapted from Logan & Graham, 1998 by LoBiondo-Wood & Haber, 2004).

Appendix H

PICU Sedation Clinical Practice Guideline

Purpose:
To provide an evidenced based clinical practice guideline to promote a standardized approach to managing sedation/analgesia for patients requiring an endotracheal tube and/or mechanical ventilation.

Policy:

- A physician's order is required for the level of sedation established by the multi-disciplinary team.
- Medications are ordered as per HSC policy.
- The Physician/ Nurse Practitioner must be informed of signs of withdrawal and appropriate actions taken to manage the symptoms.

Goals:

1. Improve patient safety:
   - By delivering pharmacological agents necessary to reduce or alleviate the pain and distress associated with endotracheal tubes and mechanical ventilation utilizing a standard approach.
   - By reducing the occurrence of unexpected (accidental) extubations.
   - By providing medication orders that will allow nursing to respond more quickly to sedation needs and prevent withdrawal and physical dependence.
2. Improve the assessment of sedation needs utilizing an evidenced based tool evidenced by documentation on the flowsheet.
3. Maintaining or reducing the total number of patient ventilator days.
4. Maintain or reduce the total number of PICU patient days.
5. Improve staff satisfaction with managing sedation for the target population.

Definition of Terms:

Evidenced based refers to an approach to clinical decision-making that integrates the best available evidence or research with clinical expertise and patient values for the purpose of optimizing clinical outcomes and quality of life.

Clinical practice guideline refers to systematically developed statements to assist the practitioner and patient decisions about appropriate health care for specific clinical circumstances.

Mechanical ventilation applies to all ventilators used in the PICU including BIPAP.

Tolerance refers to a decrease in effectiveness of a drug after prolonged use or as the requirements of larger doses to achieve the same effect.

Withdrawal is a syndrome of physiologic symptoms occurring in reaction to sudden discontinuation of a medication.

Physiologic dependence refers to the requirements for medication to prevent the signs of withdrawal.

Target Population:
This guideline applies to all infants and children admitted to the PICU who require sedation to maintain placement of an endotracheal tube and/or facilitate mechanical ventilation including BIPAP/CPAP.

The COMFORT Behavior Scale is validated for infants and children ≤ 3 years of age but may be used with caution in older children.

Exclusion criteria:
The sedation assessment tool (COMFORT Behavior Scale) does not apply to patients who are severely mentally challenged, have severe hypotonia, or patients receiving paralytic agents, as this tool is not validated in these populations. Assessment for adequacy of sedation must be determined by clinical judgement in these cases. These patients may still be levelled according to the Penn State Sedation Protocol to establish an appropriate goal of sedation..

Equipment/Tools:
- Penn State Sedation Protocol (CPG Appendix A)
- COMFORT Behavioural Scale (CPG Appendix B)
- Sedation weaning protocol (#6 page 4)
- Signs and symptoms of withdrawal (CPG Appendix C)

Monitoring:
- Continuous cardio-respiratory monitoring and oximetry as per PICU routine or as ordered by the physician.
- Ventilator alarms on.
- COMFORT Behavior Scale – assessment of the adequacy of sedation q 4 H and PRN when changes occur in patient status, sedation goals, or medication administration (including the use of PRN medications).
- Nurses Opinion Score (NOS) each time the patient is assessed in conjunction with the COMFORT Behavior Scale. This score will be an adjunct to incorporate clinical judgement to the assessment of sedation adequacy.

Education:

Nurses must receive education regarding the use of the COMFORT-B Scale and Penn State Sedation Protocol prior to using this guideline.

Safety Issues:

Patients must be continuously assessed for:

- Signs of tolerance and physical dependence while receiving sedation.
- Signs of withdrawal during weaning of sedation and for 48 hours after the cessation of sedation.

- The Physician/Nurse Practitioner must be informed of episodes of inadequate sedation when the sedation goal cannot be maintained despite administering available medications.

Guideline:

Determination of Sedation Goal: (Level 4 evidence, grade C recommendation)

1. Determine the appropriate sedation goals after placement of an endotracheal tube or initiation of mechanical ventilation.
   1.1 This is accomplished by determining the appropriate level on the Penn State Sedation Protocol (CPG Appendix A).
   1.2 The multidisciplinary team when possible should establish the goal of sedation.
   1.3 The goal of sedation is reassessed daily during patient rounds and PRN with changes in patient status.
   1.4 The established level of sedation is ordered by the practitioner and written on the Physician's order sheets.
2. Medications appropriate for the patient are ordered using a multidisciplinary approach that allows titration of infusion rates and the administration of PRN medications to maintain the established sedation goal.
3. The nurse uses clinical judgement and COMFORT-B scores to maintain the established sedation goals as indicated for each level on the Penn State Sedation Protocol utilizing the appropriate medications.
4. Monitor for signs of tolerance (eg. agitation, irritability, insomnia).

Assessment of Sedation Adequacy: (Level 4 evidence, grade C recommendation)

5. The COMFORT Behavior Scale (COMFORT-B Scale) is used to assess the adequacy of sedation (CPG Appendix B).
   5.1 The assessment of the adequacy of sedation should be performed a minimum of every 4 hours and PRN and scores documented on the patient flowsheet.
   5.2 Adequacy of sedation should also be assessed after the administration of PRN sedatives or change in infusion rates of sedatives to indicate effectiveness.
   5.3 A COMFORT-B score between 10-22 is a goal for adequate sedation.
6. A nurse's opinion score (NOS) is used as an adjunct to the COMFORT-B score based on clinical judgement. It indicates the nurse's opinion regarding the adequacy of sedation in conjunction with the COMFORT-B score.
   4.1 The nurse should record their opinion of sedation adequacy each time adequacy of sedation is assessed.
   Nurses Opinion Score (NOS): Under-sedated = 1
   Adequately sedated = 2
   Over-sedated = 3

Sedation Weaning Protocol: (consult with Pharmacy)

7. Children receiving low to moderate doses of sedation for less than one week:
   - Decrease dose initially by 25-50%.
   - Decrease subsequent doses by 20% every 6-8 hours as tolerated.
   - Wean sedation over a minimum of 72 hours.
8. Children receiving high doses of sedation or for greater than one week:
   - Use tapering technique over several days (suggest tapering over a period equal to the number of days sedation has been administered).
   - Reduce infusion rates by 10-20% every 12-24 hours as tolerated.
   - Consider addition of alternate sedative as adjunct to reduce the risk of dependence and assist in weaning other sedatives.
   - Consider conversion of intravenous medication to enteral routes.
   - Consider conversion of infusions to intermittent dosing.

Monitoring for Signs of Withdrawal: (Level 4 evidence, grade C recommendation)

9. Monitor patients continuously for signs of withdrawal during the weaning process and for up to 48 hours after sedation has been discontinued. (CPG Appendix C).
10. Should signs of withdrawal occur:

    11.1 Inform the Physician/Nurse Practitioner of signs of withdrawal and document on the PICU patient flowsheet.

    11.2 Consult with Pharmacy and revise the weaning plan to manage physical dependence.

    11.3 Consider resuming the previous infusion rate and wean sedation more slowly.

    11.4 Consider the addition of a benzodiazepine (eg. Lorazepam PRN) or choral hydrate to manage symptoms.

Documentation:

Physician / Nurse Practitioner:

- **Physician's Order Sheet:** ordered sedation level and medications.
- **Patient Progress Note (PPN):** document sedation goals with medication plan, changes in sedation plans and untoward events.

Nursing:

- **PICU Patient Flowsheet**: COMFORT-B scores, NOS scores, PRN medication administration (including reason and effect), & signs of withdrawal with management..
- **Medication Administration Record (MAR):** administration of scheduled sedation.

CPG APPENDIX A

Penn State Sedation Protocol

Sedation Level	Goal Patient Behavior	Nursing Action
1	Awake & interactive with environment.	PRN anxiolytics / analgesics.
2	Sleep, arouses to light stimulation, becomes excited with nursing care & suctioning, moves spontaneously, turns head, consistently breaths over ventilator rate.	PRN anxiolytics / analgesics, with or without continuous infusions of anxiolytics / analgesics, paralytics only if PRN sedatives fail.
3	Asleep most of the time, arouses to pain, coughs with suctioning, breathes above ventilator, little spontaneous movement or head turning.	PRN anxiolytics / analgesics, with or without continuous infusions of anxiolytics / analgesics, paralytics only if PRN sedatives fail.
4	Asleep all the time, arouses to pain, coughs with suctioning, returns to sleep immediately, very little spontaneous movement, no head turning.	Continuous anxiolytics / analgesics, PRN anxiolytics / analgesics for breakthrough agitation, paralytics only if PRN sedatives fail.
5	Asleep all the time, minimal response to suctioning, no respiratory effort, very brief /few episodes of spontaneous movement	Continuous anxiolytics / analgesics, PRN anxiolytics / analgesics for breakthrough agitation, liberal use of paralytics if PRN sedatives fail.
6	Asleep, continuous paralysis.	Continuous anxiolytics / analgesics, continuous paralytics, PRN anxiolytics / analgesics titrated to vital signs. Observe for minor movements between supplemental doses.

(Adapted with permission from Popernack, Thomas, & Lucking, 2004, Penn State University Hospital).

CPG APPENDIX B

COMFORT Behavior Scale (COMFORT-B Scale)

Alertness	**1**	Deeply asleep (eyes closed, no response to changes in environment)
	2	Lightly asleep (eyes mostly closed, occasional responses)
	3	Drowsy (child closes eyes frequently, less responsive to environment)
	4	Awake and alert (child responsive to environment)
	5	Awake and hyperalert (exaggerated response to stimuli)
Calmness-Agitation	**1**	Calm (child appears comfortable)
	2	Slightly anxious (child shows mild anxiety)
	3	Anxious (child appears agitated but remains in control)
	4	Very anxious (child appears very agitated, barely in control)
	5	Panicky (child appears severely distressed and out of control)
Respiratory Response	**1**	No spontaneous respirations, no coughing
	2	Spontaneous respirations with little response to ventilator
	3	Some resistance to ventilator
	4	Active breathing against ventilator or regular coughing
	5	Fighting against ventilator/coughing/choking
Physical Movement	**1**	No movement
	2	Occasional (3 or fewer) slight movements
	3	Frequent (more than 3) slight movements
	4	Vigorous movements limited to extremities
	5	Vigorous movements including torso and head
Muscle Tone	**1**	Muscles totally relaxed, no tone
	2	Reduced muscle tone, less resistance than normal
	3	Normal muscle tone
	4	Increased muscle tone and flexion of limbs/hands
	5	Extreme muscle rigidity and flexion of limbs/hands
Facial Tension	**1**	Facial muscles totally relaxed
	2	Normal facial tone
	3	Periodic tension of facial muscles (not sustained)
	4	Tension of facial muscles (sustained)
	5	Facial muscles grimacing
Total COMFORT B score		

(Adapted from van Dijk, Peters, van Deventer & Tibboel, 2005, Wielenga, De Vos, de Leeuw & De Hann, 2004)

CPG APPENDIX C
Signs and Symptoms of Withdrawal from Opioids and Benzodiazepines

- Signs and symptoms of withdrawal affect the autonomic, neurological and gastrointestinal systems.
- Symptoms may become evident 1-24 hours after discontinuing medications.
- Symptoms may persist for up to 6-8 weeks.

Signs of withdrawal from opioids

- Irritability/agitation
- ↑ wakefulness
- poor organization of sleep states
- hyperactive deep tendon reflexes
- ↑ muscle tone
- high pitched cry/inconsolable
- convulsions
- tremors
- twitching/jittery
- pyrexia
- diaphoresis
- mottling
- gagging
- poor feeding
- uncoordinated suck
- nausea/vomiting
- diarrhea
- tachycardia
- tachypnea
- skin excoriation / trashing
- nasal stuffiness

Signs of withdrawal from benzodiazepines

- anxiety (mild to severe)
- confusion
- insomnia
- perceptual disorders
- depression
- agitation
- visual hallucinations
- facial grimacing
- ataxia
- myoclonus
- retrograde amnesia
- antegrade amnesia
- poor visual tracking
- dyskinetic movements

(Grehn, 1998; Carnevale & Ducharme, 1997; Bennett, 2003, Anand & Ingraham, 1996).

Appendix I
PICU CPG Weaning Recommendations

Sedation Weaning Protocol: (consult with Pharmacy)

11. Children receiving low to moderate doses of sedation for less than one week:
    - Decrease dose initially by 25-50%.
    - Decrease subsequent doses by 20% every 6-8 hours as tolerated.
    - Wean sedation over a minimum of 72 hours.
12. Children receiving high doses of sedation or for greater than one week:
    - Use tapering technique over several days (suggest tapering over a period equal to the number of days sedation has been administered).
    - Reduce infusion rates by 10-20% every 12-24 hours as tolerated.
    - Consider addition of alternate sedative as adjunct to reduce the risk of dependence and assist in weaning other sedatives.
    - Consider conversion of intravenous medication to enteral routes.
    - Consider conversion of infusions to intermittent dosing.

Appendix J: Evaluation Questionnaire

Evaluation of the Clinical Practice Guideline for Managing Sedation
PICU team member questionnaire

After completing the consent form and reviewing the clinical practice guideline (CPG) please complete the following questionnaire. Place a checkmark (✓) in the box that best describes your response to the statements below. Spaces for narrative comments are also provided. Your participation is voluntary and data will remain anonymous. Your feedback will be used to revise the CPG and will be presented to the PICU Patient Care Team after completion of the data collection period. Place completed forms in a sealed envelope addressed to Cindy Holland in the PICU nursing mailbox.

Question	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
The CPG will improve patient safety.					
The CPG will facilitate communication between team members regarding the desired sedation goal for patients.					
The CPG will standardize the approach to managing sedation.					
The CPG will increase nursing autonomy in the delivery of medications to maintain the established sedation gaol.					
The CPG will increase overall team satisfaction with sedation practices.					
The CPG is easy to read and understand.					
The CPG is in a format pleasing to the eye.					
The CPG contains all the information required for me to follow the recommendations made in the CPG.					

I suggest the following revisions be made to the CPG:

_____

_____

_____

_____

I foresee the following barriers to the implementation of the CPG and provide suggestions for managing these barriers: _____

Other comments:

I support the implementation of the CPG for managing sedation in the PICU: Please check the box that best suits your answer. yes no

Thank you for your participation in this project. Feel free at any time to speak to me about this project or e-mail me at umholla2@cc.umanitoba.ca.

Sincerely,

Cindy Holland RN,BN

Student Nurse Practitioner

Appendix K

PICU Evaluation Report

Title: *Development of a Clinical Practice Guideline for Managing Sedation in Intubated Patients in the PICU.*

Completed by: Cindy Holland, practicum project

Results:

Number of packages developed: 77

Number of responses: 19 (24.7% response rate)

Number supporting implementation of the guideline: 15 (78.9%)

Number not supporting implementation of the guideline: 1 (5.6%)

Number undecided: 3 (16.7%)

(spaced left blank were coded as undecided).

Question	Strongly Agree (5)	Agree (4)	Undecided* (3)	Disagree (2)	Strongly Disagree (1)
The CPG will improve patient safety.	5 26.3%	8 42.1%	6 31.6%		
The CPG will facilitate communication between team members regarding the desired sedation goal for patients.	5 26.3%	12 63.2%	2 10.5%		
The CPG will standardize the approach to managing sedation.	4 21.1%	10 52.6%	5 26.3%		
The CPG will increase nursing autonomy in the delivery of medications to maintain the established sedation gaol.	4 21.1%	10 52.6%	5 26.3%		
The CPG will increase overall team satisfaction with sedation practices.	2 10.5%	5 26.3%	11 57.9%	1 5.3%	
The CPG is easy to read and understand.	6 31.6%	9 47.4%	2 10.5%	2 10.5%	
The CPG is in a format pleasing to the eye.	6 31.6%	8 42.1%	2 10.5%	3 15.8%	
The CPG contains all the information required for me to follow the recommendations made in the CPG.	3 15.8%	8 42.1%	3 15.8%	5 26.3%	

Overall, feedback from the 19 respondents was positive. The majority of participants agreed the sedation guideline would improve patient safety, allow for improved communication regarding the desired sedation goal, standardized sedation practices,

and increase nursing autonomy for drug administration. More than half did not agree or felt uncertain the guideline would improve overall team satisfaction with sedation practices. The majority of respondents agreed the guideline was easy to read and it was printed in a pleasant format. Just over half felt the guideline contained all the information necessary to implement the guideline while a quarter felt it was lacking in some regard.

Compilation of Narrative Comments:

Suggested Revisions:

Suggested revisions focused on either format or content changes. Suggestions for changes in format include streamlining the guideline, emphasizing the guideline portion, simplifying the "how to use" section. Content changes included the addition of managing and monitoring for over-sedation, definition of terms (high/moderate/low drug doses, physician, "a few hours" and age groups), differentiating between sedation for anxiety and analgesia for pain, monitor for withdrawal for greater than 24 hours, adding a RT opinion score when weaning ventilator in conjunction with the NOS, clarification of the Penn State levels descriptions, delete physical dependence (may not be avoidable), define how long to monitor after administration of PRN med or infusion change, delete chloral hydrate as an option for managing withdrawal, delete Oxford Level of Evidence, develop high/moderate/low ranges for the COMFORT B scores, develop a list of specific medications and dosage ranges for each sedation level, level of sedation, signs of withdrawal and untoward events to be recorded on the flowsheet not PPN, delete NOS (nurses opinion score) – too many scales, and a few minor wording changes.

Barriers to Implementation / Suggestions to Implementation:

Barriers to implementation and suggestions for implementation focused on five general themes including education or training, multidisciplinary collaboration, communication, resistance and evaluation.

Education / Training: Recommendation included the need for a comprehensive education process that includes the Residents, re-education 4-6 months after implementation, a trial period, and placement of guideline at each bedside.

Multi-disciplinary Collaboration: Recommendations emphasized the need for full team acceptance of the guideline and the need for each discipline be involved in the usage of the guideline.

Communication: Recommendations focusing on communication include the need for Physicians to be aware on a daily basis the amount of medication being administered, the need to report the COMFORT B score in rounds and during report to reinforce using the guideline as well as adequacy of sedation, and the development of a form to check during rounds indicating the patients sedation goal / level for each day.

Resistance: Concerns certain team members may resist the guideline pertained to Physicians and Nursing. There was concern that Physicians would be reluctant to

relinquish control over sedation (the guideline implies increased nursing autonomy) or that Physicians may change specific drugs or order different drugs according to bias. It was preferred that standardized drugs and dosages are written for each sedation level/goal and a consensus agreement be made by all Attending Physicians. Concerns were raised regarding certain nurses not following the guideline because of a variation in the degree of tolerance to patient movement leading to variation in drug administration. There was concern the need for monitoring for withdrawal may not be continued onto the ward after transfer (at least 48 hours post cessation of sedatives).

Evaluation: It was suggested there be a data collection period to prove the worth of the guideline and achievement of goals.

Miscellaneous Questions:

Questions surrounded four topics including the scoring tools for assessing sedation, levelling of evidence, medications and evaluation of the guideline.

Assessment/Scoring tools:

5. Do we need all three tools? (NOS, COMFORT B score and Penn State sedation level).
6. Is there a plan to include a tool for scoring withdrawal?
7. How many signs constitute withdrawal?
8. Is there a plan to include the Neonatal Abstinence Score?

Level of Evidence:

4. How does this apply to the guideline?

Medications:

1. How will we manage drug dosages that are higher than what is recommended in the Pediatric drug guideline?
5. What if a new Resident orders too wide a range for a drug infusion?
6. Who recommends the medications?

Evaluation:

4. How long will the data collection period be?
5. Will the nurse's level of understanding be evaluated?
6. What will be done with the NOS data?

Other Comments:

The miscellaneous comments were positive and praised the guideline. One respondent stated the guideline may improve the management of sedation by more quickly

responding to a patient's sedation needs. It was noted that this guideline is needed to allow nurses more freedom and uniformity in caring for this population and reduce the number of accidental extubations and fluctuations seen in sedation practices.

Plan:

The sedation guideline will be revised according to the suggested revisions. The findings from this evaluation, the revised guideline and a plan for formally implementing and evaluating the guideline will be presented to the PICU Patient Care Team in September. The team will decide upon the next step for the guideline at that time.

Thank you for participating in this project. Your assistance has been greatly appreciated.

Sincerely,

Cindy Holland RN, BN

Appendix L: Ethics Approval

APPROVAL CERTIFICATE

16 June 2005

TO: **Cindy Holland** (Advisor D. Fraser Askin)
Principal Investigator

FROM: **Stan Straw, Chair**
Education/Nursing Research Ethics Board (ENREB)

Re: **Protocol #E2005:056**
"Development of a Sedation Guideline for Intubated and/or Mechanically Ventilated Patients in the Pediatric Intensive Care Unit"

Please be advised that your above-referenced protocol has received human ethics approval by the **Education/Nursing Research Ethics Board**, which is organized and operates according to the Tri-Council Policy Statement. This approval is valid for one year only.

Any significant changes of the protocol and/or informed consent form should be reported to the Human Ethics Secretariat in advance of implementation of such changes.

Please note that, if you have received multi-year funding for this research, responsibility lies with you to apply for and obtain Renewal Approval at the expiry of the initial one-year approval; otherwise the account will be locked.

Appendix M

Consent Form

Informed Consent

Project Title: Review of a clinical practice guideline for managing sedation in patients requiring an endotracheal tube and/or mechanical ventilation in the Pediatric Intensive Care Unit (PICU).

Project Leader: Cindy Holland RN,BN, Student, Nurse Practitioner Program, University of Manitoba.

This consent form, a copy of which will be sent to you for your records and reference if you wish, is only part of the process of informed consent. It should give you the basic idea of what the research or project is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and understand any accompanying information.

Description of the project:
As part of my requirements for my Master's of Nursing, Nurse Practitioner program I must complete a scholarly project during my final practicum. This project involves the development of a clinical practice guideline, utilizing the best available evidence, for managing sedation in the patients requiring an endotracheal tube or mechanical ventilation.

Your participation is requested for the review and revision of the guideline by completing the questionnaire provided to you. The data will be used to revise the guideline and will be presented to the PICU Patient Care Team and all PICU staff for consideration. Reports will be made available one week after the completion of the data collection period. A copy of the report will be posted in the multi-purpose room and one for the PICU nursing station. This information will assist the team in the decision to adopt and implement the guideline in the PICU setting. A plan for implementation and evaluation will also be provided to the team, to be executed by the team, if the guideline is accepted for adoption.

Face-to-face sessions with the project leader will be held daily in the PICU over a two-week period (Monday – Friday) beginning one week after the approval of the Ethics Committee. Written packages will be available in the multi-purpose room and through the PICU Patient Care Team representatives for those team members unable to attend a session.

Your feedback and responses will remain anonymous and confidential. Your name is not required on the questionnaire. Consent forms and questionnaires will not be linked or traced back to the participant. Only the project leader will have access to the consent forms and questionnaires. Therefore, this project can be deemed low risk for harming the participant. The only recording device to be used will be the questionnaire. Any discussion outside of the questionnaire will not be recorded or used in this project.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the project and agree to participate as a subject. In no way does this waive your legal rights nor release the project leader, or involved institutions from their legal right and professional responsibilities. You are free to withdraw from the study at any time, and/or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Cindy Holland, project leader
Student, Nurse Practitioner program

Debbie Fraser Askin, Professor
Faculty of Nursing, U of M
Debbie_ Askin@umanitoba.ca
474-9927

The Nursing Research Ethics Board has approved this project. If you have any concerns or complaints about this project you may contact any of the above named persons or the Human Ethics Secretariat at 474-7122.

_____ _____

Participant's Signature Date

_____ _____

Project Leader Signature Date

Check the box below if you would like me to send you a copy of this consent form.

☐ Yes, I would like a copy of this consent form sent to me

Address or location: _____