

PEDIATRIC PROCEDURAL PAIN MANAGEMENT PRACTICES: A CROSS-SECTIONAL REVIEW OF PAIN MANAGEMENT INTERVENTIONS USED FOR BLOOD DRAWS

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Abstract

BACKGROUND: Hospitalized children continue to experience procedural pain due to inconsistent implementation of pain interventions.

OBJECTIVES: To explore the prevalence of needlesticks, pain management strategies, and child-caregiver satisfaction with these interventions.

METHODS: A cross-sectional study using paired chart reviews and child-caregiver surveys. Data were analyzed using descriptive statistics.

RESULTS: A majority (68%) of children experienced needlesticks during their admission. Documented use of pharmacological interventions were low. Nursing documentation for any pain interventions was infrequent (21% of charts) and often inconsistent with participant reports. Almost all children (98%) reported receiving at least one pain intervention for their needlestick. Most participants perceived pain management interventions as effective (59%) and were satisfied with pain interventions (82%).

CONCLUSION: Pain reduction strategies were rarely ordered/used, poorly documented, but were mostly perceived as effective. Participants tend to be satisfied with interventions. More research is needed to explore pain management experiences of children, caregivers, and nurses.

Preface

The original aim of this thesis was to explore the procedural pain management strategies that nurses were using when performing bloodwork on toddlers, as well as to observe toddlers' responses to these strategies. Despite multiple strategies to recruit eligible toddlers, no eligible toddlers could be recruited into the study over a ten-week period (January 30 to April 9, 2019). The study was therefore amended to exploring the procedural pain management that nurses are using for all pediatric inpatients undergoing needle sticks. The methods and results of the toddler-focused study can be found in Appendix A. The methods and results of the amended study are detailed within the body of this thesis document, and the discussion chapter synthesizes findings from both study methods within the context of existing literature and pain management initiatives.

The toddler-focused research project received research ethics approval from the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, No. 6025147, November 15, 2018, and the University of Ottawa Office of Research Ethics and Integrity, No. H-11-18-1418, January 15, 2019. Required amendment approvals were obtained as necessary for both the toddler-focused study and the final study that reviewed painful needlesticks for all pediatric inpatients.

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Table of Contents

Abstract	ii
Preface	iii
Co-Authorship	iv
Acknowledgements	v
Table of Contents.....	vi
List of Abbreviations	ix
List of Tables	x
List of Figures	xi
Chapter One: Introduction.....	1
Types of Needle Procedures	2
The Consequences of Poorly Managed Procedural Pain	3
Overview of Procedural Pain Management	4
Current Local Pain Management Practices	5
Thesis Organization	8
Chapter 2: Literature Review	9
Ongoing Undertreatment of Pediatric Pain	10
Evidence-Based Pain Management Interventions	15
<i>Breastfeeding</i>	16
<i>Skin-to-Skin Contact</i>	17
<i>Oral Sucrose and Sweet-Tasting Solutions</i>	17
<i>Topical Anesthetics</i>	19
<i>Vapocoolants</i>	26
<i>Pre-Analgesia with Oral Acetaminophen</i>	27
<i>Procedural Sedation</i>	28
<i>Non-Nutritive Sucking</i>	30
<i>Positioning</i>	31
<i>Restraint</i>	35
<i>Other Physical Interventions</i>	36
<i>Psychological Interventions</i>	36
<i>Caregiver Involvement</i>	39
Study Aims and Objectives.....	41
Chapter Three: Methods	42
Methodology	43
Setting	44
Sample	45
Recruitment & Study Promotion	46
Data Collection	47
Data Collection Tools	48
Study Procedure	49
Data Analysis	50
Ethics	51
Chapter Four: Results.....	53

Participant Recruitment and Demographics	54
<i>Recruitment and Enrolment</i>	54
<i>Participant Demographics</i>	55
Summary of Painful Bloodwork Procedures	57
PPM Practices	57
<i>Pharmacological PPM Ordering Practices</i>	57
<i>Documented PPM Practices During Needlestick</i>	59
<i>Children and Caregivers' Reported PPM Practices</i>	60
<i>Comparison of Reported Versus Documented PPM Practices</i>	65
<i>Use of the 3-P Approach</i>	65
Child-Caregiver Perceptions of Current PPM Practices	67
Qualitative Feedback from Participants	70
Chapter Five: Discussion	73
Epidemiology of Painful Procedures	75
Ordering Practices for Topical Anesthetics and Oral Sucrose	76
Documented & Reported PPM	78
Reports of PPM Effectiveness and Satisfaction	83
Sample Recruitment Considerations	87
Pain Management as a Growing Global Concern	90
Implications and Recommendations	94
<i>Pre-Selected Orders and Medical Directives</i>	95
<i>A Pain Management Kit</i>	97
<i>Standardized Documentation</i>	98
Study Strengths	100
Study Limitations	100
Recommendations for Future Research	102
Conclusion	103
References	105
Appendices	125
Appendix A: Proposed Methods & Results from Originally Proposed Protocol	126
Methodology	126
Setting	127
Sample	128
Recruitment & Study Promotion	129
Data Collection	130
Data Collection Tools	132
Study Procedure	133
Data Analysis	135
<i>Demographic Analysis</i>	135
<i>Procedure and PPM Analysis</i>	135
<i>Associations and Correlations</i>	136
Ethics	137
Results	138
Appendix A1: Proposed Methods - Recruitment Poster for Caregivers	140
Appendix A2: Proposed Methods - Caregiver Consent Form	141

Appendix A3: Proposed Methods - Media Release Consent Form	143
Appendix A4: Proposed Methods - Sample Staff Recruitment Email	144
Appendix A5: Proposed Methods - Data Collection Form.....	145
Appendix A6: The FLACC Pain Assessment Tool.....	148
Appendix A7: Initial Ethics Approval	149
Appendix A8: Ethics Amendment #1	152
Appendix B: Consent and Assent Forms.....	154
Appendix C: Data Collection Form	159
Appendix D: Ethics Amendment #2	161

List of Abbreviations

CCSEO – Cancer Centre of South-Eastern Ontario

COPC – Children’s Outpatient Centre

CNO – College of Nurses of Ontario

ED – Emergency Department

FLACC - Face, Legs, Activity, Cry, and Consolability Scale

HDH – Hotel Dieu Hospital

IVR – Interventional Radiology

IV – Intravenous

KGH – Kingston General Hospital

KHSC – Kingston Health Sciences Centre

MAR – Medication Administration Record

NNS – Non-nutritive sucking

PCCU – Pediatrics Critical Care Unit

PICC – Peripherally inserted central catheter

PSO – Pre-selected orders

PI – Primary Investigator

PPM – Procedural pain management

RNAO – Registered Nurses’ Association of Ontario

SSC – Skin-to-skin contact

SKIP - Solutions for Kids in Pain

USA - United States of America

List of Tables

Table 1. Demographic Characteristics ($n = 50$)	56
Table 2. Most Recent Needle Procedure by Location ($n = 34$)	57
Table 3. Pharmacological PPM Ordering Practices by Age Group ($n = 50$)	59
Table 4. Documented PPM Interventions ($n = 34$ needlesticks).....	60
Table 5. Child-Caregiver Reported PPM Interventions by Age ($n = 34$)	64
Table 6. Use of 3-P Approach by Location ($n = 34$)	66
Table 7. Use of 3-P Approach by Age Group ($n = 34$).....	66
Table 8. Use of 3-P Approach by Procedure ($n = 34$).....	67

List of Figures

Figure 1. Screening Flow Chart	55
Figure 2. Perceived effectiveness of PPM during last procedure.....	68
Figure 3. Reported PPM satisfaction for last procedure	69
Figure 4. Overall PPM satisfaction	70

Chapter One: Introduction

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On average, a child admitted to a Canadian hospital is subjected to approximately seven painful procedures every day (Stevens et al., 2011). Despite increased research and implementation of procedural pain management (PPM) strategies, nearly all young children undergoing painful medical procedures continue to experience high levels of moderate to severe procedural pain (Harrison et al., 2014; Stevens et al., 2011). Poorly managed procedural pain may result in immediate and future physical and psychological sequelae (McMurtry et al., 2015b). However, as per previous reports, less than two-thirds of painful procedures include pharmacological interventions, just over half included the use non-pharmacological interventions, and less than one-third of nursing documentation noted the use of any pain reduction intervention regardless of child age, gender, culture, or previous experiences (Harrison et al., 2014; Stevens et al., 2011). As children report needle procedures as one of the most painful, feared, and stressful medical procedures (McMurtry et al., 2015b), pain management practices during these procedures need to be improved.

Types of Needle Procedures

The most common painful needle procedures carried out among pediatric patients include, but are not limited to: venipuncture, heel sticks, peripheral intravenous (IV) cannulation, port-a-cath access, peripherally inserted central catheter (PICC) line insertion, lumbar punctures, IV injections, and intramuscular immunizations (Ali, McGrath, & Drendel, 2016; Harrison et al., 2014; Stevens et al., 2011; Zhu et al., 2012). Venipuncture, the most frequently performed needle procedure for hospitalized children (Harrison et al., 2014; Stevens et al., 2011), is a needle-based medical procedure performed for assessment, diagnosis, and monitoring (Taylor, Sellick, & Greenwood, 2011). Unlike other procedures such as immunization, lumbar punctures, and bone

marrow aspiration, venipuncture is performed in the direct visual field of the child. This can make disengagement of the child's focus challenging. When compared to IV cannulation, the process of venipuncture is typically shorter in duration and may require fewer pain management interventions to be employed (Taylor et al., 2011). Given the prevalence of venipuncture in hospital, it is an ideal procedure to study to develop an awareness of PPM interventions being used by hospital-based nurses working in pediatric care. Exploring which PPM interventions are being used and observing their effectiveness allows for the planning of interventions to support nurses' use of appropriate PPM while potentially positively impacting large numbers of hospitalized children through a reduction in procedural pain.

The Consequences of Poorly Managed Procedural Pain

Up to two-thirds of children report at least some degree of needle fear (McMurtry et al., 2015b). The median age of onset of clinically diagnosable needle fear is 5.5 years (Bienvenu & Eaton, 1998) but caregivers have reported needle fear in up to 51% of 249 children aged 12-36 months ($n = 127$) and up to 56% of 729 ($n = 408$) of children between 4 and 8 years of age (Taddio et al., 2012). Proximal consequences of needle fear include increased pain, distress (a combination of fear, anxiety, and pain), and procedural elongation, disruption, or failure (Duff, 2003). Long-term consequences of needle fear may present as increased pain and analgesic requirements for future medical procedures (McMurtry et al., 2015b), fear of and anxiety related to healthcare providers (Taddio et al., 2015a), and the development of needle phobia (McMurtry et al., 2015b; Taddio et al., 2015a).

Needle phobias develop in a significantly smaller proportion of children when compared to needle fear (McMurtry et al., 2015a). In comparison to fears, needle phobias present additional challenges due to the presence of persistent, maladaptive stimuli-induced disturbances which are

out of proportion to a stimulus (American Psychiatric Association, 2017). Without effective management and treatment, needle phobias can persist into adulthood and have life-long consequences (McMurtry et al., 2015b). Fear of healthcare providers and needle phobia should be of high concern for nurses as these can manifest as avoidance of healthcare (Ellis, Sharp, Newhook, & Cohen, 2004; Taddio et al., 2012), vaccine non-compliance in up to 21% of adults with needle fear (Taddio & McMurtry, 2015), refusal of lifesaving therapies (Ellis et al., 2004), generalization of fears to other healthcare settings (Andrews, 2011), and higher morbidity and mortality (Taddio et al., 2009; Taddio et al., 2012). Unmanaged needle fear and needle phobia may also interfere with travel plans, education, pregnancy, and legal proceedings (Taddio et al., 2012; Willemsen, Chowdhury, & All, 2002). When appropriate PPM is consistently provided through the use of combined physical, psychological, and pharmacological approaches, the development of needle fear and its associated immediate and longer-term adverse outcomes may be avoided (McMurtry et al., 2015a). Reducing the incidence of high levels of procedural pain therefore has the potential to optimize future health.

Overview of Procedural Pain Management

Many studies have shown that a combination of age-appropriate, child-specific interventions is the most effective PPM approach for children (Dalley & McMurtry, 2016). Current methods to reduce pediatric pain during immunization include pharmacological, psychological, and physical methods such as the application of topical anesthetics (Harrison et al., 2015a; Taddio et al., 2015a), oral sucrose administration (Harrison et al., 2015c; Stevens, Yamada, Ohlsson, Haliburton, & Shorkey, 2016), breastfeeding (Harrison et al., 2016; Shah, Herbozo, Aliwalas, & Shah, 2012), positioning and minimal restraint (Cavender, Goff, Hollon, & Guzzetta, 2004), caregiver presence and involvement (Stevens & Marvicsin, 2016), distraction

(Birnie, Noel, Chambers, Uman, & Parker, 2018; Taddio et al., 2015b), and holding infants skin-to-skin (Johnston et al., 2017). However, routine use of these interventions in practice is inconsistent at best (Harrison et al., 2014; Harrison et al., 2015b; Stevens et al., 2011).

While some of these PPM interventions are known to reduce pain for neonates (0-28 days), infants (28 days-12 months) and older children (older than 36 months), evidence to support their efficacy among toddlers (12-36 months of age) is limited (Birnie et al., 2018; Harrison et al., 2015c; Pillai Riddell et al., 2015). Very few studies relating to the use of PPM interventions specific to the toddler age group have been conducted, and even fewer have been shown to be effective (Harrison et al., 2015a). Appropriate assessment and management of pain in toddlers also poses an ongoing challenge for healthcare providers despite advances in research, PPM strategies, and education to front-line staff (Thrane, Wanless, Cohen, & Danford, 2016). Toddlers, if they are able to self-report, tend to report pain at the extreme ends of scales (“no pain” or “extreme pain”) with minimal variability as a result of the dichotomous thinking in this age group (St. Laurent-Gagnon, Bernard-Bonnin, & Villeneuve, 1999). Furthermore, up to the age of 3 years, a child’s ability to clearly describe their pain in terms of degree, location, or sensation is limited (Desprie & Langeland, 2016). Management of procedural pain is further complicated when working with this age group due to limited assessment tools for fear and distress which have not been well validated for use among toddlers (McMurtry, Noel, Chambers, & McGrath, 2011; Trost et al., 2017). Through a combination of these factors, toddlers are undoubtedly at an increased risk for unrecognized and untreated pain (Desprie & Langeland, 2016).

Current Local Pain Management Practices

Kingston Health Sciences Centre (KHSC) is the umbrella organization of two hospital

sites in Southeastern Ontario. Kingston General Hospital (KGH) is a large tertiary care teaching hospital, while Hotel Dieu Hospital (HDH) functions as a day-surgery and outpatient clinic-focused facility. The 14-bed pediatric in-patient unit of focus for this thesis is at KGH. KHSC has no policies to guide PPM through the use of any pharmacological, physical, or psychological interventions for nurses working in inpatient or outpatient settings. Little was known about the PPM practices that KHSC pediatric nurses were employing during routine painful procedures. The pediatrics unit manager, clinical educator, and staff nurses had also voiced a need for improved pain management education and resources. At the beginning of this project, no hospital policies existed to guide nurses' PPM practices, and high-quality evidence-based PPM resources were not readily available to front-line staff.

The hospital's pediatric venipuncture policy stated "there is a need to consider the impact of pain on the patient" (p. 1) but provided no further direction for pain management interventions (KGH, 2014). A variety of pain assessment scales exist but are inconsistently used at the discretion of the primary nurse, and nurses are provided with multiple documentation forms. This, in turn, leads to inconsistent pain assessment and documentation practices. Both medical and surgical pediatric admission order sets include space for ordering analgesics and topical anesthetics, but physician completion of these sections is not mandatory (KGH, 2016; KGH, 2017). The short rotation times of physician residents through various programs in the hospital can limit physicians' abilities to familiarize themselves with the pediatric unit nursing staff and program routines which has the potential to result in inadequate and inconsistent PPM ordering practices. The acute pain management service Nurse Practitioner (NP) generally focuses on post-operative, disease-exacerbation, and acute-on-chronic pain management. However, her registration as an adult NP inhibits her from working independently as all care decisions must be

approved by the pediatrics physician team. The NP was self-reportedly never involved in PPM for minor painful procedures. KHSC also employs Child Life Specialists (CLS) who are trained to help prepare children for upcoming procedures and are available to be present at procedures to provide emotional and distraction-based support.

As an organization, KHSC management supports family presence as a key component in patients' overall well-being. Caregivers are considered to be a vital part of their child's care and are therefore allowed on the unit 24-hours a day (KGH, 2018). The KGH pediatric unit website states that caregivers are encouraged to be involved with their child's care, participate in physician daily rounds, and interact with their child as much as possible in all aspects of care. However, there is no formal policy to guide caregiver involvement in their routine child's care or during painful procedures.

Evidence-based PPM guidelines specific to neonates and infants are abundant and readily available through a variety of resources external to KHSC (Desprée & Langeland, 2016; Taddio et al., 2015a). While there are also no specific guidelines to manage pain in older children at KHSC, this pediatric population is more likely to be able to readily express their fears, pain, and preferred coping interventions. The limited PPM resources within KHSC increases the risk of poorly managed procedural pain at this facility for all pediatric patients. However, toddlers are at an even higher risk due to their cognitive developmental stage, and the fact that strategies that work for young infants and older children are not as effective for toddlers. Therefore, developing an awareness of nursing PPM practices and observing toddler responses to the different PPM interventions being used is essential to initiate the development of hospital policies and evidence-based materials to support implementation and continued use of effective PPM interventions for the toddler population.

Thesis Organization

This thesis document is composed of five chapters. *Chapter One*, this chapter, includes a brief introduction to painful procedures, the importance of adequate pain management and associated management practices, and a description of the study setting.

Chapter Two is a summary of an extensive literature review that was used to identify existing, relevant literature to inform the thesis study design and subsequent data analyses. Literature was also reviewed to inform a discussion about ongoing pediatric pain management practices, toddler-specific pain management and assessment considerations, and evidence-based PPM practices. This chapter then introduces the study's aims and objectives that were developed in response to the knowledge and practice gaps identified in the literature review and review of the study setting.

Chapter Three is used to present the methods for the study that guided the research component of this thesis. *Chapter Four* presents the results of this research.

Chapter Five provides an integrated discussion of the difficulties from the initially proposed study and the findings from the actual study. This discussion situates the current study findings within the larger body of existing literature and pediatric-focused organizations, provides practice recommendations, and then identifies study limitations and areas for future research.

Chapter 2: Literature Review

Chapter 2: Literature Review

Sub-optimal PPM is a well-established problem. This chapter is a review of existing literature that explores pain epidemiology in hospitals, including numbers of painful procedures performed and current PPM practices from other Canadian facilities, and critically reviews the current state of evidence for PPM interventions. The information gathered during this literature review was used to inform the subsequent research study design. Due to the initially proposed toddler-focused research protocol for this thesis project (Appendix A) and the knowledge gap surrounding the efficacy of PPM interventions for this age group, the following review of PPM strategies includes an increased focus on this age group.

Ongoing Undertreatment of Pediatric Pain

Most early pediatric pain studies focused on postoperative and oncological pain management, were cross-sectional and observational in nature, used small sample sizes, and did not explore the epidemiology of procedural pain. Johnston, Abbott, Gray-Donald, and Jeans (1992) used a survey of 150 children and found that 130 children (87%) between 4 and 14 years had experienced at least one episode of pain in a 24-hour period and 86 of the 150 children (57%) rated their pain as moderate or severe. In another survey, 98 of 200 children (49%) reported having experienced clinically significant pain in the previous 24-hours (Cummings, Reid, Allen Finley, McGrath, & Ritchie, 1996). A decade later, pain prevalence remained high as 186 of 241 children (77%) reported that they had experienced pain in the previous 24 hours regardless of the reason for their admission (Taylor, Boyer, & Campbell, 2008). Despite this prevalence, only 65 charts (27%) included documentation of any pain score (Taylor et al., 2008). Two of the identified epidemiological studies for this review did not use a 24-hour period of reference but also showed high rates of pain prevalence. Ellis et al. (2002) reported that just

under half of a sample of 223 children experienced pain at least once over an 8-hour period while 45 (20%) experienced pain at each 2-hour interval over the same timeframe. More recently, Harrison et al. (2014) reported that 51 of 62 children (84%) experienced pain at some point during their hospitalization.

Existing literature also demonstrates that, despite the high prevalence of pain, analgesics are not being administered frequently enough. In 1992 only 93 of 150 children (62%) experiencing pain had received an analgesic, and only 44 of these 93 children (47%) received more than one dose (Johnston et al., 1992). Children in the post-operative period were found to be significantly more likely to receive analgesics than those admitted with a medical diagnosis (63 vs. 25%) regardless of the severity of pain reported by either population (Johnston et al., 1992). In a different survey-based study, Cummings et al. (1996) found similar analgesia administration rates; 8 of 13 children (62%) who reported clinically significant pain due to headache, disease process, or surgery where analgesia would be considered an appropriate treatment were not given any form of analgesia. When analgesics were given, the doses were often not adjusted based on the severity of children's pain (Cummings et al., 1996). Taylor et al. (2008) identified that 78 of 186 children (42%) received no analgesic despite the presence of pain. When analgesia was given, 26 of these 78 children (33%) were given intermittent analgesia, 20 (25%) received routine analgesia (doses given at regularly ordered intervals), but only 41 (53%) received analgesia that was considered appropriate for their level of pain (Taylor et al., 2008). While Taylor et al. (2008) found that analgesia administration rates had increased from previous studies (Cummings et al., 1996; Johnston et al., 1992), it is clear that optimal analgesia was not being administered often enough.

Stevens et al. (2011) used a cross-sectional, multi-centre chart audit in Canadian

paediatric hospitals and found that, in a 24-hour period, 2987 of 3822 children (78%) included in the study had undergone at least one painful procedure, and that, on average, each child had experienced almost seven painful procedures. In another cross-sectional study with a much smaller sample, every one of 62 pediatric inpatients (100%) at a Canadian hospital had undergone at least one painful procedure during their hospital admission (Harrison et al., 2014). The most common painful needle procedures carried out for pediatric patients included, but were not limited to: phlebotomy, heel sticks, peripheral IV cannulation, and intramuscular immunizations, as well as port-a-cath access, PICC line insertion, and lumbar punctures (Harrison et al., 2014; Stevens et al., 2011).

Over the past two decades, there has been a heavy focus on research and implementation efforts to improve the use of pain management strategies due to the high frequency of these unavoidable painful procedures (Harrison et al., 2014; Stevens et al., 2011). Despite these efforts, observational studies have demonstrated that nearly all children undergoing needle procedures continue to experience moderate to severe procedural pain and pain management interventions are underused. For example, in a 150-bed hospital, nurses and laboratory staff were asked to record information about PPM over 23 days (Ellis et al., 2004). In this time 387 procedures were recorded, of which 374 (97%) were needlesticks (Ellis et al., 2004). Of these 374 needlesticks, only 72 procedures (19%) used Eutectic Mixture of Local Anesthetics (EMLA; lidocaine-prilocaine), and two (0.5%) used Ametop (Ellis et al., 2004). In a different study, when the charts for 2987 inpatients who had experienced a needlestick in a 24-hour period were reviewed, it was identified that 1980 charts (84.8%) included documented evidence for the use of a pharmacological pain intervention, physical interventions for pain were documented in 609 charts (26.1%), and 584 charts (25.0%) had a documented psychological intervention (Stevens et

al., 2011). However, only 844 of these 1980 charts (28.3%) contained documentation to indicate that the pain intervention was used specifically for a painful procedure (Stevens et al., 2011). Of these 844 charts, 791 (93.7%) noted pharmacological agents, 80 (9.5%) described physical interventions, 21 (2.5%) had documented evidence of a psychological intervention, and 44 (5.2%) noted that the patient had received a combination of interventions (Stevens et al., 2011). It was also found that as the number of painful procedures performed during an admission increased so did the proportion of children who received pharmacological and physical PPM interventions (Stevens et al., 2011). Conversely, as the number of procedures increased, the proportion of psychological interventions documented tended to significantly decrease (Stevens et al., 2011). The reason for this inverse relationship was not discussed in the study report.

PPM strategies reported by children and caregivers are rarely consistent with what is documented by healthcare providers. Harrison et al. (2014) found that despite only 11 of 62 patient charts (17%) containing PPM documentation, 33 of 62 children and caregivers (53%) recalled receiving at least one pharmacological intervention, while 19 (32%) reported the use of non-pharmacological interventions (Harrison et al., 2014). This practice-documentation gap may have negatively affected previous assessments of analgesic administration and PPM interventions as most epidemiological studies were based only on chart reviews (Johnston et al., 1992; Stevens et al., 2011; Taylor et al., 2008). This highlights that poor documentation must be considered when assessing reports of pain assessment and intervention rates. However, even reported rates of topical anesthetics ($n = 14$, 23%) and oral sucrose ($n = 16$, 26%) are low in comparison to practice guideline recommendations (Harrison et al., 2014).

Findings of low rates of pain assessment and use of recommended PPM interventions are not limited to Canada or hospital environments. A mail-in questionnaire about pediatric pain

management practices was sent to 19 Italian Emergency Departments (EDs), all of which replied, and findings were that nine of the hospitals surveyed (47%) did not have pain management protocols in place, and only five (26%) departments routinely assessed pain at any time during a patient's visit (Ferrante et al., 2013). Only three of the hospitals surveyed (16%) reportedly reassessed pain after pain interventions, and only two (11%) reported the use of topical anaesthetics (Ferrante et al., 2013). In the same year, an email survey about pain management interventions used for early childhood immunization was sent to 274 members of the Australian Nurses Federation (Victorian Branch) Immunisation Nurses Special Interest Group, of which 125 nurses (46%) replied. The researchers identified that many clinics (15%) did not have PPM policies in place for routine immunization (Harrison, Elia, Royle, & Manias, 2013). Respondents reported that topical anesthetics were "occasionally" used 21% of the time, and 14 nurses (11%) reported their clinics did not have any topical anesthetics available (Harrison et al., 2013). Despite evidence showing efficacy for the use of sweet solutions to decrease immunization-related pain in infants (Harrison et al., 2015c; Taddio et al., 2015a), almost no use of sweet solutions was reported by survey respondents (Harrison et al., 2013).

Despite improved research-based knowledge, evidence-based findings, and research in both general and procedure-related pain, children are still experiencing high levels of procedural pain. Although the rates of pain and painful procedures remain high, pain is still being assessed and documented infrequently, PPM interventions are being inconsistently documented and the use of pharmacological and non-pharmacological pain interventions has only marginally improved over the past 25 years. These inconsistent practices consequently place children at an unacceptably high risk for poorly managed pain, suboptimal PPM, and in turn, the consequences associated with poorly managed pain.

Evidence-Based Pain Management Interventions

Appropriate assessment and management of pediatric procedural pain pose ongoing challenges for healthcare providers despite advances in research, pain management strategies, and education to front-line staff (Thrane et al., 2016). The “3-P” approach is based on the PPM intervention components from Taddio et al.’s (2015a) “5-P” approach that considers *procedure* and *process* in tandem with *pharmacological*, *physical*, and *psychological* interventions to improve PPM. The 3-P approach is considered the minimum standard of care for children undergoing painful procedures due to a combination of at least one pharmacological, one physical, and one psychological intervention (Taddio et al., 2015a). This approach was designed to form a basis for nurses to select age-appropriate interventions during routine vaccination but can be applied to any painful procedure (Taddio et al., 2015a).

The description and quantification of children’s pain is often complicated by the uniqueness of each child’s history of medical procedures, medical conditions, and variable responses to pain (Merkel & Malviya, 2000) which emphasize the importance of consistent pain assessment approaches and individualized pain management interventions. Several pharmacological and non-pharmacological PPM interventions such as breastfeeding, skin-to-skin holding (kangaroo care), and oral sucrose administration are known to be effective for infants (Harrison et al., 2015c; Harrison et al., 2016; Johnston et al., 2017; Shah et al., 2012), while children older than 3 years can benefit from topical anesthetics, procedural preparation and cognitive distractions (Birnie et al., 2018; Taddio et al., 2015a). These interventions have either not been rigorously evaluated for toddlers (aged 1-3 years) or have been shown to be ineffective or less effective than when used for older children (Birnie et al., 2018; Harrison et al., 2015c; Harrison et al., 2016; Taddio et al., 2009). Furthermore, existing PPM interventions are largely

considered less effective for toddlers when compared to older children due to their early emotional and cognitive developmental stage (Merkel & Malviya, 2000; Thrane et al., 2016). Toddlers' limited vocabulary, tendency to report pain with minimal variability (i.e.: "no pain" or "extreme pain"), and inability to fully describe their pain further complicates the prevention, assessment, and management of toddlers' procedural pain (St. Laurent-Gagnon et al., 1999). For these reasons, the majority of the remaining literature review will discuss PPM strategies for infants and older children with an added focus on studies that included toddlers in their samples.

Breastfeeding

Evidence from dozens of individual trials and systematic reviews that included up to 20 studies and thousands of infants have shown analgesic effects from breastfeeding neonates during procedures such as heel lances, venipuncture, and vaccination (Benoit, Martin-Misener, Latimer, & Campbell-Yeo, 2017; Shah et al., 2012) and for older infants up to 1 year of age during vaccination (Harrison et al., 2016; Shah et al., 2015). Breastfeeding is believed to reduce distress through physical comfort, sucking, ingestion of sweet-tasting milk, distraction, and through the endorphins that are present in breast milk (Taddio et al., 2015a) and has been shown to be more effective at decreasing distress than skin-to-skin contact (SSC), topical anesthetics, maternal holding, oral sweet solution administration, and music therapy for healthy, full-term infants (Benoit et al., 2017). Breastfeeding is beneficial as it is readily available if mothers are breastfeeding, cost-effective, and does not require significant time to initiate and is recommended for routine use for infants up to one year of age (Taddio et al., 2015a). However no published studies have been identified which have evaluated analgesic effects of breastfeeding in children beyond 1 year of age during painful procedures (Harrison et al., 2016).

Skin-to-Skin Contact

Skin-to-skin contact (SSC), also called kangaroo care, has been rigorously examined for its efficacy in reducing procedural pain in newborn infants. Johnston et al. (2017) conducted a systematic review of 25 studies including 2001 infants undergoing venipuncture, heel lance, intramuscular injections, vaccination, and tape removal using physiological and behavioural measurements to evaluate SSC efficacy. SSC was determined to be a safe and effective PPM strategy but the size of the benefit remained unclear (Johnston et al., 2017). The authors consequently suggested SSC be studied in tandem with other PPM interventions (Johnston et al., 2017). There is currently no conclusive evidence based on well-powered randomized controlled trials (RCTs) for the use of SSC to reduce procedural pain in children older than 1 year (Johnston et al., 2017) and no studies examining the effect of SSC beyond infancy were identified during the literature review for this thesis.

Oral Sucrose and Sweet-Tasting Solutions

Extensive, high-quality evidence has confirmed needle pain reduction through the oral administration of small volumes of sweet-tasting solutions, predominantly sucrose, to infants and is considered best-practice in this age group when breastfeeding and/or SSC cannot be used (Harrison et al., 2015c). Contrastingly, the findings from the identified studies examining the effects of sweet solutions for decreasing procedural pain in toddlers are inconsistent. While findings from some trials have shown potential PPM efficacy (Desprie & Langeland, 2016; Yilmaz, Caylan, Oguz, & Karacan, 2014), one trial and one systematic review showed conflicting and insignificant results (Allen, White, & Walburn, 1996; Harrison et al., 2015c).

The earliest identified RCT to study oral sucrose efficacy with toddlers included in the sample involved 285 children, 2 weeks-18 months old, undergoing immunization at an

ambulatory care clinic in Nebraska, United States of America (USA). The authors reported that 12% oral sucrose tended to be effective (though not statistically significant) at reducing pain, but only in two-week-old infants and only when a single needle was given, $F = 5.92$, $p < 0.005$ (Allen et al., 1996). Allen et al. (1996) also found mean (SD) cry times tended to be longer in the sucrose group versus the control group (88.4 (47) versus 77.5 (51.2) seconds) but the difference was not significant. In contrast, findings from an RCT by Desprée and Langeland (2016), which included 114 15-month-old toddlers undergoing routine immunization at Norwegian outpatient centres, were that a 30% sucrose solution reduced pain. In Desprée and Langeland's (2016) trial, toddlers who received water ($n = 55$) cried significantly more (33 seconds) than those who were given 30% oral sucrose ($n = 59$, 18 seconds; $p \leq 0.001$). However this was a more concentrated sucrose solution than the 12% sucrose solution used by Allen et al. (1996). Direct comparison of results between these two RCTs is difficult as different concentrations of sucrose were used and Allen et al. (1996) reported pain scores and crying times while Desprée and Langeland (2016) only reported distress using cry time. Interestingly, in Allen et al.'s (1996) study, children who received oral sucrose had longer mean crying times while the inverse was found by Desprée and Langeland (2016). A three-armed RCT was conducted in Turkey which involved a large sample of 16-to-19-month-old toddlers ($n = 537$) receiving intramuscular immunizations at outpatient clinics. The study aimed to explore the effect of oral water ($n = 179$), 25% sucrose ($n = 179$), and 75% sucrose ($n = 179$) on cry times, pain, and distress (Yilmaz et al., 2014). Participants receiving the 75% sucrose solution demonstrated significantly less total crying time and pain when compared to the 25% solution and control groups, $p < 0.001$, and the 25% solution group demonstrated significantly less total crying time and pain when compared control group, $p < 0.001$ (Yilmaz et al., 2014). It was determined that while 25% and 75% solutions are both

effective in reducing procedure-related crying time and pain, the more concentrated solution was more effective (Yilmaz et al., 2014). Comparison between these three RCTs suggests that as child age increases, higher concentrations of sucrose may be beneficial in decreasing pain and crying time. No single studies identified examined sucrose in the context of non-immunization procedures, making the generalization of conclusions to other painful procedures difficult.

Despite the potential efficacy for oral sucrose that was demonstrated in the findings from the previously discussed trials, a systematic review and meta-analysis of six RCTs that included a total of 808 children showed that oral sucrose did not significantly reduce pain or duration of crying for children 1-4 years of age, 95% CI [-54,24 seconds], $p = 0.45$ (Harrison et al., 2015c). However, four of the trials included in Harrison et al.'s (2015c) meta-analysis included small samples and which may have been underpowered to detect statistically significant differences. These conflicting results leave a need for future research using rigorous, adequately-powered RCTs with samples that include toddlers (Harrison et al., 2015c). Future studies for the use of sweet solutions in children over 4 years of age are not warranted as the meta-analysis of two trials showed that chewing sweet gum before or during procedures did not significantly reduce self-reported pain scores for school-aged children (Harrison et al., 2015c). However, sucrose remains a strongly recommended form of PPM for minor procedural pain for all children under 1 year of age, with the possibility of some effect for children up to 2 years of age (Harrison et al., 2015c; Taddio et al., 2015a).

Topical Anesthetics

Topical anesthetics are applied to the superficial layers of potential needle-stick sites to cause temporary local numbing. Topical anesthetics are most commonly administered in the form of creams and gels such as EMLA, lidocaine-epinephrine-tetracaine (LET), and tetracaine

hydrochloride (Ametop) but newer options include needleless air delivery systems such as the J-tip® and powdered lidocaine systems. Application of topical anesthetic does involve potential risks including local sensitivity, bruising, erythema, and minor bleeding and should only be applied to sites with intact, healthy skin (Taddio et al., 2015a). Unlike non-pharmacological interventions which can provide immediate benefit, many topical anesthetic agents can take up to 60 minutes to become effective, and if venipuncture is unsuccessful a new site must be chosen. It is therefore suggested that at least two potential venipuncture sites be chosen for simultaneous topical anesthetic application unless the J-tip® or powdered lidocaine are used as these applications take immediate effect.

The use of topical anesthetic, regardless of its form, has been repeatedly shown to not interfere with procedure success (Lunoe et al., 2015; Taddio, Gurguis, & Koren, 2002; Wrzosek, Hogan, & Taddio, 2009; Zempsky et al., 2008). Dozens of studies and systematic reviews have been used to evaluate the overall efficacy of topical anesthetics for a variety of needle procedures. For example, one systematic review included 28 studies and meta-analyses of seven of these studies (children aged 1-11 years; Wrzosek et al., 2009). One meta-analysis included six trials and a total of 534 children between 3 months and 15 years (Lander, Weltman, So, & Hobson, 2006), while a second meta-analysis included 15 trials with over 1400 children under 12 years of age (Shah et al., 2015). However, it is important to note that topical anesthetics do not function in the same manner for all children of all ages (Wrzosek et al., 2009). While evidence to support the use of topical anesthetics in children over 4 years of age is strong (Lander et al., 2006; Wrzosek et al., 2009), there is limited research to support the efficacy of topical anesthetics for use with neonates, infants, and toddlers (Shah et al., 2015).

Early evaluations of topical anesthetic predicted that a smaller body surface area was

correlated with a higher density of pain receptors and therefore resulted in increased pain in younger children during needle-related procedures (Arts et al., 1994; Goodenough et al., 1999). If this were true however, topical anesthetics should be equally or more effective in toddlers who are typically smaller in size when compared to their older counterparts. More recently, it has been theorized that topical anesthetics are more beneficial for school-aged children (aged 4 years and above) than toddlers due to advances in cognitive processing, the maturation of pain mechanisms, or simply improved pain assessment and enhanced self-reporting capabilities for older children (Wrzosek et al., 2009).

Using a meta-analysis of thirteen studies that included 269 children undergoing immunization injections, Shah et al. (2015) found lower rates of observed acute distress for infants and children 0–11 but no effect on self-reported pain for children 4–11 years when EMLA or Ametop were used alone for intramuscular or subcutaneous injections. In the same systematic review, analysis of two studies including an unspecified number of children older than 12 years found self-reported pain was lower but observed acute distress was not affected by topical anesthetic application (Shah et al., 2015). No studies evaluating the effect of topical anesthetics for other common needle procedures such as venipuncture or IV cannulation were included in this meta-analysis. In a non-randomized experimental study involving the application of prilocaine-lidocaine versus standard care (no cream) for venipuncture pain and distress in 132 Japanese children aged 2 to 4 years, children tended to cry less with application of the active preparation ($n = 117$) compared to children whose caregivers refused to have the topical anesthetic applied ($n = 15$; Yamamoto-Hanada et al., 2015). However, this difference was not statistically significant (59.8 vs. 46.7% of the procedure time, $p = 0.706$; Yamamoto-Hanada et al., 2015). This study did not include a true control group as its primary purpose was to

determine the feasibility of combining topical anesthetics with psychological PPM strategies and, unlike Shah et al. (2015), this Japanese trial only reported cry times. In a different RCT, Tak and van Bon (2006) found EMLA had a medium-sized effect on decreasing self-reported venipuncture pain in a sample of 136 children 3-12 years when EMLA was used with distraction and procedural preparation versus when a placebo cream and no distraction or preparation were used, $d = 0.53$, $p < 0.05$. In this case, there was no report for consideration of the potentially confounding effect of procedural preparation (Tak & van Bon, 2006). However, similar to Shah et al.'s (2015) findings, observed distress was only decreased at the time of skin-break when compared to the placebo cream regardless of if distraction was or was not used (Tak & van Bon, 2006).

Instead of comparing topical preparations to placebo creams, Taddio et al. (2002) aimed to determine the efficacy of specific formulations (lidocaine-prilocaine versus tetracaine) for PPM in children 3-15 years through a systematic review that included eight studies and more than 450 children undergoing venipuncture, IV cannulation, Port-a-Cath access, and laser therapy procedures. Due to variability in study measures, meta-analyses were not able to be conducted, but procedure-specific analysis was reported (Taddio et al., 2002). All four studies exploring IV cannulation for over 300 children between 1 and 15 years found lower self-reported or observed behaviour-based pain scores with tetracaine (Taddio et al., 2002). In one small study examining venipuncture in 66 children, 1-15 years of age, children demonstrated lower pain when a behaviour-based pain scale was used, but in another study that only included 34 children, 1-14 years of age, researchers found no difference in self-reported pain (if appropriate based on child age), parent-reported pain, or observed behaviour-based pain scale scores (Taddio et al., 2002). Overall, when applied for the appropriate duration, it was determined that lidocaine-

prilocaine tended to be less effective than tetracaine, but that the main benefit to using tetracaine was the decreased time from application to full effect (30 min. for tetracaine versus 60 min. for lidocaine-prilocaine; Taddio et al., 2002). The mixed results for the effect of topical anesthetic creams on pain and distress, the large age range of included participants, and the different painful procedures studied demonstrates that the efficacy of specific topical anesthetics, as well as topical anesthetic creams overall, remains unclear for toddlers. Furthermore, the only study to report the effect of topical anesthetic exclusively for toddlers was not an RCT and included only a small comparison group of children who did not receive topical anesthetics (Yamamoto-Hanada et al., 2015).

The administration of subcutaneous lidocaine through a forced-air, needle-free system (the J-tip®) shows promise as a pain management intervention and has been confirmed to be more effective than EMLA for children older than 7 years (Kearl, Yanger, Montero, Morelos-Howard, & Claudius, 2015). However, only two identified RCTs that included toddlers, both of which were conducted in the USA, have evaluated the J-tip® for efficacy, and only in venipuncture procedures. The first, a two-phased RCT, included 690 participants between 1 month and 21 years of age. Phase one was used to evaluate the J-tip® alone, while the second phase was used to evaluate the impact of using a J-tip® with or without a BUZZY® (a cold, vibrating device that operates based on Gate Control Theory). When the J-tip® was used alone for venipuncture only 41 of 195 (21%) children's pain scores for the venipuncture procedure were greater than three out of 10 using age-appropriate pain assessment tools, compared to 20 of 28 (71%) in the control group (Kearl et al., 2015). When the J-tip® was combined with the BUZZY® (n = 133) this proportion dropped to 18 of 133 (13.5%), supporting the efficacy of the J-tip®, especially when combined with the BUZZY®. Of note, only 66 of 334 (20%)

participants who received a J-tip® treatment reported or were assigned pain scores greater than 3/10 during J-tip® application (Kearl et al., 2015).

The second RCT was used to examine the J-tip® for pain reduction during venipuncture, included 205 children 1-6 years of age, and produced similar results to Kearl et al. (2015). Participants were randomized into three groups: 96 received the J-tip® and a spray of cold saline, 56 received a placebo J-tip® and vapocoolant spray, and 53 were in the control group and received only vapocoolant spray. While participants in all groups experienced an increase in Face, Legs, Activity, Cry, and Consolability (FLACC) pain scale scores from the treatment application through to the end of the procedure, the change was not significant in the active J-tip® group (mean change = 0.26; 95% CI [-0.31, 0.82]) but was significant for the control group (mean change = 2.82; 95% CI [1.91, 3.74]) and the placebo J-tip® with vapocoolant group (mean change = 1.68; 95% CI [0.8, 2.52] ; Lunoe et al., 2015). Overall procedure success rates were similar among all three groups (Lunoe et al., 2015), demonstrating that, in addition to decreasing distress, use of the J-tip® and/or vapocoolant does not interfere with procedure success.

Toddlers were not observed as an independent age group in either J-tip® study. Additionally, the J-tip® has not yet been evaluated for other needle procedures, and has yet to be studied alone, as it was combined with other interventions (placebo, vapocoolant, or BUZZY®) in both Lunoe et al. (2015) and Kearl et al.'s (2015) studies. Although the J-tip® itself does not induce pain at the time of application, the loud pop it emits may induce distress in older infants and toddlers and future research looking to support the use of air-delivered lidocaine systems must be carefully designed so as to not confuse this fright reaction with pain, especially if using observed behaviour-based pain measurements as the primary outcome (Kearl et al., 2015).

Powdered lidocaine systems use a single-use, disposable, and needleless system to release pressurized lidocaine powder that penetrates the epidermis and, unlike the J-tip®, can be applied directly over veins (Zempsky et al., 2008). Only two RCTs studying this system were identified. The first study included 579 children, 3-18 years, and results indicated that participants who received the active preparation reported significantly lower pain scores in all age groups during venipuncture and IV cannulation procedures (Zempsky et al., 2008). The effect of powdered lidocaine had no significant interaction with age, $p = .25$, demonstrating a potential benefit for all children between 3-18 years, regardless of age (Zempsky et al., 2008). The second study, a follow-up to Zempsky et al.'s (2008) study, included 508 participants aged 3-18 years undergoing venipuncture or IV cannulation (Schmitz, Zempsky, & Meyer, 2015). Active powdered lidocaine was used for 256 children while 252 were allocated to receive a sham placebo (Schmitz et al., 2015). The overall self-reported pain score was 23% lower ($p = 0.002$) for those who received active lidocaine, but the effect was less significant for the older children aged 8-18 years, $p = 0.186$ (Schmitz et al., 2015). Parents also perceived that children who received the active preparation experienced less pain ($p = 0.002$; Schmitz et al., 2015). Most participants reported no pain with device administration and the system was determined to be safe to use (Schmitz et al., 2015), confirming Zempsky et al.'s (2008) findings. However, consideration must be given to the accuracy of self-reported pain in the young children included in both of these RCTs. Further analysis of age-specific efficacy was not discussed in Schmitz et al.'s (2015) report. Given that these studies were part of the same program, and used similar populations, settings, and procedures, results should be confirmed using larger samples and with other needle procedures.

The above-explored literature supports the generalized efficacy of various topical

anesthetic applications. However, the limited analysis for effectiveness by age group in most of these studies makes it unclear whether topical anesthetics are effective for toddlers, or whether the significant findings were a result of including older children, for whom topical anesthetics are known to be effective (Wrzosek et al., 2009), in the same samples. Due to the limited risks and potential benefits, topical anesthetic application has been recommended as standard care for toddlers (as no identified evidence indicates otherwise) and older children undergoing needle procedures but is generally considered most effective for children over 3 years of age (Registered Nurses' Association of Ontario [RNAO], 2013; Taddio et al., 2015a).

Vapocoolants

Vapocoolants are sprays that cool but do not numb the skin's surface. Vapocoolants are thought to provide some analgesic effect and have the added benefit of taking immediate effect (Griffith, Jordan, Herd, Reed, & Dalziel, 2016) without affecting procedure success (Griffith et al., 2016; Lunoe et al., 2015). The first identified meta-analysis for vapocoolants included 12 studies and 509 children and researchers found no significant pain reduction in children receiving a vapocoolant versus placebo or no treatment during venipuncture and IV cannulation, and could not recommend vapocoolants for use in routine practice (Hogan, Smart, Shah, & Taddio, 2014). More recently, the routine use of vapocoolants in children over 3 years of age was recommended based on evidence from one systematic review of nine studies that included 1070 children and adult participants that demonstrated an overall reduction in pain during IV cannulation with no effect of procedure success (Griffith et al., 2016). However, due to the sudden cold spray that may surprise a young child, vapocoolants are not recommended for use with toddlers (Taddio et al., 2015a). Overall, evidence for vapocoolant efficacy in pain reduction for any pediatric age group remains mixed. No study has solely explored the effect of

vapocoolants for use with toddlers, and no meta-analysis has examined vapocoolants strictly for use in the pediatric population.

Pre-Analgesia with Oral Acetaminophen

The RNAO recommends oral administration of non-opioid analgesia for patients who are experiencing mild pain and as a co-analgesic for more severe pain, but does not support the administration of acetaminophen prior to immunization procedures or intraprocedural pain management (RNAO, 2013). This recommendation is reflected in evidence-based clinical practice guidelines for vaccination which state that the administration of oral analgesics is ineffective for pain management at the time of needlestick (Taddio et al., 2007; Taddio et al., 2015a). For example, a randomized, double-blind, placebo-controlled trial was used to evaluate the benefits of acetaminophen administration 60-90 minutes before a heel stick for intraprocedural pain reduction in 75 neonates but no significant effect on pain ($p = 0.38$) or crying duration ($p = 0.60$) was found (Shah et al., 1998). Interestingly, Taddio et al. (2012) used a cross-sectional survey to explore immunization practices used by a convenience sample of 883 caregivers and 1024 children and found 433 caregivers (49%) administered oral analgesia prior to a scheduled vaccination despite a lack of evidence demonstrating benefits. The actual or perceived efficacy of caregiver-administered pre-analgesia on immediate procedural pain was not explored by Taddio and colleagues (2012) in this survey.

To date, only one identified study included the toddler age group while exploring the use of oral acetaminophen for needle procedures. Using an RCT, Hedén, Von Essen, and Ljungman (2014) showed pre-administration of oral acetaminophen did not affect the pain ($p > 0.110$) or fear ($p > 0.361$) reported by children, parents, and nurses for 51 children with cancer, aged 1-18 years, who were receiving at least one needlestick as part of their treatment plan. These results

are consistent with those reported by Shah et al. (1998). Of note, children 7 years and older did report a significant decrease in distress ($p = 0.026$) while parents and nurses did not for the same age group ($p > 0.171$; Hedén et al., 2014). Participants in this study were not separated for age-specific efficacy analysis. Subsequently, there is no strong evidence to support the administration of oral acetaminophen before a needle procedure to decrease intra-procedure pain for any age group, but simply administering a PPM intervention has the potential to decrease child-reported distress (Hedén et al., 2014).

Procedural Sedation

In low doses, opioids and sedative medications such as fentanyl, midazolam, ketamine, nitrous oxide, and propofol can be used to safely induce analgesia and light sedation for painful procedures in relatively calm children when other methods of analgesia such as topical anesthetic are not feasible (Ekblom, Jakobsson, & Marcus, 2005; Krauss & Green, 2000). Of note, when procedures are more painful or the child is more emotional or anxious, deeper levels of sedation may be required to effectively manage pain and distress (Krauss & Green, 2000). Procedural sedation for minor painful procedures has been minimally studied, and only single-site studies focusing on procedural sedation (Cheng, Elia, & Perrett, 2018; Ekblom et al., 2005; Kanagasundaram, Lane, Cavalletto, Keneally, & Cooper, 2001) were identified.

Of the pharmacological agents used for procedural sedation, nitrous oxide has been the most frequently studied. No known studies have explored the use of procedural sedation exclusively among toddlers. When nitrous oxide is used independently from IV medications, sedation is painless, rapid, and predictable while allowing for quick recovery post-procedure (Ekblom et al., 2005). The efficacy of nitrous oxide has been well established for decreasing distress and providing light sedation in a sample of 70 fearful children between 6 and 17 years of

age who required dental care, but its role as an analgesic was not explored in this study (Ekblom et al., 2005). Kanagasundaram et al. (2001) non-experimentally evaluated the effect of nitrous oxide (concentrations of 50-70%) on observed distress scores when inhaled by 90 children older than 1 year undergoing painful procedures such as IV cannulation, lumbar punctures, and dressing changes. Similar to Ekblom et al.'s (2005) findings, nitrous oxide did reduce observed behavioural-based distress over the course of the procedure in all participants (Kanagasundaram et al., 2001). Neither of these studies compared observed distress to a control group and it is therefore unclear if the distress observed was significantly different in comparison to a child receiving standard care.

McCollum et al. (2017) used a non-randomized study by employing a post-procedure survey to evaluate if the use of nitrous oxide (concentrations of 40-70%), in addition to standard care (topical anesthetics), decreased pain and anxiety, and improved IV cannulation experiences for 393 patients between 9 months and 8 years of age (McCollum et al., 2017). Post-procedure survey data indicated that caregivers, patients, and care providers tended to be satisfied with the intervention (McCollum et al., 2017). IV cannulation success occurred in 378 of the cases (96.2%), and 5 of the 7 participants (71.4%) whose second IV start attempt was unsuccessful still reported positive experiences (McCollum et al., 2017). Of note, children under 5 years of age made up nearly half of the sample size (43%), yet the youngest children (those under 2 years) represented less than 4% of the entire sample. There was no report on the effects of nitrous oxide administration on procedural pain or distress in this study but the reports of increased satisfaction likely correlate well with Kanagasundaram et al. (2001) and McCollum et al.'s (2017) findings of decreased distress.

The Royal Children's Hospital in Melbourne, Australia offers an immunization under

sedation program for children with anxiety disorders, behavioural and developmental disorders, and needle phobias (Cheng et al., 2018). A review of 352 medical records was undertaken to evaluate the services being used and the outcome of the procedures by this program (Cheng et al., 2018). Over four years, 400 vaccines were administered and 114 patients (32%) had multiple vaccines given in a single visit. Only 10 identified procedures (5%) failed and all were found to be a result of patient non-compliance with the prescribed sedation (Cheng et al., 2018).

Procedural sedation was most commonly achieved using nitrous oxide alone ($n = 193$, 55%), and ketamine was used as an adjunct sedative in 151 cases (43%; Cheng et al., 2018). While the effect of these interventions on pain was not explored, these results confirm the potential benefits of procedural sedation for procedure success and reduced distress that were identified in the previously discussed literature. Regardless of the benefit of reducing distress and increasing procedural satisfaction, existing literature has conclusively demonstrated that nitrous oxide for use as a conscious sedation agent may reduce distress and increase satisfaction with procedures. However, nitrous oxide is not an analgesic agent and should therefore be used only in conjunction with other PPM interventions.

Non-Nutritive Sucking

Non-nutritive sucking (NNS) involves placing an object such as a pacifier into a child's mouth to stimulate the sucking reflex (Pillai Riddell et al., 2015). A systematic review and meta-analysis that included dozens of RCTs exploring NNS for children up to 3 years of age was conducted by Pillai Riddell et al. (2015) and demonstrated age-dependent efficacy for pain reactivity (pain experienced during the procedure) and pain regulation (ability to calm from peak distress) during needle procedures. The use of NNS and swallowing of water was examined in six studies including 329 preterm infants and found to be ineffective in reducing acute procedural

pain but five studies including 260 preterm infants suggested NNS may improve pain regulation, especially when combined with oral sucrose solutions (Pillai Riddell et al., 2015). NNS was determined to be effective at reducing pain reactivity through five studies with a combined sample of 270 neonates (Pillai Riddell et al., 2015). NNS also improved immediate pain regulation when seven studies with a total of 325 neonates were examined (Pillai Riddell et al., 2015). Findings from two studies that included a total of 151 participants suggest that NNS has the potential to improve immediate pain regulation in older infants (Pillai Riddell et al., 2015). In general, the efficacy of NNS was not improved when caregivers were involved in procedures (Pillai Riddell et al., 2015). Additionally, one study in this systematic review concluded that toddlers' ability to self-regulate and calm themselves improved when NNS was used post-procedure (Pillai Riddell et al., 2015). While the evidence for using NNS as a form of PPM for preterm infants, neonates, and older infants is strong, the inclusion of toddlers in only two studies with a combined sample of 151 older infants and toddlers demonstrates the need for more research for the efficacy of NNS in this age group. Additionally, the two studies included in the analysis for older infants evaluated different procedures (one intramuscular injection and one venipuncture) in different geographic regions (Alberta, Canada and Taipei, Taiwan) making comparison and generalization of these results even more difficult. Despite these limitations, NNS can be considered as a potential intervention for calming infants during procedures and potentially for toddlers post-procedure if pacifier sucking is a normal part of the toddler's care (Pillai Riddell et al., 2015).

Positioning

Sitting upright during invasive procedures is known to promote feelings of control and safety and consequently decreasing fear and distress in children as young as 3 months of age

while lying supine increases the perception of pain and fear in young children (Sparks, Setlik, & Luhman, 2007). Children placed in a supine position will often begin to fight against caregivers and care providers before the occurrence of a painful stimulus which can increase distress, trauma, and negative memory development (Cavender et al., 2004). To date, four trials, all with small sample sizes, have explored positioning to decrease pain during IV cannulation and venipuncture procedures with children between 2 months and 11 years (Cavender et al., 2004; Dunbar, 2016; Kahler, 2003; Sparks et al., 2007).

An RCT involving 44 children (3-7 years) was used to evaluate the combined effects of distraction and positioning on pain responses during IV cannulation (Kahler, 2003). No significant difference was found between procedure times or the number of staff required for a successful procedure, and parents' assessments of their child's pain tended to correlate well with children's self-reports (Kahler, 2003). Although not statistically significant, preschoolers (3-5 years) who were positioned upright on their parent's lap tended to report less pain than those who were placed supine for the procedure (Kahler, 2003). Given that the scale used for child self-report in this study (Beyer-Oucher) is validated for children older than 4 years of age and is considered to be more accurate as child age increases (Beyer et al., 1992 as cited in Kahler, 2003), use of this scale when 3 to 4 year-olds were included in the sample could have affected the results.

In a similar study that included 43 children between 4 and 11 years who were undergoing venipuncture or IV cannulation, the effect of combined upright position and distraction ($n = 20$) compared to routine care (explanation and parental presence, $n = 23$) was evaluated (Cavender et al., 2004). No statistically significant effect on self-reported pain, fear, or distress was found for these interventions, $p = 0.680$, but similar to Kahler's study (2003), children's self-reported pain

scores (ranging from one to five) tended to be lower in the experimental group (2.3 ± 1.87 vs. 2.74 ± 1.61 ; Cavender et al., 2004). Children positioned upright and being distracted also tended to self-report less fear than those who received standard care (2.15 ± 1.81 versus 2.74 ± 1.86 , $p = 0.058$; Cavender et al., 2004). Observed fear scores, as measured by trained healthcare providers and parents, were found to be (statistically) significantly lower in the upright and distracted group, $p < 0.003$, whereas care provider measured distress was found to be the same between both groups, $p = 0.13$ (Cavender et al., 2004).

Sparks et al. (2007) found similar effects to Kahler (2003) and Cavender et al. (2004) when combining distraction and upright holding for 118 children, 9 months to 4 years of age. In this RCT, children were randomly assigned to be positioned supine ($n = 59$) or upright and held by a parent or family member during IV cannulation ($n = 59$) and were distracted if parents chose to do so (Sparks et al., 2007). Observed distress scores were found to be lower in all three procedure periods as well as overall for the upright group, $p < 0.044$ (Sparks et al., 2007). Parents in the experimental group tended to be more satisfied overall despite a non-statistically significant increase in the number of IV attempts needed when a child was held upright (1.41 vs. 1.32 attempts, $p = 0.546$; Sparks et al., 2007). The effect of using distraction as an additional experimental variable in Kahler (2003), Cavender et al. (2004) and Sparks et al.'s (2007) studies were not clearly addressed or ruled out as a confounding factors through statistical methods in any of the three studies and may have influenced conclusions related to the effect of upright positioning. However, the use of the same interventions (position and distraction) across three studies that showed similar trends supports the possibility of a clinically significant benefit for upright positioning, especially in combination with distraction, even in the absence of statistically significant results.

Secondary data analysis of a larger RCT comparing the use of sucrose with placebo solutions for pain management in toddlers (1-3 years) undergoing venipuncture was conducted to determine if upright positioning reduced procedural pain and distress (Dunbar, 2016). Twenty-nine children were evaluated based on the position chosen by the participants in the initial RCT, with eight (28%) sitting upright, and 21 (72%) supine (Dunbar, 2016). Unlike previous researchers who described position as upright or supine, Dunbar included descriptions of five different position categories with variations in parent contact, on/off the bed, or on a parent's lap with 16 of 28 participants (55%) having been placed supine on the patient's bed with parent/guardian contact (Dunbar, 2016). No statistically significant difference in crying time or duration of crying were found for any position, $p > 0.24$, but, unlike the previously discussed studies, patients in upright positions cried, on average, 8-seconds longer than those in a supine position, $p = 0.10$ (Dunbar, 2016). The impact of sucrose administration was not examined due to the ongoing data collection for the primary RCT and no validated composite pain assessment scale scores were reported (Dunbar, 2016). Similar to Sparks et al.' (2007) results, patient position did not affect procedure success (Dunbar, 2016).

All studies exploring the impact of positioning on pain and distress included relatively small sample sizes which may have resulted in the studies being underpowered, thereby decreasing the probability of finding significant differences in outcome measurements (if they did exist). The use of different measurement scales for pain and distress in each of the above-discussed studies, as well as the addition of confounding variables of distraction in the Kahler (2003), Cavender et al. (2004), and Sparks et al. (2007), and sucrose in Dunbar's (2016) secondary analysis makes the direct comparison of study findings and potential future meta-analysis difficult. However, with the exception of Dunbar (2016) who found a slight but

insignificant increase in cry time (8 seconds), all studies exploring upright positioning found that child distress was decreased when the child was held in an upright position for venipuncture and IV cannulation. Aside from Dunbar (2016), none of the discussed studies examined the effect of upright positioning specifically for toddlers or for other common painful needle procedures such as immunization. However, based on clinical significance, it can be recommended that all patients should be held in a position of comfort, usually on a caregivers' lap in a hugging position with the child's front facing out for painful needle procedures, but that the position the child or parent prefers and is feasible and safe depending on the procedure and situation, is ultimately the best option.

Restraint

Children undergoing painful procedures are often physically restrained to improve procedure success (Crellin et al., 2011). The use of restraints during painful procedures has been minimally studied in toddlers but has long been considered part of routine practice (Crellin et al., 2011). The only identified study to explore the use of restraint in young children for painful procedures was conducted by Crellin et al. (2011) at an Australian hospital. Crellin et al. (2011) reported that physical restraint was used for 89 of 124 (72%) observed procedures including IV cannulations, nasogastric tube insertions, measurement of oxygen saturation, and metered-dose inhaler administration for a convenience sample of children aged 6-42 months. All children (100%) undergoing IV cannulation ($n = 33$) and nasogastric tube insertion ($n = 30$) were restrained. The authors reported that as age increased, the use of restraint tended to decrease (87% of children aged 6-18 months compared to 66% of children aged 18-30 months) and as procedure difficulty and length increased, the use of restraint also increased (Crellin et al., 2011). Crellin et al. (2011) emphasized the fact that current pain assessment scales for pre-verbal

children do not account for the use of restraint when observing behavioural reactions to pain and therefore a true understanding of how increased restraint is related to the degree of pain experienced is unavailable, especially when behavioural-based pain rating scales are commonly used for this age group. To truly understand the impact of restraining children for painful procedures, additional rigorous studies with larger samples, other painful procedures, and scales that consider the effect of restraint on behavioural measurements of pain must be conducted.

Other Physical Interventions

Other potentially efficacious physical PPM interventions for young children include swaddling/tucking, rocking, touch, and massage. A large systematic review was used to demonstrate that swaddling/tucking (n = 9 studies, 331 participants), and rocking (n = 4 studies, 212 participants) are supported by sparse, low-quality evidence for immediate pain regulation in neonates while rocking shows minimal efficacy for older infants and young children up to 3 years of age for immediate pain regulation (n = 1 study, 106 participants; Pillai Riddell et al., 2015). Swaddling/tucking and rocking interventions have only been examined in one study for older infants and children up to 3 years of age undergoing immunizations (Pillai Riddell et al., 2015). Based on the same systematic review, touch or massage are considered minimally effective in pain reactivity of preterm infants (n = 2 studies, 65 neonates), largely ineffective for immediate pain regulation in neonates (n = 2 studies, 98 neonates), but may have some effect for older infants and young children (n = 2 studies, 124 older infants) on both pain reactivity and immediate pain regulation (Pillai Riddell et al., 2015). Additional experimental studies with larger samples should be conducted to further explore these interventions for all age groups.

Psychological Interventions

Psychological interventions such as distraction, procedural preparation, cognitive

behavioural treatment, structured breathing, suggestion, and hypnosis have been repeatedly shown in systematic reviews and meta-analyses to reduce the pain experienced by older children during a variety of needle procedures in multiple settings, cultures, and international healthcare systems. Many of the studies that have explored cognitive interventions during procedures used a variety of child self-report, observer global report, and behavioural-based measurements for anxiety, distress, and fear as primary study outcomes (Birnie et al., 2018) which makes conducting meta-analyses and direct comparison between different study results difficult. However, the relationship between decreased fear, distress (including pain), and anxiety must be considered as a decrease in one may decrease the severity of another related response (Birnie et al., 2018). Therefore, the overall trend of study outcomes must be considered when discussing cognitive PPM interventions.

Based on a systematic review of over 60 clinical trials, distraction is by far the most commonly studied psychological intervention for children older than 3 years and can involve, for example, the use of dolls, blowing bubbles, pinwheels, simple pictures, books, video games, and animation to decrease pain across a wide variety of painful procedures (Birnie et al., 2015; Pillai Riddell et al., 2015). With older children, distraction can include, but is not limited to, watching movies, listening to music or stories, handheld video games, playing with toys, and caregiver-led distraction (Birnie et al., 2018). Although distraction is generally considered effective in reducing procedure-related anxiety, distress, and fear in children and adolescents, there is currently little evidence to support the use or non-use of distraction for children less than 1 year of age (Birnie et al., 2015; Pillai Riddell et al., 2015).

Although only two studies exploring distraction that included toddlers were identified, some evidence to support the use of distraction for younger children does exist but only in small

samples of children. The use of toys to facilitate age-appropriate play-based distraction has recently been shown to help a small sample of 10 Brazilian children between 3 and 6 years of age to express their feelings while allowing them to interact with their environment in a non-threatening manner during venipuncture (Soares da Silva et al., 2016). In an RCT, Yoo et al. (2011) used videos and electronic games as a form of distraction for 20 Korean children (3 -7 years) undergoing venipuncture and found that, when compared to 20 children who received no intervention, these interventions significantly decreased behaviour-based pain scores, $p < 0.002$, as well as blood cortisol, $t = 2.132$, $p = 0.043$, and glucose levels, $t = 3.207$, $p = 0.003$. Due to the inclusion of children beyond the toddler age group in both of these studies, readers must be cautious in making assumptions of intervention efficacy specifically to toddlers. It is also important to note that both of these studies examined distraction for venipuncture. Removing a child's focus from venipuncture procedures can be difficult, given that is performed in the direct visual field of the child (Taylor et al., 2011). Therefore, the efficacy of these interventions may be altered when procedures, such as immunization, occur outside of the child's visual field.

While blowing bubbles, inflating a balloon, or watching a video can significantly decrease pain in children aged 3-7 years, the efficacy of these interventions with younger children has not been explored in any identified studies (Birnie et al., 2018; Lilik Lestari, Wanda, & Hayati, 2017; Pillai Riddell et al., 2015). Data from a combination of 18 studies have shown that guided imagery, music, and storytelling can decrease anxiety in older children but do not appear to be beneficial for toddlers (Birnie et al., 2018). Medical play using toys and medical supplies such as dolls, syringes, needles, and Band-Aids for use in preparation for venipuncture has often been found to decrease anxiety and distress through demonstration of procedures for children aged 3-6 years but only in single studies (Birnie et al., 2018; Soares da Silva et al.,

2016). However, the effect of procedural preparation to decrease pain has demonstrated conflicting results from meta-analyses and systematic reviews and therefore the benefit remains inconclusive (Birnie et al., 2018; Pillai Riddell et al., 2015; Tsao, Kuo, Lee, & Yiin, 2017). Consequently, additional studies involving significantly larger samples of young children are required to explore the efficacy of distraction for this age group.

The wide age range of participants undergoing a variety of painful procedures in various locations and across many studies examining distraction makes identification of age-specific efficacy and therefore practice recommendations for specific interventions and age-groups difficult to establish (Birnie et al., 2018). Regardless of the psychological PPM intervention chosen, effectiveness is highly dependent on each child's level of cognitive development, existing coping mechanisms, and their individualized preferences (Birnie et al., 2018; Yamamoto-Hanada et al., 2015). Therefore, a combination of several child and caregiver selected psychological interventions continues to be the recommended standard of practice (Birnie et al., 2018).

Caregiver Involvement

Caregiver presence and involvement in painful procedures have been topics of research for decades. A systematic review of 28 trials from various countries and settings found that caregiver presence during procedures does not affect procedure outcomes for a variety of procedures including, but not limited to: immunization, venipuncture, lumbar puncture, and central line placement (Piira, Sugiura, Champion, Donnelly, & Cole, 2005). A relationship between caregiver presence and decreased child anxiety and distress has been found repeatedly in over 40 studies and is thought to be a direct result of caregivers' abilities to articulate and facilitate the use of the preferred coping mechanisms of pre-verbal children (Piira et al., 2005;

Racine et al., 2016).

Despite these established benefits, caregivers often reported receiving little-to-no direction from medical staff, including nurses, before and during procedures which often left them feeling unsure of how to support their child (Piira et al., 2005). Once given simple instructions, caregivers can easily engage their child in activities such as cuddling, distraction, and encouraging supportive comments to support their child during painful procedures (Stevens & Marvicsin, 2016). After caregivers implemented these instructions, children under 3 years of age demonstrated up to a 10% decrease in clinician-reported pain (Bauchner, Vinci, Bak, Pearson, & Corwin, 1996). If care providers choose to have caregivers engage in caregiver-led distraction, it is important to remember, as discussed in the psychological intervention section above, the efficacy of distraction for young children is unclear and highly dependent on the child's level of cognitive development (Birnie et al., 2018; Yamamoto-Hanada et al., 2015). Therefore, caregiver involvement should be used in combination with other well-validated, age-appropriate PPM interventions.

Caregiver reactions have also been shown to influence coping or non-coping responses among a sample of 66 children 3-12 years undergoing venipuncture (Taylor et al., 2011). In an observational study, adult reassurance-type behaviours often elicited behaviours that indicate distress such as crying, while adult-led distraction more often led to the use of coping behaviours (Taylor et al., 2011). These results have not been repeated in any other identified studies. Despite these results and given that caregiver presence and caregiver-facilitated distraction has been found to have no consistent impact on observed pain, caregiver presence is recommended in routine practice if the caregiver wishes to be involved in a painful procedure (Birnie et al., 2018).

Study Aims and Objectives

Without an awareness of the interventions that nursing staff are using, appropriate policy and resource development cannot begin and knowledge translation interventions cannot be properly introduced to guide and improve nursing practice (Ellis et al., 2004; Straus, Tetroe, & Graham, 2013). This thesis was therefore designed to develop this awareness to provide baseline data for improving current PPM practices. Initially, this thesis aimed to explore current PPM practices used by staff at KHSC when performing venipuncture on toddlers and to observe and assess the pain responses of toddlers undergoing venipuncture in relation to the PPM intervention(s) employed by KHSC staff. The proposed methods and results from this proposed protocol are presented in Appendix A. Due to an unpredicted difficulty in recruiting toddlers for the study, the thesis aims and methods were amended. The final thesis aims were to explore current PPM practices used and documented during blood collection procedures for all pediatric inpatients and to explore patient and/or caregiver perception of, and satisfaction with, PPM at KHSC. The objectives of the final study were as follows:

- (1) Develop a baseline description of bloodwork procedure frequency and the PPM interventions KHSC nurses are using when caring for the pediatric population (ages 0-18 years) when children undergo needlesticks.
- (2) Determine if the documented PPM interventions align with those reported by children and their caregivers.
- (3) Determine whether current nursing PPM practices comply with the recommended “3-P” (combined pharmacological, physical, and psychological) approach.
- (4) Explore child-caregiver perceptions of effectiveness and satisfaction with PPM practices at KHSC.

Chapter Three: Methods

Chapter Three: Methods

Despite the availability of abundant, high-quality evidence for PPM interventions for most pediatric age groups, the use of these interventions in clinical practice remains inconsistent (Harrison et al., 2014; Stevens et al., 2011). Furthermore, nursing documentation of PPM intervention use varies from the interventions that caregivers and children report were used prior to and during recent painful procedures (Harrison et al., 2014). In order to identify current nursing PPM practices, child-caregiver satisfaction with these practices, and child-caregivers' perceived effectiveness of PPM interventions on pain management during painful needle-based bloodwork procedures (from here forward referred to as "needlesticks") in hospital, a descriptive, cross-sectional study design was used. This study was based on similar studies carried out by Taylor et al. (2008), Harrison et al. (2014a) and Wilding et al. (2019) which explored pain management practices, pain prevalence, and pain assessment at Canadian pediatric hospitals.

Methodology

Descriptive, cross-sectional study designs are a type of non-experimental research used to collect data about the prevalence of a phenomenon during a single data collection period. This methodology is commonly used for population-based surveys in clinical samples, and have the added benefit of being relatively fast and inexpensive to conduct (Polit & Beck, 2012; Setia, 2016). In cross-sectional surveys, participants are selected based only on inclusion and exclusion criteria for the study (Setia, 2016) which was deemed feasible for the successful recruitment of target participants for this revised study in a small pediatrics unit. Results from cross-sectional studies are ideal for planning, monitoring, and evaluating changes from health initiatives and can be used as a precursor for future cohort studies (Setia, 2016). Despite these benefits, cross-

sectional designs are not ideal to infer changes over time due to rapid changes in medical technology, social norms, and innate differences between participants (Polit & Beck, 2012). Since data is collected at a single point in time for each participant, this methodology also makes deriving causal relationships between variables difficult (Setia, 2016).

Checklists and rating scales, in line with a structured approach, are the preferred methods for quantitative observations to be recorded as measurable data, and self-reporting by study participants can be used to collect versatile and direct information (Polit & Beck, 2012). Potential concerns related to the use of self-reporting include risks to content validity and accuracy as the reports rely on the ability of the research participant to clearly recall the event being explored (Polit & Beck, 2012). Furthermore, when self-reporting, people tend to attempt to portray themselves in a positive way that may conflict with the truth (Polit & Beck, 2012). The data collected for this current study was factual rather than opinion-based and focused on the recollection of actions by others which could have reduced the effect of this tendency. Survey results were also collected in conjunction with a chart audit to develop an overall understanding of PPM practices used for each child's most recent needlestick. This minimized the risk of PPM interventions not being recorded as having been implemented.

Setting

The pediatric inpatient unit at KGH is a Level III pediatric inpatient care unit consisting of ten medical-surgical beds and four pediatric critical care unit (PCCU) beds. The unit is staffed by 30 Registered Nurses in both full- and part-time positions. KGH is included in the KHSC hospital network that services a catchment area of over 20,000 square kilometers, including many northern rural communities (KGH, 2018). KGH is also one of five tertiary care members of the Ontario Pediatric Critical Care Network (KGH, 2018). In one year, the pediatric unit at

KGH admits an average of 1700 children, 0-18 years of age. There was no inclusion of outpatient clinics in this study as the focus was on patients within the inpatient setting.

Sample

Due to the strictly descriptive nature of this initial study, a convenience sample of 50 participants was proposed. This sample size was based on the assumption that an average of 1700 annual (approximately 142 monthly) pediatric admissions would continue to occur. Due to the part-time availability of the Primary Investigator's (PI; Jennifer Revell (JR)), schedule, combined with the assumption that general pediatric research follows the 15-20% non-consent rate found in pediatric critical care research (Menon et al., 2012), it was predicted that data for 50 children could be collected over a period of approximately one month. This one-month period was considered suitable, to ensure data collection from a sufficient number of children in order to be able to draw meaningful conclusions and to fit within the timeline of MScN candidature.

Eligible participants were defined as pediatric inpatients, aged 0 days to 18 years, who were inpatients on the pediatrics inpatient unit (Kidd 10) at KGH. To be eligible, a legal caregiver of the child (if under 14 years of age) must have understood English and have been present to provide informed consent. A child over 14 years of age was deemed able to self-consent by the overseeing ethics boards and were eligible if they understood English and were capable of self-consenting. Eligible participants must have not previously participated in this study. Children were deemed ineligible if they demonstrated profoundly decreased levels of consciousness in a manner that could have affected their reaction to the needlestick. Because the study was strictly descriptive and could have been based on caregiver report when a child was deemed incapable of participation, receipt of a muscle relaxant, sedative, or opioid analgesic in the previous 24 hours and diagnosed developmental delay did not exclude a child from this

study. Children who had been admitted to the neonatal intensive care unit (NICU) during their current admission were also excluded due to varied PPM practices, policies, and admission ordering practices between the NICU and the rest of the hospital system.

Recruitment & Study Promotion

Although hospital staff were not actively involved in the collection of study data, their role in identifying potential participants was essential to study success. Once approval from the unit manager and the required ethics boards had been received an e-mail was sent to the pediatrics staff to introduce them to this study. This study had the added benefit of unit staff having already been familiarized with the PI from interactions with the previously proposed toddler-focused study (Appendix A).

On each data collection day, JR, in conjunction with the charge nurse or unit clerk, reviewed the unit census in full to identify eligible participants. The child's primary nurse was asked to briefly approach potential participants and/or their caregivers to inquire about their interest in study participation and to obtain permission for the child and/or caregiver to be approached by the PI. Once the primary caregiver and/or child had expressed interest in study participation, the PI confirmed eligibility. Once deemed eligible, the PI met with the child (if over 14 years of age) and/or caregiver(s) of potential participants to explain the study's purpose and procedures. Children and caregivers were reassured that study participation was voluntary, and the risks and benefits of participation in the research were stated. A corresponding signed informed consent form from the caregiver (or child if over 14 years of age) was obtained at this time (Appendix B). A written assent form was obtained from children younger than 14 years who were deemed able to understand the content of the form (Appendix B). The assent form was obtained after consent was obtained from a caregiver, as assent alone was insufficient to allow

for study participation. If a child refused to provide assent but the caregiver consented to study participation, the child's data was still included in the study, but data was only collected from the consenting caregiver(s). A signed copy of the consent form, and assent form when appropriate, was given to the child and/or their caregiver, and a second copy was stored by the PI.

Data Collection

Convenience sampling, recruiting those who were readily available to the PI (Polit & Beck, 2012), was used as the PI had access to all potential participants who were present on the pediatrics unit during data collection periods. Data collection occurred on weekdays and weekends between 1200 and 1800hrs subject to the availability of the PI. This time frame was selected to avoid nursing shift changes and daily physician morning rounds as both these events interfere with nursing staff, patient, caregiver, and medical chart availability. Each inpatient was only eligible for one paired chart review and child-caregiver survey. If a child was discharged and readmitted, they were not eligible for a second chart review or survey. The PI planned to be present for a period of approximately one month or until 50 data sets (paired chart review and child-caregiver surveys) had been collected, whichever came first.

Once informed consent was obtained, participants were assigned a randomly generated identification number. Collected demographic data included age in months, sex, admission history, and reason for admission. Date of birth (for more accurate age analysis) was not collected as it was considered to be an identifying factor. The chart review occurred after the child-caregiver survey to ensure the same needlestick was examined for both data collection components.

A structured data collection method, in-line with the positivist research paradigm, was used. This approach required structured and descriptive observations (Salmon, 2015) to allow for

the quantification of specific behaviours related to the phenomenon being studied. The use of a structured approach ensured data completeness while preventing contamination based on the researcher's preconceived beliefs and biases (Salmon, 2015; Twycross, 2002). As there was no policy to guide PPM at KHSC at the time of this study, the PI could not fully predict which PPM interventions would be observed. Therefore, a field notes section was included in the data collection sheet to allow for unexpected PPM interventions (for example, the application of heat or cold), as well as child-caregiver feedback, to be included in the data.

Data Collection Tools

A categorical and rating scale data collection tool that was modified from the Harrison et al.'s (2014a) and Wilding et al.'s (2019) study protocols was used to collect all research data (Appendix C). The data collection tool used for this study included a demographic data collection section as well as two distinct components: a chart review and a brief child-caregiver survey. The first component, the chart review tool, collected information on documented physical, psychological, or pharmacological (3-P) interventions used prior to, during, and immediately after the child's most recent needlestick (as identified by participants). If pharmacological interventions were used prior to the needlestick, they were only recorded in this section if there was documentation to demonstrate their administration was for the purpose of pain management for the upcoming painful procedure.

The second component of the data collection tool, the child-caregiver survey, consisted of six structured questions pertaining to the child's most recent needlestick. The survey required children and/or caregivers to identify the child's most recent needlestick, which PPM interventions were used, and a rating of the child and/or caregiver's perceived effectiveness of pain management for the identified procedure. Child self-report was used when possible;

caregiver report was used when the child was unable to self-report or refused to assent. The primary and secondary respondents were noted on the data collection form. Four-point scales were used to quantify the child's or caregiver's perceived effectiveness of PPM interventions and PPM satisfaction scores. Effectiveness was described to participants as how well the interventions worked to minimize pain. Satisfaction was described to participants as how much they felt their expectations for pain management were met. Satisfaction was rated for the child's most recent needlestick and then overall to include all painful procedures at KHSC for this specific admission. The use of rating scales for portions of the child-caregiver surveys allowed for measurement of variables along a descriptive continuum while facilitating consistent measurements for all participants (Polit & Beck, 2012). When rating scales are used in conjunction with a categorized data collection method, richer data about the phenomenon can be obtained (Polit & Beck, 2012). Inclusion of field notes and an "other" category in each section allowed for unpredicted PPM interventions and general qualitative feedback to be categorized and included in the data set. The thesis committee, deemed experts in this field, reviewed both study tools for clarity and appropriateness prior to use.

Study Procedure

On each data collection day, the unit census was reviewed by the PI in conjunction with the charge nurse and/or unit clerk to identify eligible participants and the bedside nurses obtained permission from children and caregivers to be approached by JR. JR then explained the study to the caregivers and child (if appropriate), informed written consent from the caregiver or child if over 14 years of age, and assent from the child (if able) was obtained. The PI conducted the child-caregiver survey in the presence of the child and caregiver(s) (if required). When the caregiver and child were both competent to respond to the survey, only one mutually agreeable

response was recorded. The primary and secondary respondents were noted on the data form as “child” or “caregiver” as appropriate. Chart reviews occurred immediately following the survey and only reviewed documentation related to the procedure identified during the child-caregiver survey. All chart reviews must have been paired with a completed child-caregiver survey to be included in the study. This improved the accuracy of the description of current PPM practices. If a child or caregiver withdrew consent, or if only one data tool was completed, the data would not have been included in the study. Data were entered into an electronic data management system, and hard copies were retained in a locked office. Data were, and will continue to be, securely conserved for five years after the conclusion of the study period and then destroyed as per the requirements of the ethics boards approving this study.

Data Analysis

Data were entered into Microsoft Excel, cleaned, and then imported into the IBM SPSS 25.0 data analysis program. Data were analyzed using uni- and bivariate descriptive statistics. Frequencies, ranges, means and standard deviations or medians and interquartile ranges were used based on data distribution (Polit, 2010). Due to the small sample size, data were considered to be normally distributed if skewness was between -2.00 and 2.00 (Polit, 2010). The frequency of procedures and use of a 3-P approach was analyzed for all units where procedures occurred. The PPM interventions that were reported were further analyzed within six pre-defined age categories as some PPM interventions are only recommended to be used for specific age groups. The age categories were defined as neonates (0-28 days), infants (28 days-12 months), toddlers (12-36 months), pre-schoolers (3-7 years), school-aged (7-13 years), and adolescents (13-18 years). These age categories were selected to facilitate comparison to previous, similar epidemiological studies by Harrison et al. (2014), Stevens et al. (2011), and Wilding et al.

(2019). Although breastfeeding can be considered a 3-P approach, for the purpose of this study breastfeeding was categorized on the data collection tool and subsequently analyzed as a physical intervention to facilitate comparison to existing PPM studies and practice guidelines.

As each chart review was paired with a child-caregiver survey, comparisons were made between the PPM interventions reported during the child-caregiver surveys and any documented PPM interventions identified during the chart review. Ordering frequency for topical anesthetic and sucrose were cross-tabulated for each age group. Correlations between the number of PPM interventions used/patient age and reported PPM effectiveness/satisfaction were explored using Kendall's Tau rank correlations due to its robust nature with small sample size and the interval, nominal, and ordinal nature of the variables being measured (Polit, 2010). Pearson's correlation coefficient was calculated when interval or ratio variables were compared (Polit, 2010).

Qualitative information was only recorded when freely given by participants as this study was not designed as qualitative research, and no probing questions beyond the structured survey were used to explore participants' experiences. Qualitative data collected in the field notes were read in-depth and then manually categorized into themes.

Ethics

The pediatrics unit manager at KGH was approached and granted support and permission to carry out this chart-review and survey-based study. This proposal was submitted as an amendment (Appendix D) to the initial toddler-based study protocol to the same two ethics boards as the initially proposed study (Appendix A7). The PI continued to hold a Hospital Research Appointment through Kingston General Hospital Research Institute (KGHRI) for the duration of this study, as per KGHRI policy.

Once identified as potential research participants, caregivers of eligible inpatients were

given an explanation of the purpose of the study, survey requirements, and the nature of the chart review process. All caregivers of potential participants, or the child if over 14 years of age, were asked to sign a consent form that included information about the study, a guarantee of confidentiality and the right to terminate study participation at any time without consequence to them or their child. A written assent form was collected from children under 14 years of age when the child was deemed able to understand the form's content. If a child under 14 years of age refused to provide study assent, data was still collected from a caregiver if caregiver consent to participate was provided. No compensation was provided for study participation.

Chapter Four: Results

Chapter Four: Results

Participant Recruitment and Demographics

Recruitment and Enrolment

Data collection occurred on Kidd 10, the KHSC inpatient pediatrics unit at the KGH site, from May 16 to June 5, 2019 (21 days). Data collection occurred every day with the exception of May 28 due to PI illness. There were 76 children screened, of which 58 were approached for participation in this study. As depicted in Figure 1, 13 children had no caregiver available, one caregiver of a young child did not speak English, one child was over 14 years of age but was deemed non-consentable and had no caregiver present, and one had been admitted to the NICU and then transferred to the pediatrics inpatient unit. Additionally, one nurse refused to allow the PI to approach the caregivers of a child being managed under palliative care, and one child was off the unit at the time of data collection. Of the 58 children who were approached, seven parents and one child over 14 years of age refused to consent to participate, giving a refusal rate of 14%.

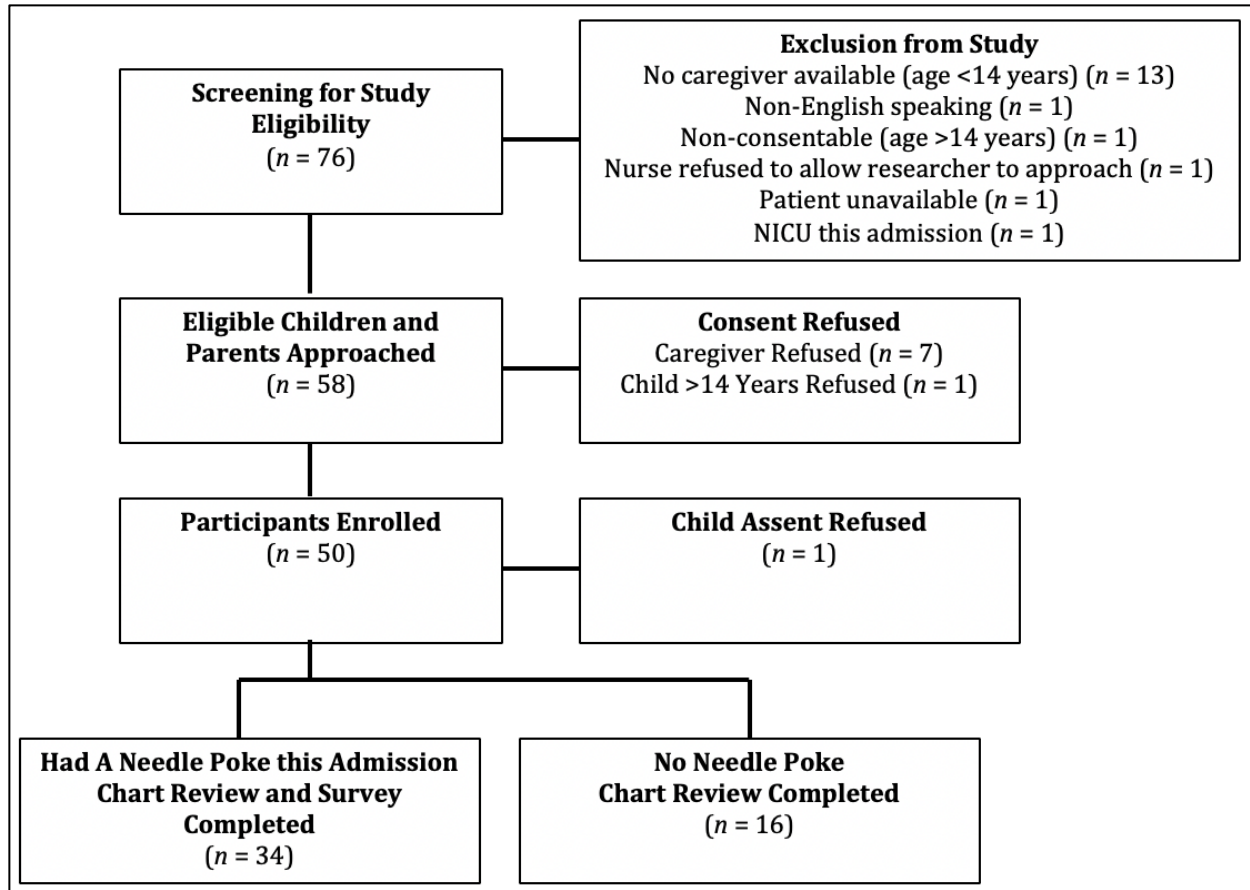


Figure 1. Screening Flow Chart

Participant Demographics

A total of 50 children were included in this study, 26 males (52%) and 24 females (48%). Participants were divided into age groups as follows: neonates ($n = 3$, 6%), infants ($n = 6$, 12%), toddlers ($n = 9$, 18%), pre-schoolers ($n = 7$, 14%), school-aged ($n = 16$, 32%), and adolescents ($n = 9$, 18%). The mean age in years ($\pm SD$) was 7.06 ± 5.53 . Just under half ($n = 24$, 48%) of the participating children were admitted to the hospital for the first time. The number of days since admission was positively skewed (2.615) and participants had been admitted for a median of 1 day ($IQR = 1$) at the time of data collection. Participants were most often admitted for non-infectious gastrointestinal ($n = 10$, 20%), infectious respiratory ($n = 6$, 12%), or elective surgery ($n = 6$, 12%) reasons. Most surveys were completed on the day of the participant's admission (n

= 18, 36%) or the day after admission ($n = 26$, 52%). The three neonates included in the survey were admitted as overflow from the post-partum unit and had never left the hospital. Most survey respondents were caregivers ($n = 31$, 62%) while children and caregivers together completed 14 (28%) of the surveys, and four children (8%) completed the survey without a caregivers' assistance. Additional participant characteristics are displayed in Table 1.

Table 1. Demographic Characteristics ($n = 50$)

Participant characteristic		n	(%)
Age Group	Neonate (0-28 days)	3	(6)
	Infant (28 days-12 months)	6	(12)
	Toddler (12-36 months)	9	(18)
	Pre-School (3-6 years)	7	(14)
	School-Aged (7-12 years)	16	(32)
	Adolescent (13-18 years)	9	(18)
Sex	Male	26	(52)
	Female	24	(48)
Reason for Admission	GI (Non-Infectious)	10	(20)
	Elective Surgery	6	(12)
	Respiratory (Infectious)	6	(12)
	Respiratory (Non-Infectious)	5	(10)
	Other	5	(10)
	Trauma/Urgent Surgery	3	(6)
	Newborn Overflow	3	(6)
	Neurological	2	(4)
	Endocrine	2	(4)
	Exacerbation of Chronic Condition	2	(4)
	Genitourinary	2	(4)
	Oncology	2	(4)
	Cardiovascular	1	(2)
	GI (Infectious)	1	(2)
First Hospital Admission	Yes	24	(48)
	No	23	(46)
	Newborn	3	(6)
Had Bloodwork Done	Yes	34	(68)
	No	16	(32)
Interview Respondent	Caregiver	31	(62)
	Both	14	(28)
	Child	4	(8)
	Not Recorded	1	(2)

Summary of Painful Bloodwork Procedures

The first objective of this study was to develop a baseline description of needlestick procedures that occurred for pediatric inpatients at KHSC. Each child and/or caregiver self-identified their most recent needlestick and the KHSC unit where the needlestick occurred. Contingency tables were constructed to compare the frequency of each type of needlestick with the locations where needlesticks were reported to have occurred (Table 2). Of the 50 participants, 34 (68%) reported having had a needlestick during their admission at KHSC. Procedures occurred in six units within KHSC. Over half of these 34 participants ($n = 20$, 59%) reported their most recent needlestick had occurred on Kidd 10. Other locations where needlesticks occurred were the ED ($n = 7$, 21%), the Operating Room ($n = 3$, 9%), Urgent Care ($n = 2$, 6%) and one (3%) each in Intervention Radiology (IVR) and COPC. As shown in Table 2, the two most frequent types of needlesticks reported, accounting for 82% of all needlesticks, were blood draws with IV cannulation ($n = 15$, 44%), and venipuncture ($n = 13$, 38%).

Table 2. Most Recent Needle Procedure by Location ($n = 34$)

Location	Blood Draw with IV Cannulation	Veni- puncture	Heel Lance	Finger Stick	PICC Line Insertion	Total
	n (%)¹	n (%)¹	n (%)¹	n (%)¹	n (%)¹	n (%)²
Kidd 10	7 (35)	8 (40)	3 (15)	2 (10)		20 (59)
ED	4 (57)	3 (43)				7 (21)
OR	3 (100)					3 (9)
Urgent Care		2 (100)				2 (6)
IVR					1 (100)	1 (3)
COPC	1 (100)		3 (9)			1 (3)
Total	15 (44)	13 (38)	3 (15)	2 (6)	1 (3)	34 (100)

PPM Practices

Pharmacological PPM Ordering Practices

Prescriber ordering practices for topical anesthetic (Table 3) were reviewed through the examination of each participant's Medication Administration Record (MAR) as all orders for

pharmacological agents must be transcribed onto the patient's MAR as per hospital policy.

Fourteen participants (28%) had standing orders for Ametop. No participant MARs were noted to have EMLA or LET ordered. Ametop ordering rates were below 50% for all age groups but was most frequently ordered for school-aged children ($n = 7$, 44% of age group) and was ordered for at least one participant in each age group except for neonates. In one case (2%) the MAR was unavailable for review at the time of data collection.

Participant MARs were also reviewed for the presence of a sucrose order (Table 3) as oral sucrose must be ordered by a physician prior to administration. Two of the three neonates in the study (67% of age group) and one of the five infants (20% of age group) whose charts were reviewed had an order for sucrose administration during painful procedures. One infant's chart (17% of age group) was unavailable for review at the time of data collection. No child in any other age group ($n = 41$, 82%) had a standing order for oral sucrose.

Table 3. Pharmacological PPM Ordering Practices by Age Group (*n* = 50)

Pharmacological Agent Ordered		Yes	No	Not Recorded
		n (%) ¹	n (%) ¹	n (%) ¹
Topical Anesthetic (Ametop)	Neonate		3 (100)	
	Infant	2 (33)	3 (50)	1 (17)
	Toddler	3 (33)	6 (67)	
	Pre-School	1 (14)	6 (86)	
	School-Age	7 (44)	9 (56)	
	Adolescent	1 (11)	8 (89)	
Total ²		14 (28)	35 (70)	1 (2)
Sucrose	Neonate	2 (67)	1 (33)	
	Infant	1 (17)	4 (67)	1 (17)
	Toddler		9 (100)	
	Pre-School		7 (100)	
	School-Age		16 (100)	
	Adolescent		9 (100)	
Total ²		3 (6)	46 (92)	1 (2)

¹Proportion of age group; ²Proportion of all participants

Documented PPM Practices During Needlestick

The PPM interventions noted in the chart review for the 34 of 50 (68%) children who reported at least one needlestick were cross-tabulated by age group to explore PPM practices as documented by KHSC nursing staff. The results are depicted in Table 4. Documented PPM interventions were only found in seven of the 34 (21%) children's charts, while 27 of the 34 (79%) children who had a needlestick were found to have no documentation noting the use of any PPM interventions. The only physical intervention documented during needlesticks was breastfeeding, and only for one of four children under 12 months of age (25% of this age group). Breastfeeding and nitrous oxide were the only PPM interventions documented for any member of the infant age group. The charts for two school-aged children (18% of age group) and one adolescent (13% of age group) contained documentation noting the use of a topical anesthetic. Pre-analgesia was documented for one infant (33% of age group) who received nitrous oxide, one school-aged child (9% of age group) who received IV midazolam, and one adolescent (13%

of age group) who received IV fentanyl. For children with documented pharmacological interventions ($n = 6$, 18%), the last reported needlestick was either blood draw with IV cannulation ($n = 5$) or PICC line insertion ($n = 1$). No documentation noted the use of more than one pharmacological intervention for any child's most recent needlestick. There was no documentation of pharmacological interventions for any child in the neonatal, toddler, or pre-school age groups. Aside from the single case of breastfeeding use during one infant's procedure there was no documentation of physical PPM interventions being used, and no psychological PPM interventions were documented regardless of child age.

Table 4. Documented PPM Interventions ($n = 34$ needlesticks)

	Neonates ($n = 1$)	Infants ($n = 3$)	Toddlers ($n = 6$)	Pre- Schoolers ($n = 5$)	School- Aged ($n = 11$)	Adolescents ($n = 8$)	Total ($n = 34$)
PPM Interventions	n (%) ¹	n (%) ¹	n (%) ¹	n (%) ¹	n (%) ¹	n (%) ¹	n (%) ²
Topical Anesthetic					2 (18)	1 (13)	3 (9)
Sucrose							0 (0)
Pre-Analgesia		1 (33)			1 (9)	1 (13)	3 (9)
Breast Feeding		1 (33)					1 (3)
No PPM Documentation	1 (100)	1 (33)	6 (100)	5 (100)	8 (73)	6 (75)	27 (79)

¹Proportion of each age group; ²Proportion of all procedures

Children and Caregivers' Reported PPM Practices

The PPM interventions reported by children and caregivers who described a needlestick during their admission were correlated and cross-tabulated by age group to explore PPM practices; the results are depicted in Table 5. Only one participant (3%), a school-aged child, reported that no PPM interventions were used for their last needlestick. The caregivers of one toddler (3%) and one school-aged child (3%) were "unsure" of which PPM interventions had been used. The use of physical interventions was reported for at least one participant in each age group. No pharmacological interventions were reported for any toddlers ($n = 6$). Of the 34

participants who reported at least one needle stick, twelve participants (35%) reported at least one pharmacological strategy, 26 (77%) reported at least one physical strategy, and 29 (85%) reported at least one psychological strategy. These 34 participants reported that an average of 3.97 ± 1.616 ($Min = 0$, $Max = 7$) PPM interventions were used for their most recent needlestick. Number of interventions reported was weakly, positively correlated with participant age ($r = .132$, $p = .470$).

The most commonly reported PPM interventions for the sample of 34 children who underwent needlesticks, when age group was not considered, were verbal support ($n = 25$, 74%), procedural explanation and preparation ($n = 22$, 65%), position of comfort ($n = 18$, 53%), distraction ($n = 14$, 41%) and cuddling ($n = 14$, 41%). Distraction was most often reported as helping the child to look away ($n = 6$, 18%) and talking and/or touching ($n = 5$, 15%). Topical anesthetic was the most common pharmacological agent used but was only used for 8 of the 34 (24%) identified needlesticks.

The caregiver of the only neonate ($n = 1$) who had received a needlestick reported breastfeeding and swaddling/cuddling child (physical PPM). Three of six infants included in the sample had experienced at least one needlestick procedure. Caregivers of two infants reported sucrose was used, while breastfeeding, topical anesthetic and pre-medication using nitrous oxide were each reported once. Physical PPM was reported by three parents, and included NNS ($n = 1$), breastfeeding ($n = 1$), swaddling ($n = 1$), and cuddling ($n = 1$). Verbal support ($n = 2$) was the only form of psychological PPM reported for this age group. The average number of PPM interventions reported for infants was 3.33 ± 2.08 .

Six of nine toddlers had undergone a needlestick and no parents reported the use of any pharmacological PPM. An average of 4.20 ± 0.58 PPM interventions were reported for toddlers.

No pharmacological interventions were reported by the caregivers of any toddlers. Reported physical PPM interventions for these six toddlers included cuddling ($n = 4$), swaddling ($n = 3$), using a position of comfort ($n = 3$), and NNS ($n = 2$). Caregivers of toddlers reported psychological PPM through verbal support ($n = 4$), explanation and preparation ($n = 3$), and distraction ($n = 2$). One parent reported their toddler was reportedly restrained for the procedure. The only form of distraction used for toddlers was talking and/or touching the child.

Parents of five of the seven pre-schoolers reported a needlestick, but only one received a topical anesthetic. No other pharmacological PPM was reported for this age group. Reported physical interventions for the five pre-schoolers who had a needlestick were limited to cuddling ($n = 3$), swaddling ($n = 2$), and position of comfort ($n = 1$), while the psychological interventions of distraction occurred for toddlers using talking and/or touching ($n = 2$). Verbal support and explanation and preparation were each reported four times within this age group while distraction was reported twice. Procedures involving pre-schoolers were reported to have used an average of 3.40 ± 1.34 PPM interventions.

School-aged children who underwent a needlestick ($n = 11$ of 16) reported an average of 4.10 ± 2.18 PPM interventions. Topical anesthetic ($n = 2$) and pre-analgesia ($n = 2$) with IV midazolam ($n = 1$) and nitrous oxide ($n = 1$) were pharmacological interventions used, while position of comfort ($n = 7$) and cuddling ($n = 3$) were the only reported physical PPM interventions for this age group. Breathing strategies ($n = 5$) and distraction ($n = 5$) using looking away ($n = 2$), talking and/or touching, videos, and phone games ($n = 1$ for each) were reported for the school-aged group. Verbal support ($n = 9$) and explanation and preparation ($n = 8$) were commonly reported for this age group. One school-aged child was restrained for the procedure.

Of the eight adolescents (87%) who had a needlestick procedure, topical anesthetics were

reportedly used for four procedures and was the only pharmacological intervention used for this age group. Physical interventions included the use of a position of comfort ($n = 7$), cuddling with a parent ($n = 2$), and application of a hot blanket ($n = 1$). Three-quarters of adolescents ($n = 6$) reported the use of verbal support and nearly all ($n = 7$) reported that explanation and preparation had been used. Half ($n = 4$) reported the use of breathing strategies, and five reported distraction in the form of either looking away ($n = 4$) or playing on an iPad ($n = 1$). One adolescent was reported to have used parent-led relaxation strategies but indicated this intervention was not effective for pain management. Overall, adolescents reported 4.38 ± 1.41 PPM interventions were used during their most recent needlestick.

Table 5. Child-Caregiver Reported PPM Interventions by Age (*n* = 34)

		Neonates (<i>n</i> = 1)	Infants (<i>n</i> = 3)	Toddlers (<i>n</i> = 6)	Pre- Schoolers (<i>n</i> = 5)	School- Aged (<i>n</i> = 11)	Adolescents (<i>n</i> = 8)	Total (<i>n</i> = 34)
PPM Interventions		<i>n</i> (% ¹)	<i>n</i> (% ¹)	<i>n</i> (% ¹)	<i>n</i> (% ¹)	<i>n</i> (% ¹)	<i>n</i> (% ¹)	<i>n</i> (% ²)
Pharmacological	Topical Anesthetic		1 (33)		1 (20)	2 (18)	4 (50)	8 (24)
	Sucrose		2 (67)					2 (6)
	Pre-Analgesia		1 (33)			2 (18)		3 (9)
	Other							
Physical	Non-Nutritive Sucking		1 (33)	2 (33)				3 (9)
	Cuddling	1 (100)	1 (33)	4 (67)	3 (60)	3 (27)	2 (25)	14 (41)
	Kangaroo Care							
	Swaddling	1 (100)	1 (33)	3 (50)	2 (40)			7 (21)
	Position of Comfort			3 (50)	1 (20)	7 (64)	7 (88)	18 (53)
	Breast Feeding	1 (100)	1 (33)					2 (6)
	Other	1 (100)					1 (13)	2 (6)
Psychological	Distraction			2 (33)	2 (40)	5 (46)	5 (63)	14 (41)
	Blowing Bubbles							
	Verbal Support		2 (67)	4 (67)	4 (80)	9 (82)	6 (75)	25 (74)
	Guided Imagery							
	Explanation & Preparation			3 (50)	4 (80)	8 (73)	7 (88)	22 (65)
	Breathing Technique					5 (46)	4 (50)	9 (27)
	Other						1 (13)	1 (3)
No PPM Reported						1 (9)		1 (3)
Unsure of PPM Used				1 (17)		1 (9)		2 (6)

¹Proportion of each age group; ²Proportion of all needlesticks

Comparison of Reported Versus Documented PPM Practices

Comparisons were made between nurse-documented and child-caregiver reported PPM practices for the reported needlesticks ($n = 34$). No documentation was made for any physical intervention except for breastfeeding ($n = 1$, 3%) or and no psychological interventions were documented despite physical and psychological interventions being frequently reported by children and caregivers ($n = 26$, 76% and $n = 29$, 85%, respectively). Pharmacological interventions were reported ($n = 12$, 35%) more often than they were documented ($n = 6$, 18%). Topical anesthetic was reported but not documented for six children (18% of procedures), documented but not reported for two children (6%), and both reported and documented for two children (6%). Pre-analgesia was reported but not documented for one child (3%) who received lidocaine, documented but not reported for one child (3%) who received IV fentanyl, and both reported and documented for two children (6%), one of whom received nitrous oxide and one who received IV midazolam. Breastfeeding was used for one infant's needlestick (3%) and was both reported and documented but was only reported, not documented, for one neonate's heel stick (3%). There was no documented administration of sucrose despite being reported by two (6%) caregivers.

Use of the 3-P Approach

Data from the child-caregiver survey and chart review were combined and explored to identify the use of combined pharmacological, physical, and psychological approaches (3-P approach) for the 34 participants who had undergone a needlestick during their current admission. An approach was considered to have been used if the chart review and/or child-caregiver survey noted the use of one or more interventions in a category (pharmacological, physical, and psychological). Use of a 3-P approach was noted to have been used for 9 (26%) of

the 34 children who experienced at least one needlestick and at least once in four of the six units where recent needlesticks had occurred (Table 6). The only units to consistently utilize a 3-P approach were the operating room ($n = 2$) and IVR ($n = 1$). A 3-P approach was never reported for COPC or the Urgent Care Centre. Use of a 3-P approach was variable within each age group (Table 7) and type of procedure (Table 8). The 3-P approach was used during a needlestick for one infant, four school-aged children, and four adolescents. A 3-P approach was never reported for the neonate, toddler, or pre-school age groups. It was unclear from participant reports if a 3-P approach was used for two (6%) procedures (one venipuncture and one IV cannulation). A 3-P approach was reported for eight IV cannulations and the single PICC line insertion.

Table 6. Use of 3-P Approach by Location ($n = 34$)

Location	Yes n (%) ¹	No n (%) ¹	Unsure n (%) ¹
Kidd 10	4 (20)	15 (75)	1 (5)
ER	2 (29)	5 (71)	
COPC		1 (100)	
HDH Urgent Care		2 (100)	
IVR	1 (100)		
OR	2 (67)		1 (33)
Total ²	9 (26)	23 (68)	2 (6)

¹Proportion of needlesticks on each unit; ²Proportion of all needlesticks

Table 7. Use of 3-P Approach by Age Group ($n = 34$)

Age Group	Yes n (%) ¹	No n (%) ¹	Unsure n (%) ¹
Neonate		1 (100)	
Infant	1 (33)	2 (67)	
Toddler		5 (83)	1 (17)
Pre-school		5 (100)	
School-aged	4 (36)	6 (55)	1 (9)
Adolescent	4 (50)	4 (50)	
Total ²	9 (26)	23 (68)	2 (6)

¹Proportion of age group; ²Proportion of all participants

Table 8. Use of 3-P Approach by Procedure (n = 34)

Type of Procedure	Yes n (%) ¹	No n (%) ¹	Unsure n (%) ¹
Heel Lance		3 (100)	
Venipuncture		12 (92)	1 (8)
Blood Draw with IV Cannulation	8 (53)	6 (40)	1 (7)
Finger Stick		2 (100)	
PICC Line Insertion	1 (100)		
Total	9 (26)	23 (68)	2 (6)

¹Proportion of each procedure

Child-Caregiver Perceptions of Current PPM Practices

Survey participants were asked to rate their perceived effectiveness of the PPM interventions using during their last needlestick. When the location of the participants' last needlestick was not considered, perceived PPM effectiveness rates were reported as follows: 12 of the 34 participants who had a needlestick (35%) reported the PPM was extremely effective; eight (24%), moderately effective; six (18%), mildly effective; two (6%), not at all effective; five (15%), unsure of effectiveness, and one (3%) reported nothing specific was used for PPM. Perceived effectiveness of PPM for a participants' last needlestick was negatively correlated ($\tau = -.290, p = .048$) with the number of PPM interventions reported and weakly, negatively correlated ($\tau = -.145, p = .268$) with patient age.

Of the participants who had a needlestick on Kidd 10 ($n = 20$), eight (40%) reported they believed the utilized PPM interventions were extremely effective, while six (30%) believed the interventions were only moderately effective (Figure 2). For participants whose last needlestick was not on Kidd 10 ($n = 14$; Figure 2), four (29%) participants reported extremely effective pain management and two (14%) reported moderate effectiveness. Only one survey for the Kidd 10 group (5%) and one participant whose last reported needlestick was not on Kidd 10 (7%), reported that all PPM interventions used had no perceived effect on the child's pain.

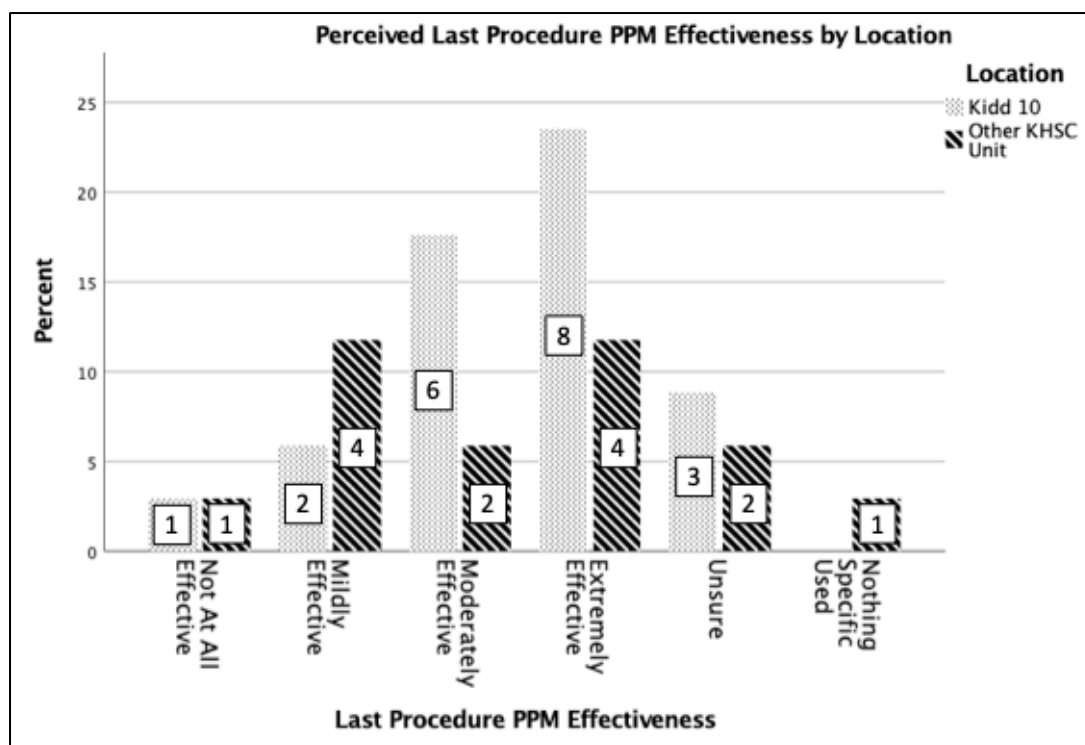


Figure 2. Perceived effectiveness of PPM during last procedure

Children and/or their caregivers were then asked to rate their satisfaction with the PPM interventions using during their last needlestick. Overall, 20 (59%) participants were very satisfied, eight (21%) were somewhat satisfied, three (9%) were somewhat dissatisfied, and one (3%) participant was very dissatisfied. One participant whose needlestick was on Kidd 10 and two whose needlesticks occurred elsewhere at KHSC were unsure of their level of satisfaction. PPM satisfaction was not correlated with the number of PPM interventions reported ($\tau = .012, p = .937$) or with patient age ($\tau = -.103, p = .450$).

Satisfaction results were then examined based on if their last needlestick was on Kidd 10 ($n = 20$) or elsewhere in KHSC ($n = 14$). These results are depicted in Figure 3. Three-quarters of participants whose last needlestick was on Kidd 10 felt very satisfied with PPM practices ($n = 15, 75\%$), while only five (36%) participants whose last needlestick was not on Kidd 10 reported

being very satisfied. No participants whose last needlestick was on Kidd 10 reported being very dissatisfied compared to one (7%) participant whose last needlestick was elsewhere at KHSC.

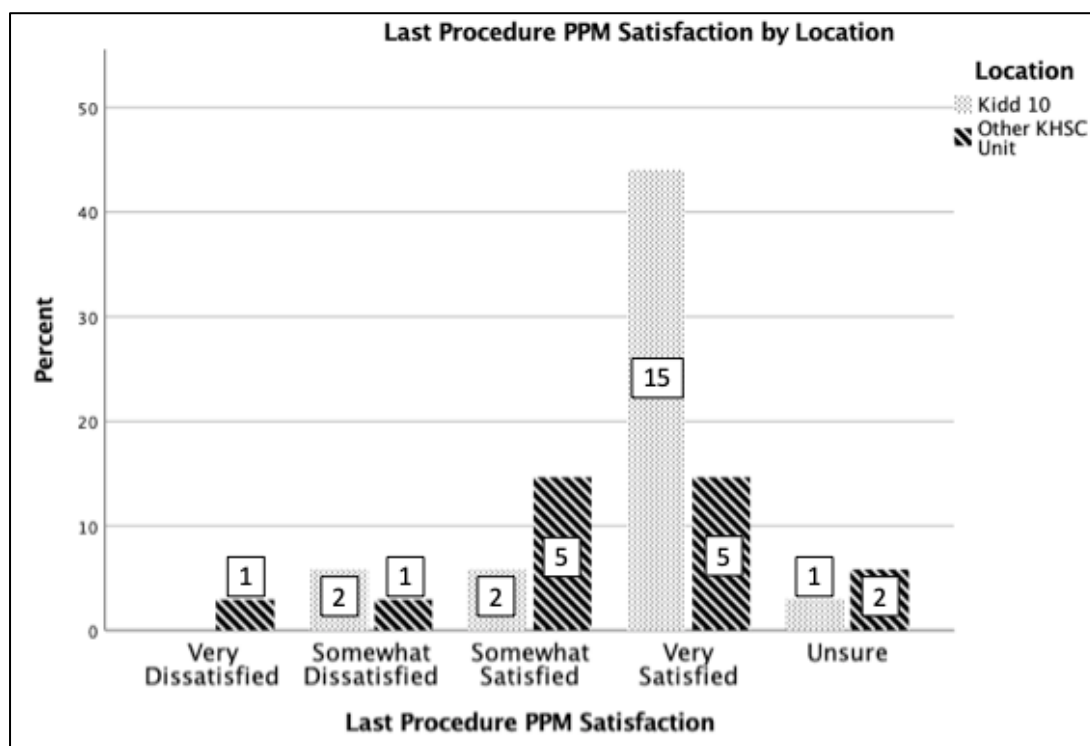


Figure 3. Reported PPM satisfaction for last procedure

Lastly, participants were asked to rate their overall satisfaction with PPM at KHSC for this specific admission. Overall, 18 of 34 (53%) participants who had at least one needlestick during their admission were very satisfied with overall PPM practices at KHSC. Remaining participants tended to be somewhat satisfied ($n = 11$, 32%), while a few were somewhat dissatisfied ($n = 3$, 9%) and one was very dissatisfied ($n = 1$, 3%). Only one parent-child survey identified that respondents were “unsure” of how to rate their overall satisfaction. Overall PPM satisfaction was not correlated with age ($\tau = -.025$, $p = .856$) or number of days since admission ($\tau = -.096$, $p = .541$).

Satisfaction data was also analyzed within the same location groups as those used for the analysis of last procedure PPM satisfaction. The proportion of participants whose last needlestick

was on Kidd 10 who were very satisfied with overall PPM was high ($n = 13$, 65%) compared to only 36% for participants ($n = 5$) whose last needlestick was not on Kidd 10. One participant (5%) reported being somewhat dissatisfied with overall PPM on Kidd 10 compared to 14% ($n = 2$) at other KHSC units. There were no reports of parents being very dissatisfied with overall PPM when the last needlestick took place on Kidd 10, while one participant (3%) whose last poke was not on Kidd 10 was very dissatisfied with overall PPM at KHSC.

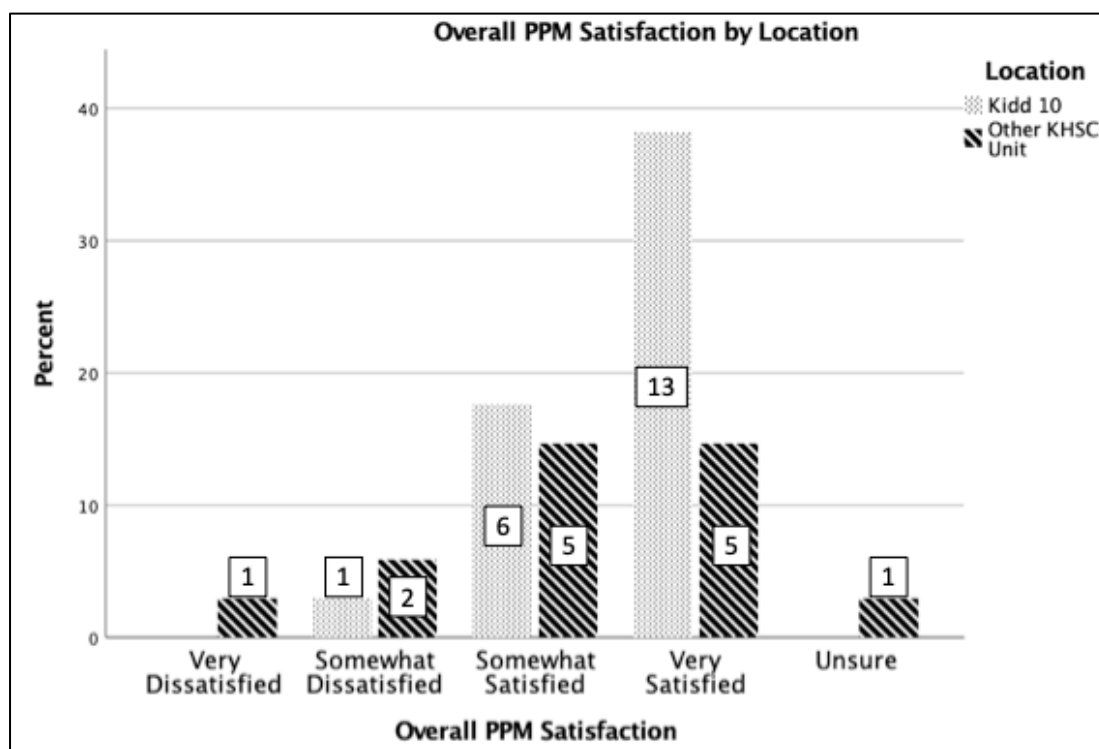


Figure 4. Overall PPM satisfaction

Qualitative Feedback from Participants

At the end of the survey, participants were allowed to provide any additional feedback related to PPM practices at KHSC to capture data that was not obtained in the structured survey responses. Of the 50 surveys collected, 20 included qualitative feedback. This feedback was categorized into five identified themes: (1) child-specific, (2) procedure-specific, (3) medication availability, (4) caregiver knowledge of and involvement in PPM, and (5) nursing feedback.

Child-specific feedback included statements that the child had not undergone any prior needlesticks for bloodwork, the child being a “difficult poke” due to having fragile veins, and distress related to a pre-procedure medical condition which worsened during the procedure. One child-caregiver dyad reported that the child had a history of severe anxiety related to bloodwork.

Procedure-specific feedback was generally related to the number of attempts required for procedure success. Parents expressed frustration when their children required multiple needlesticks for the same procedure (up to 13 attempts at IV cannulation were reported). One participant was satisfied with staff choosing a location for the peripheral IV that was ideal for the child (i.e.: not surrounding moving joints). One caregiver described asking for the indwelling hemodialysis access line to be accessed for a child who has chronically difficult IV access but was repeatedly told this was not possible as the Renal Unit refused to come and draw blood samples because the patient was not undergoing hemodialysis at the time.

Feedback also identified barriers to PPM use that were related to medication availability. One caregiver reported that previous administration of oral ketamine at COPC was beneficial for PPM but described being told this was not an option on Kidd 10. This child subsequently received IV midazolam instead. One participant reported requesting but being denied the application of topical anesthetic. Others reported having received topical anesthetic for previous procedures during the current admission but not the one discussed for this survey.

The lack of caregiver knowledge of available PPM was identified in several comments. Caregivers commonly stated that they did not know what could be done to improve pain and that they would like to know what was available for pain management before procedures begin. Others reported wanting to help reduce pain but did not know how to and wished that there was more that could be done to decrease procedural pain. Some caregivers suggested that nurses

could give caregivers a list of PPM options before the procedure, and children and caregivers could then select the strategies that would best suit the child. One caregiver suggested bringing a “pain kit” that includes items such as toys, bubbles, and books to the bedside. This caregiver also believed providing a variety of PPM options would return a sense of control to the child and caregiver, which may contribute to reduced procedural distress. One caregiver discussed concerns with being asked to help restrain a child during the last needlestick. This caregiver explained that helping to restrain a child could cause the child to associate the caregiver as being a source of pain. It was also suggested that having caregivers participate in procedural restraint limits their (the caregivers’) ability to provide distraction.

Feedback specific to the nursing staff was generally positive. Caregivers and children reporting that the “staff are amazing” on Kidd 10 and “[could not] say enough good things” about the nurses. Caregivers and children were happy that the staff on Kidd 10 were aware of skills limitations, and that nurses obtained assistance when they were not confident in their ability to complete a needlestick. One caregiver explained that when the CLS staff were involved in a child’s previous needlesticks, the experience was significantly more positive. However, the same caregiver reported that CLS support was not offered or involved in the most recent needlestick. This caregiver believed CLS should always be involved in painful procedures. Comments were also made in regard to the Emergency Department nursing staff not knowing how to manage procedural pain.

Chapter Five: Discussion

Chapter Five: Discussion

The use of evidence-based PPM and a 3-P approach is considered to be the best standard of care for all children undergoing needlesticks and appropriate PPM has been shown to reduce both immediate and future physical and psychological sequelae (McMurtry et al., 2015b). Despite advances in research and evidence-based guidelines, PPM strategies have not been fully implemented into pediatric nursing practice (Harrison et al., 2014; Harrison, Martelli, Reszel, Macartney, & Wilding, 2019; Stevens et al., 2011; Wilding et al., 2019; Zhu et al., 2012) and a majority of children undergoing painful needle procedures in Canadian hospitals have continued to report moderate to severe procedural pain (Harrison et al., 2014; Harrison et al., 2019; Stevens et al., 2011; Wilding et al., 2019).

The initially proposed study was designed to explore nursing PPM practices used for toddlers during venipuncture at KHSC, and toddlers' responses to pain ("proposed methods"). Due to unforeseen complications with participant recruitment, the study was amended to a cross-sectional study including all hospitalized children admitted to Kidd 10, using a paired chart review and child-caregiver survey. The amended study ("actual methods") was designed to provide a snapshot of the current PPM practices used by KHSC staff for pediatric inpatients' most recent needlestick. The study also provided insight into the perceived effectiveness of PPM interventions, and caregiver-child satisfaction with PPM at KHSC.

This was the first known study of its kind to be conducted at this tertiary care hospital and the results provide a benchmark for comparing current PPM practices at KHSC to other pediatric centres and to itself in the future. Of concern, the results of this study were comparable to previously published studies exploring, at least in part, procedural pain and PPM interventions. The number of painful procedures remained high, PPM was inconsistency utilized and poorly

documented, and practices were discordant with the recommended 3-P approach. However, children and caregivers tended to be satisfied with PPM practices despite the non-compliance with recommended practice guidelines and the plethora of available high-quality PPM evidence.

Epidemiology of Painful Procedures

The most common needle procedures previously reported for children are peripheral IV cannulation, venipuncture, and heel sticks (Ellis et al., 2004; Harrison et al., 2014; Harrison et al., 2019; Stevens et al., 2011). The findings from this study were no exception with these three procedures representing over 90% of the participants' most recent needlesticks. The rates of painful needle procedures were found to be high overall, and over two-thirds (68%) of the children in this study reported at least one needlestick during their current admission. This rate is consistent with recent reports on painful procedures at other facilities (Harrison et al., 2014; Harrison et al., 2019; Stevens et al., 2011)

The use of unnecessary procedures and diagnostic testing in the Canadian healthcare system is a common problem, with up to 30% of procedures and tests being deemed unnecessary (Choosing Wisely Canada [CWC], 2019). Routine and repetitive use of blood tests is not only painful, but can lead to hospital-acquired anemia, extra costs to the healthcare system, and has the potential to mislead patient care (CWC, 2019). Although KHSC has not yet partnered with the CWC campaign to reduce unnecessary testing, the reduced rate of painful procedures compared to decade-old reports may be a result of healthcare professionals beginning to re-evaluate current diagnostic ordering practices in favour of less invasive assessment and monitoring approaches.

During execution of the proposed methods, the nursing staff in one outpatient clinic anecdotally discussed a decrease in the routine use of laboratory testing in young children. They

stated that, historically, any child less than 3 years of age presenting with a fever was assessed by a physician and then ordered to have blood cultures and a bloodwork panel completed, and an in-and-out urinary catheterization was performed to identify potential sources of infection. Staff described how this practice had become significantly less common over the past year with physicians opting to use physical assessment findings in tandem with the history of the presenting illness in place of painful tests and procedures. In another outpatient clinic, the nursing coordinator identified the rapid placement of central venous access lines as a priority for patients who were expected to undergo long-term treatment and monitoring for their illness. Nursing staff from Kidd 10 identified that most blood sampling was being drawn before admission to the inpatient unit. This sampling was often reported to have been done when IV catheters were placed in the Emergency Department, COPC and Urgent Care Centre. While nurses were aware that aspiration from existing IV catheters was not considered best practice for blood specimen collection, this practice was commonly reported as one way in which nurses attempt to reduce the pain and distress inflicted on pediatric patients. Despite these anecdotal explanations for decreased rates of painful procedures, the fact that 68% of children in this study had undergone at least one needlestick continues to stress the need for appropriate, evidence-based PPM interventions and the organizational development of PPM policies and guidelines.

Ordering Practices for Topical Anesthetics and Oral Sucrose

Topical anesthetics are considered to be the standard of care for children 1 year and older who are undergoing a painful needle procedure (Taddio et al., 2015a) and Ametop (the only topical anesthetic found to be ordered during this current study) is stated by the manufacturers of the product to be safe for children older than 1 month (Smith&Nephew Canada, 2019). However, in the current study, orders for topical anesthetics were only found in 12 (30%) charts for

children who were 1 year of age or older and never for any child younger than 1 year. Although this ordering rate was low given best-practice recommendations, the ordering rates for topical anesthetic at this facility were more than double the pre-intervention rate of 10% that was recently found at another pediatric hospital (Rosenberg et al., 2016). After implementing a multidisciplinary intervention that included the pre-selection of topical anesthetic orders on admission, Rosenberg et al. (2016) found topical anesthetic use rates rose to 36.5% and topical anesthetic was found to be ordered for 100% of their post-intervention sample (pre and post-intervention sample combined included 4298 children). Rosenberg et al.'s (2016) post-intervention usage results were still comparable to the pre-intervention findings from the current study.

Oral sucrose is known to be effective and is considered PPM best practice for children younger than 1 year (Harrison et al., 2015a; Taddio et al., 2015a) when breastfeeding or SSC cannot occur. There is also some evidence to support benefit when administered to children up to 2 years of age (Harrison et al., 2015c; Taddio et al., 2015a). Despite this recommendation, in the current study sucrose was only found to be ordered for one-third of children less than 1 year of age and never for toddlers. No medical directives exist at KHSC for use of either sucrose or topical anesthetics. As both topical anesthetic and oral sucrose are considered medications at KHSC, nurses at KHSC are unable to administer these effective PPM interventions during painful needlestick procedures without physician orders.

While not explored in this study, several reasons for this low rate of medical ordering can be hypothesized. One possibility was that the structure of the residency program at KHSC results in physicians being rotated through different departments of the KHSC organization. This may have result in residents spending limited time familiarizing themselves with the pediatric unit as

well as pediatric best practices and may explain, at least in part, these missing orders. In addition to training in multiple areas in the hospital, physicians may have simply be forgetting to select the option for sucrose or topical anesthetic orders when completing electronic admission orders. Furthermore, several different sets of admission orders were identified during preparation for this study including general pediatrics admission, surgical pediatrics admission, and newborn admission variations. The orders for topical anesthetic and oral sucrose were, by default, not selected on any of these admission order sets. These variations in order sets and the default unselected order set-up may have further contributed to the observed low ordering rates.

Documented & Reported PPM

Comparisons between interviews and chart audits have repeatedly found that nurses' perceptions of their PPM practices are often superior to their practice in reality (Melhuish & Payne, 2006; Nuseir, Kassab, & Almomani, 2016; Twycross, 2007). Furthermore, previous studies exploring PPM practices have suggested that nurses may not be documenting all PPM interventions used during painful procedures (Harrison et al., 2014; Harrison et al., 2019; Stevens et al., 2011). If this were true, nurses may be using undocumented PPM interventions. Consequently usage rates may have been underestimated by previous studies that only used a retrospective chart review approach. At the time of the current study's commencement, only one other identified study had used a combined chart review and child-caregiver survey to improve awareness of which PPM interventions nurses are using. In Harrison et al.'s (2014a) study, documentation of non-pharmacological interventions was found in only 17% of charts but, similar to the current study, children and caregivers reports suggested that these interventions had been used more often. After implementing targeted pain management awareness programs, Harrison et al.'s (2014a) study was repeated and similar rates of pain management strategy

documentation were identified (Harrison et al., 2019). However, in Harrison et al.'s 2019 study executive summary, it was unclear if the interventions that were documented had been used specifically for painful procedures or for any painful experience including post-surgical pain.

The current study found only one instance of documentation for a non-pharmacological intervention (breastfeeding for one infant) despite more than three-quarters of participants reporting that at least one physical intervention had been used, and 29 of the 34 (85%) participants who underwent a needlestick reported that at least one psychological intervention had been used during their last needlestick. Pharmacological interventions were documented in 18% of charts ($n = 6$) but reported by more than one-third of participants. Therefore, the current study findings support the concept that chart reviews alone are insufficient to develop a true awareness of PPM intervention use. For most participants in the current study, no procedure documentation was present in the interprofessional progress notes ("narrative") section of the patient's chart. When PPM documentation was present in the narrative portion of the patients' charts, documentation was noted to be variable in content. No documentation reviewed for this study included an assessment of PPM intervention effectiveness.

Nursing documentation is an essential component of nursing practice. Accurate and timely documentation provides knowledge about a patient, the rationale to support decisions that have been made, records the outcomes of these decisions, provides evidence of patient progress, and communicates this knowledge to other healthcare providers (Blair & Smith, 2012). Despite the importance of documentation, the observed nursing documentation practices for this study fell below mandatory practice standards. In existing literature, commonly cited barriers to documentation include a lack of documentation guidelines and policies, staff ambivalence toward documentation, staff preferences toward providing instead of documenting care, time

constraints, and mismatches between available staff and patient workloads (Blair & Smith, 2012).

At the time of the current study's commencement, no documentation policy existed at KHSC. In June 2019, the "Inter-Professional Documentation Minimum Standards" policy was implemented to "promote patient safety by ensuring clear and accurate communication through standardized documentation" (KHSC, 2019b, p. 1). This new policy provided guidelines for the mechanics of documentation but failed to provide any guidance for documentation content. The absence of a clear documentation policy may explain, at least in part, the sub-standard and variable documentation found during the current study but does not justify poor nursing documentation practices. Most KHSC units use unit-specific flow-sheets with tick-boxes that capture a majority of standard nursing care. Patient charts also contain, at a minimum, a Kardex to communicate between nursing staff members, a MAR documenting pharmacological agent administration, and a narrative "Interprofessional Progress Notes" section. Having multiple locations for and methods of documentation may have contributed to data not being fully captured in chart audits used for quality improvement and research purposes.

The College of Nurses of Ontario (CNO) establishes the minimum requirements for entry to nursing practice, articulates practice standards to protect the public and guide nursing practice, and enforces nursing conduct and adherence to these standards (CNO, 2017). All nurses employed at KHSC are required to be registered with the CNO and are therefore accountable to work within the CNO practice standards. The CNO documentation practice standard describes the legal and regulatory minimums for nurses' documentation (CNO, 2008). This standard states that nursing documentation must provide a clear picture of the goals and needs of clients, the nurse's actions based on these needs, and the outcome and evaluation of the nurse's actions to

monitor and communicate a client's progress to other healthcare providers (CNO, 2008).

Therefore, the absence of a complete documentation policy at KHSC is not an acceptable reason for nurses to not be fully documenting their nursing care. Documentation is often left until the end of a nursing shift in an attempt to spend more time providing direct patient care. When documentation is hurried, entries often fail to include depth and detail due to difficulty in reconstructing memories of events (Jefferies et al., 2010). Further assessment of documentation practices has found that nurses' entries tended to consist of a list of tasks performed and often failed to communicate a patient's condition or response to the care provided (Jefferies et al., 2010). It was in all likelihood a combination of multiple factors that contributed to the observed incompleteness of nurses' documentation in healthcare records.

Despite the near-absence of nursing documentation about PPM interventions, the inclusion of a child-caregiver survey in this study allowed for a more complete overview of the PPM interventions that were actually used. Fifteen years ago, Ellis et al. (2004) used staff surveys after 378 needlesticks to evaluate the use of topical anesthetics, verbal support, and distraction interventions. They found that the reported rate of topical anesthetics was 19% ($n = 72$), verbal support was used for 75% of needlesticks ($n = 284$), and distraction was used for 28% of needlesticks ($n = 108$; Ellis et al., 2004). The current study found that while rates of distraction were slightly higher than other reports (Ellis et al., 2004; Harrison et al., 2014; Harrison et al., 2019), the reported use of distraction has remained relatively consistent over the past 15 years despite the advances in PPM research to support the use of multiple approaches including combined PPM. The rate of topical anesthetic use at KHSC, as reported by children and caregivers, were higher than the documented rate of use. This finding was similar to what was found by Harrison et al. (2014a) but was a disappointingly small increase when compared to

rates from 15 years ago (Ellis et al., 2004). The rate of sucrose use as reported by caregivers for neonates, infants, and toddlers was double the rate identified by child-caregiver reports in Harrison et al.'s (2014a) and Taddio et al.'s (2015a) studies but well below the guideline recommendation of usage for all children younger than 1 year of age. No child-caregiver survey respondents in the current study reported the use of oral sucrose for toddlers despite emerging evidence for its potential effectiveness among this age group (Harrison et al., 2015c; Taddio et al., 2015a).

When PPM interventions were used, they were inconsistently implemented but were age-appropriate. For example, sucrose was only used for children under 12 months of age, while topical anesthetics were never used for neonates or infants. However, as stated above, there is some evidence of sucrose efficacy beyond 12 months of age, and sucrose is recommended in the 2015 HELPinKIDS guideline for toddlers two years and younger (Taddio et al., 2015b). Therefore, if sucrose had been used in this age group, it would have been considered appropriate. At least one physical intervention was used for at least one member of every age group and when physical interventions were used they aligned well with age-specific practice guidelines (Taddio et al., 2015a). Psychological interventions beyond breastfeeding were appropriately used for at least one child in each age group beyond the neonatal period (for which most known effective PPM interventions are pharmacological and physical). However, a combination of several interventions, including multiple interventions from each category (a 3-P approach), continues to be the recommended standard of practice (Taddio et al., 2015a). Furthermore, as intervention effectiveness is highly dependent on each child's level of cognitive development, existing coping mechanisms, and their individualized preferences, it is recommended that child-specific interventions be selected (Birnie et al., 2018). The frequent report in this study of more than one

psychological intervention having been used for each child aligns well with this recommendation.

Examination of the results from the current study demonstrates that PPM practices at KHSC are sub-optimal based on best practice guidelines for specific interventions (i.e.: topical anesthetic, sucrose, distraction) and the recommended 3-P approach. The fact that a 3-P approach was used for only four of the six units where recent needlesticks had occurred and for only one-third of identified recent procedures at KHSC is concerning, but not inconsistent with reported practices at other pediatric-focused facilities. Of the studies that had previously explored PPM practices, only one presented data detailing the frequency of combined interventions. Stevens et al. (2011) found that 44 of 844 (5.2%) documentation events for procedures noted a combination of interventions but the authors did not define how they evaluated this variable. It is important to note that this study by Stevens et al. (2011) only used chart reviews. Therefore, as stated previously, the true rate of PPM use in Stevens et al.'s (2011) study may have been higher. Comparatively, the rate of a 3-P approach at KHSC was significantly higher (35% of procedures), but only when child-caregiver survey reports were considered. Overall, the inconsistent adoption of PPM interventions suggests that a more consistent and evidence-informed approach is required at KHSC.

Reports of PPM Effectiveness and Satisfaction

Although compliance with the recommended 3-P approach at KHSC was limited, children and their caregivers tended to perceive PPM strategies as effective and were often satisfied with PPM for both their most recent needlestick and overall for all painful procedures. There tended to be higher rates of satisfaction and perceived PPM effectiveness when a child's most recent needlestick had been performed on Kidd 10 versus elsewhere at KHSC. The reason

for this trend was not explored in this study but possible explanations do exist.

One explanation may be that Kidd 10 is a dedicated pediatrics unit where nursing staff have purposefully chosen to work. When staff have a desire to provide quality care for children, improved pain management practices are often facilitated (Marshall, 2018). A majority of these staff only work within the pediatric program and receive pediatric-specific training. This training and population-specific experience likely led to higher use of PPM, and the nurses' increased ability to provide recommended PPM interventions when compared to nurses in generalized all-ages units such as the Urgent Care Centre and the ED. The dedicated pediatric focus of Kidd 10 may have also unintentionally suggested to parents that the staff are more competent in providing care for their child when compared to units elsewhere in the hospital. This could have positively influenced perceptions of PPM intervention effectiveness and satisfaction, as parents may have perceived the care being delivered as more competent even if no difference in care actually existed, and parents may have consequently felt more satisfied with the care being provided.

When satisfaction with care is evaluated within the context of pediatrics, research has shown that parents have reported that knowing that their child is receiving good care, being with the child, participating in care, being informed about pain management interventions, and experiencing continuity in care are all related to increased satisfaction (Abuqamar, Arabiat, & Holmes, 2016). The pediatrics program at KHSC uses a family-centred approach where caregiver participation in children's care is highly encouraged, nursing staff assignments are structured to provide care continuity between shifts, and Kidd 10 staff received pediatric-specific training. It is therefore possible that these positive factors also contributed to the higher reported rates of satisfaction found on Kidd 10 when compared to elsewhere at KHSC.

Based on a study published nearly 15 years ago, up to 90% of healthcare recipients report

high levels of satisfaction on quantitative surveys despite experiencing pain and that most researchers employing surveys should expect approximately 80% of participants to report high satisfaction regardless of the construct being evaluated (Worthington, 2005). This paradoxical relationship between the experience of pain and reports of being highly satisfied with care has been well established in similar studies evaluating pain, even when pain management practices were not in keeping with current practice guidelines (Dawson et al., 2002; Harrison et al., 2014; Harrison et al., 2019; Quinlan-Colwell, 2009). As other researchers have suggested, this may indicate that satisfaction with pain management is also not solely related to the absence of procedural pain or the use of PPM strategies and that high rates of satisfaction do not necessarily indicate a system is performing well or according to recommended practice (Gordon et al., 2002; Harrison et al., 2014; Worthington, 2005). The tendency for consumers of healthcare to report higher levels of satisfaction even when negative experiences occur (Gordon et al., 2002) and the common difficulty for participants to differentiate between different levels of satisfaction (Collins & O’Cathain, 2003) must also be considered.

The current study found participants tended to report that PPM practices were effective and also reported being satisfied with their pain management experiences. The current study did not assess for the presence or absence of pain before or during the procedure period and did not explore individual participant correlations between satisfaction and PPM effectiveness. This made it difficult to determine if the previously established paradoxical relationship between pain experiences, appropriate pain management, and high satisfaction contributed to the high satisfaction rates found in the current study. It has also been suggested that satisfaction with pain management is higher when patients feel healthcare providers make pain management a priority (Dawson et al., 2002). Simply conducting a survey about pain experiences and pain management

may have insinuated to participants that the pediatrics unit was making pain management a priority and may have consequently but unintentionally increased satisfaction scores. In surveys not specific to pain, higher satisfaction rates have been found when satisfaction is evaluated immediately after care delivery (Jensen, Ammentorp, & Kofoed, 2010). Satisfaction may have been positively affected given that most children in the current sample had been admitted for less than one day and evaluation of their needlestick procedure occurred relatively close in time to the actual needlestick. When staff demonstrate a caring attitude (McNeill, Sherwood, Starck, & Thompson, 1998), when pain relief is achieved (Dawson et al., 2002), and when information and support are given to care consumers (Abuqamar et al., 2016) satisfaction rates also tend to be higher. Although not evaluated in the current study, it can be assumed that these characteristics were likely present during at least some of the needlestick procedures included in the data set. While no single factor affecting satisfaction was accurately identified as the cause for high reported satisfaction rates despite practices falling short of existing practice recommendations, the tendency for children and caregivers to have reported high satisfaction with care was encouraging.

Given that PPM practices tended to fall short of recommended guidelines, it was unexpected that PPM was typically perceived as effective. It is important to consider that the perceived effectiveness of PPM was explored using only subjective reports. The use of subjective pain measurements limits the ability to evaluate intervention efficacy, especially when caregiver perceptions of pain are used for pre-verbal children as caregivers have been found to underestimate their child's pain when compared to validated assessment tools (Merkel & Malviya, 2000). Therefore, while the reported perceptions of intervention effectiveness must be regarded with caution, the child-caregiver reports of perceiving PPM as generally effective was

interesting and should be explored further in future studies.

Sample Recruitment Considerations

Epidemiological studies of painful procedures have repeatedly found that venipuncture is frequently performed on children in hospitals (Ellis et al., 2004; Harrison et al., 2014; Harrison et al., 2019; Stevens et al., 2011). Combined with the fact that 15-20% non-consent rates are reported for pediatric critical care research studies (Menon et al., 2012), it was anticipated that study recruitment for the initial proposed study focused on toddlers in the general inpatient unit should have been relatively easy. Before the study, age-specific venipuncture rates were unable to be provided by the hospital's core lab, but the unit managers and nursing staff fully supported the study and believed the study to be feasible based on perceived venipuncture rates. Despite almost two months of protocol execution, no participants were enrolled due to a very low rate of venipuncture procedures in the target age group. Given that a pediatric inpatient in Canada experiences approximately 7 painful procedures (Stevens et al., 2011), revising the study methods to use a retrospective approach to explore a variety of needlestick procedures for children of all ages was much more successful.

The low rate of study enrolment experienced during the proposed study is not a rare phenomenon in pediatric research. In one pediatric hospital, nearly 31% of clinical research studies were discontinued due to low enrolment (Denhoff, Milliren, de Ferranti, Steltz, & Osganian, 2015). The same study found 34% of research protocols did not reach 80% of their enrolment target before the studies were closed to enrolment, and many others experienced significant study delays due to recruitment difficulties (Denhoff et al., 2015). Recruitment methods are considered the most common factor affecting study enrolment with recruitment in person, researcher flexibility, and researcher availability having been identified as important

factors affecting enrolment (Denhoff et al., 2015). The introduction of the recruiter to potential participants by a familiar member of the healthcare team has also been found to improve study enrolment, especially in pediatric critical care environments (Denhoff et al., 2015). Each of these factors was identifiable within the proposed toddler-focused study protocol methods and the actual methods. Through the duration of the study, it was reported by nursing staff that bloodwork was often performed on infants (such as routine newborn follow-up for bilirubin levels) and older children, but bloodwork for toddlers was often limited to the time of admission. Therefore, tight age eligibility criteria may have been a limiting factor for study enrolment but was unavoidable given the original study's purpose of exploring the PPM interventions nurses used for toddlers' needlesticks, and the toddlers' responses to these interventions. Non-consent was not a factor in the proposed study as there were no opportunities for screening or enrolment.

The intermittent absence of toddlers on the in-patient unit during execution of the proposed protocol may be attributed to unpredictable fluctuations in hospital admission rates. Additionally, toddlers who were critically ill and required frequent bloodwork often had central venous access lines placed promptly after admission to reduce needlestick requirements. When it was identified that venipuncture had been performed without researcher notification, nurses often reported forgetting about the research study, the researcher having not been present on the unit (many procedures occurred in the middle of the night), and staff having been in a rush to complete the procedure due to the child's clinical instability. Due to the 24-hour functioning of inpatient units and clinical urgency of venipuncture when it is ordered for a sick child, having more than one researcher readily available would have allowed for increased researcher presence and should be considered when designing future studies.

Of note, four of the six toddlers who were included in the sample for the completed study

reported needlesticks on Kidd 10 and would have met inclusion criteria for the initially proposed study. Three of these needlesticks were venipunctures and one was IV cannulation with a blood draw. The additional needlesticks performed on toddlers would not have fit the proposed study inclusion criteria as they were a finger-stick on Kidd 10 and an IV cannulation with a blood draw in the ED. Based on the initial protocol, the finger-stick would not have been considered an eligible procedure, and the IV cannulation in the ED would have been ineligible due to the location (not on the inpatient unit or outpatient pediatric clinics). The low rate of needlesticks for the toddlers found in the completed study was consistent with the infrequency of venipuncture that was observed in this age group during execution of the proposed methods. Therefore, the sample recruitment difficulty and low rate of toddler venipuncture experienced during execution of the proposed methods was likely due to a low incidence of needlestick procedures for toddlers on Kidd 10 rather than being due to a variance in procedure trends or the study design.

The non-consent rate of 14% ($n = 8$) for the actual study was close to but below the expected non-consent rate of approximately 20% based on previous pediatric critical care research (Menon et al., 2012). Unlike Menon et al.'s (2012) study, this study was not limited to the critical care unit. Participant recruitment and enrolment of the proposed sample size occurred in slightly under one month and was significantly easier when compared to the initially proposed study. Recruitment methods were similar for both the proposed and actual methods in that JR was introduced by a member of the healthcare team who was familiar to the caregivers and children, and efforts were made to raise awareness of the study for all staff on the involved units. However, the success of the actual study's recruitment was likely attributable to the use of a retrospective approach and more inclusive age group when compared to the original proposal.

Pain Management as a Growing Global Concern

It has been well established in the existing literature and confirmed by this study that pain management for children remains an ongoing concern despite the availability of high-quality research evidence and effective treatment strategies. These ongoing challenges can, in part, be explained by some barriers to implementing appropriate pain management strategies that have been identified by previous researchers. These include the fact that pain management has not traditionally been considered a health care priority, the limited availability of pain experts, suboptimal local resource accessibility, and limited existence (or absence) of updated local pain policies (Marshall, 2018). These barriers were reflected in the varied practices and lack of a pain management guideline or policy at the site of the current study. In response to these barriers, several national and global initiatives have formed to raise awareness about the importance of improving pediatric pain management practices.

The Pain in Child Health (PICH) program is a global research training initiative that has brought Canada into the spotlight as a leading force in pediatric pain management research (PICH, 2019). This initiative brings together expert researchers, clinicians, and research trainees to help inform changes in pediatric pain management practices through the generation and sharing of new knowledge and growth of research capacity in the field of child pain management (PICH, 2019). While the generation of research knowledge is beneficial for informing practice, findings from both the current and previous studies have consistently demonstrated the existence of an evidence-practice gap. As demonstrated by the existing evidence-practice gap, the generation of knowledge alone is insufficient to change practice (Straus et al., 2013). Mobilizing evidence into everyday policy and practice is key to ensuring sustainable changes are made (Straus et al., 2013) but has not been directly identified as a PICH priority.

In 2019, Solutions for Kids in Pain (SKIP; based at Dalhousie University, Halifax, in conjunction with Children's Healthcare Canada) received a \$1.6 million grant to develop a knowledge mobilization network to work at closing the existing evidence-practice gap by improving the availability of evidence-based pain management practices, policies, and content experts to Canadian healthcare institutions (Networks for Centres of Excellence [NCE], 2019). Upon commencement, SKIP planned to “conduct a needs assessment to identify resource gaps, conduct a readiness for change assessment, complete an environmental scan, create an asset map, organize current resources and summarize knowledge in priority areas” (NCE, 2019). As of December 2019, SKIP had developed a website with infographics explaining their purpose and was collecting stakeholder feedback through online surveys to help appropriately target their knowledge mobilization efforts. As SKIP is still in the early stages of development, its impact on pediatric pain management is not yet known. However, the program has the potential to generate new services and build upon existing pain programs, and to provide leadership and ongoing support for improving pain management practices. The planned needs assessment, environmental scan, and prioritization of specific areas suggest that SKIP is using evidence-informed knowledge translation strategies that have been shown to support sustained changes (Straus et al., 2013). If successful, SKIP has the potential to guide practice and policy changes that currently do not exist to guide PPM in many settings including KHSC.

The theme of improving the quality of healthcare can be seen throughout the Canadian healthcare system. For example, Accreditation Canada is a not-for-profit organization that assesses the quality of a healthcare organization using pre-defined best-practice standards while combining feedback from patients, families, staff, board members, directors, and community partners (Accreditation Canada, 2019b). Through an independent review process, Accreditation

Canada helps organizations “create better health care and social services” for clients by improving resource allocation, improving efficiency, highlighting quality and safety, and including intra-organization communication and risk reduction to save both time and money through the assessment of over 100 care standards (Accreditation Canada, 2019b). Of the existing standards, over 60 apply to hospital environments, but not one standard assesses pain management policy or practices (Accreditation Canada, 2019a). In 2018, KHSC was assessed on 19 care standards and met 2,927, or 97.7%, of the criteria required by Accreditation Canada to achieve accredited status (Accreditation Canada, 2018). Review of the final accreditation report revealed that the only appraisal of pain was the efficiency of the pain clinic and mention of a previously-conducted client-experience pain management survey (Accreditation Canada, 2018). While the achievement of this accredited status is one that KHSC can be proud of, it is concerning that, given the awareness and prevalence of undermanaged pain for patients of all ages, Accreditation Canada does not yet include a formal review of pain management policies or practices as a standard that is considered necessary for providing high-quality care. This is an example of Marshall’s (2018) barrier of pain not being recognized as a healthcare priority. However, two organizations do exist to support healthcare systems to improve pain practices and to encourage leaders to consider pain management as a healthcare priority.

Children’s Healthcare Canada is a Canadian organization that aims to “accelerate excellence and innovation in health care systems caring for children and youth” through the use of purposeful partnerships with members of the leadership team at organizations who provide care to children and youth (Children’s Healthcare Canada, 2019). While not solely focused on pain management, this organization hosts a knowledge mobilization platform that facilitates access to resources such as a pain management toolkit that includes existing policies, best-

practice guidelines, and education resources for pain management (Children's Healthcare Canada, 2019). Unlike Accreditation Canada however, Children's Healthcare Canada has acknowledged the importance of consistent and appropriate pain management practices.

ChildKind International was developed in 2008 to support organizations in reducing pain and needless suffering through acknowledging excellence in pediatric pain relief, recognizing the impact of inadequate pain prevention and treatment for global pediatric populations, and improving knowledge, protocol, and best practice exchange (ChildKind International, 2019). ChildKind evaluates and recognizes institutions that have taken a role as leaders in pediatric pain management through the use of a standardized, organization-wide approach to pain management and acknowledges these institutions as ChildKind Certified Hospitals (ChildKind International, 2019). The process to become ChildKind certified is similar to the process used by Accreditation Canada in that there are set standards to be met to obtain certification. To become ChildKind certified, an organization does not need to be a dedicated pediatric care facility but must address five principles: (1) facility-wide pain policies for pain assessment and treatment with a clear commitment to pain relief, (2) ongoing pain education for staff, trainees, and patients, (3) sustained use of developmentally appropriate pain assessment processes, (4) evidence-informed protocols for pain prevention and treatment using multi-modal approaches, and (5) ongoing organization self-monitoring and continuous quality improvement (ChildKind International, 2019). Despite the increased awareness of the importance of pediatric pain management, only ten North American hospitals, two of which are in Canada, have obtained ChildKind Certification (ChildKind International, 2019). KHSC at present would not be eligible for ChildKind Certification for a variety of reasons. For example, the lack of pain-specific policy at KHSC and results of the current study indicated that KHSC was not yet operating at the standards required

for certification. Although staff education practices were not thoroughly examined, pain-related learning materials were not found when the available resources were reviewed prior to study commencement. However, the current state of practice does not impede the organization from beginning to improve existing pain management practices. For example, KHSC could begin to develop policies and guidelines aimed at improving pain management practices. ChildKind's five principles could also be considered for adoption as an overarching framework as a way to target improved pain management practices using a comprehensive and consistent approach.

Implications and Recommendations

With the development of organizations to guide pediatric pain management, it is clear that changes to improve pain management are possible and that the knowledge and tools required to do so already exist. To support ongoing and sustained changes in this field, support from administration and leaders who view pain management as a priority is needed (Marshall, 2018). Researchers, educators, and patient/family advisors need to continue to advocate for the importance of appropriate and consistent pain management. Leaders at the local level should consider partnering with existing initiatives such as PICH, SKIP, Children's Healthcare Canada, and ChildKind International to gain access to relevant and updated resources as well as connect with content experts. These partnerships could provide the support, expertise, and resources necessary to commence sustainable, positive steps towards improved pain management. The lack of improvement in PPM practices following targeted PPM education found by Harrison et al. (2019) reinforces the importance of bringing hospital administrators, program managers, and front-line staff together to continue to make improvements in pain management care and suggests that ongoing monitoring through chart audits and parent and child interviews can be used to inform and strengthen future quality improvement projects.

Although not explored through this study, common barriers to adequate PPM can include time; prioritization of pain management; a lack of standing orders or policies; knowledge gaps for patients, parents, and staff; a lack of a pain management culture; and limited availability of resources required to implement PPM (Ali et al., 2014; Rosenberg et al., 2016). While strategies such as the development of a PPM policy, a culture change toward PPM practices, and addressing knowledge are required to improve PPM practices at KHSC (Rosenberg et al., 2016), more immediate and sustainable practice changes are needed. There is strong evidence available to guide PPM practices and the standardized availability of PPM strategies has been found to quickly improve PPM practices (Rosenberg et al., 2016). Based on the results of the current study in conjunction with Rosenberg et al.'s (2016) findings, the following three specific strategies are recommended: (1) pre-selected orders and medical directives for topical anesthetics and oral sucrose, (2) a bedside pain management kit, and (3) a standardized procedure documentation tool.

Pre-Selected Orders and Medical Directives

Topical anesthetics and oral sucrose are considered best practice for pharmacological PPM and are known to be highly effective and safe pain management strategies. These pharmacological agents are also readily available at the KHSC pharmacy and are easy to administer. Integrating them into practice should be regarded as a priority to improve PPM for pediatric inpatients and could be changed to be pre-selected orders (PSOs) with age-specific clauses on all of the existing electronic pediatric admission order sets. Research has shown that embedding processes into the practices of an organization is closely linked to successful and sustained change (Menon et al., 2012). Therefore, including topical anesthetic and oral sucrose (as appropriate for child age) as PSOs rather than as an optional order on admission to the

inpatient unit is the first step in supporting nurses to use appropriate pharmacological PPM. PSOs enhance care through standardized treatments, increased adherence to guidelines (Chan et al., 2012), and have been successfully used to increase ordering rates and medication administration in a variety of clinical applications (Chan et al., 2012). The use of PSOs has been shown to result in significantly increased nursing adherence to evidence-based interventions, increased overall pain management, and increased parent satisfaction (Eason, Naus, Sciberras, & Oppenheimer, 2001; Rosenberg et al., 2016). The implementation of PSOs allows nurses to seamlessly follow practice guidelines since they would not need to obtain a physician order for these pharmacological PPM interventions (Rosenberg et al., 2016). PSOs also have the advantage of being applicable hospital-wide for all admitted patients. Therefore, once a child is admitted, the order for topical anesthetic or oral sucrose is applicable even if the patient is travelling to other units in the hospital (such as the OR or IVR) where staff do not receive pediatric PPM training.

When a child has not been admitted yet, for example in COPC or the ED, PSOs do not apply. Medical directives enable nurses to initiate physician-approved treatments and diagnostic tests when a patient meets predetermined criteria. The implementation of medical directives in Canadian EDs has been found to decrease the length of time between patient arrival and administration of oral analgesics (Chan et al., 2012) and demonstrates the potential benefit of introducing medical directives for topical anesthetic and oral sucrose at KHSC's outpatient units. A medical directive could be designed to allow nurses to apply topical anesthetic when a needle procedure is predicted to occur based on the patient's clinical presentation. A second medical directive could be designed to allow nurses to initiate administration of oral sucrose for neonates, infants, and young children up to 18 months of age who are imminently undergoing a painful

procedure. Delivery of education to nurses and physicians regarding the benefits of PPM, as well as how to appropriately use these strategies through a multi-modal approach has been used to positively impact medication knowledge, application skills, and improved PPM practices (Dewhirst, Zhao, MacKenzie, Cwinn, & Vaillancourt, 2017). These strategies should therefore also be considered to improve the effectiveness of the proposed PSOs and medical directives.

A Pain Management Kit

The development of a pain management kit has the potential to improve usage rates of PPM, PPM satisfaction, and compliance with a 3-P approach. The proposed pain management kit is based on the established concept of a distraction kit and would contain age-appropriate, easy to use PPM interventions that are readily available for nurses, caregivers, and patients to use during painful procedures. The concept of a beside pain management kit was also suggested by some of the caregivers who provided feedback during the child-caregiver surveys for this study. The use of a pain management kit also takes into consideration child, caregiver, and nursing preferences (Ballard et al., 2017). Age-appropriate distraction kits are feasible for use in general clinical practice and in reducing the experience of pain for infants, toddlers, and preschoolers undergoing needle procedures in EDs (Ballard et al., 2017). The distraction kits used in the study by Ballard et al. (2017) included bubbles, finger puppets, musical teddy bears, pop-up books, stress balls, and hunt-and-see books. In addition to these distraction items, the development of age-appropriate pain management kits at KHSC must allow for inclusion of PPM interventions for each of the 3-P approaches. These kits could be kept readily available at nursing stations where they would be easily accessible when a painful procedure is planned. Physical interventions are readily available and a list of suggestions such as upright positioning, sitting on a caregivers' lap, cuddling, swaddling (when age appropriate), and selecting a position of comfort could be

included (Taddio et al., 2015a).

As per hospital policy, medications may not be kept at the patient bedside without a specific order for each medication. Inclusion of age-specific lists for possible pharmacological interventions would generate awareness of possible PPM interventions and allow children and their caregivers to select and request the intervention(s) they believe would be most effective. This list could include practices such as breastfeeding and suggest the use of oral sucrose, topical anesthetic, and vapocoolant spray where available (Taddio et al., 2015a). Providing children and caregivers with a list of possible PPM interventions before the procedure allows for an increased sense of control over the procedure and would also limit infection control concerns as only the items chosen would be brought into the patient room.

Several caregivers involved in the present study indicated they wanted more education related to PPM and some discussed concerns with the availability of age and developmentally appropriate PPM items. Including a pain management kit as a standardized part of pain management care has the potential to educate and generate awareness of PPM strategies. Additionally, by decreasing procedural pain, caregiver satisfaction with PPM may continue to improve (Ballard et al., 2017; Worthington, 2005). Once caregivers are aware of PPM intervention options, they may also feel empowered to suggest the use of these interventions elsewhere in KHSC, such as when a child is travelling for tests and procedures, and for future painful procedures outside of KHSC such as routine immunizations.

Standardized Documentation

As previously discussed, a requirement for nurses registered in Ontario is the appropriate and complete documentation of nursing interventions and an assessment of the effectiveness of those interventions (CNO, 2008). The current study findings demonstrated that nursing

documentation was not meeting this standard. Therefore, there is a clear need to improve standardized documentation practices for nursing staff. It has been suggested that in acute care settings, nurses may spend anywhere from 25-50% of their time documenting, resulting in nurses spending less time providing patient care (Novelo & Mann, 2012). Additionally, dozens of potential PPM strategies could potentially be implemented for a single needlestick procedure and nurses simply do not have the time required to document about each intervention selected. It is also unrealistic to expect nurses to narratively document all pain assessments, interventions, and responses. The use of procedure documentation templates has been shown to significantly improve efficiency, timeliness, and accuracy of procedural documentation in adult-based procedures (Novelo & Mann, 2012). The development of a pediatric procedure-specific tool that can be integrated into patient charts would allow nurses to efficiently communicate PPM interventions and intervention effectiveness and is therefore suggested for this practice setting. Unfortunately, no tool for this purpose currently exists. It is recommended that the development of such a tool should include input from content experts, such as those at SKIP and Children's Healthcare Canada. If developed appropriately and used in combination with the existing narrative charting, this tool could more efficiently communicate PPM strategies and patient responses, while also improving nurses' adherence to the CNO's documentation standards.

As more healthcare organizations plan to implement electronic documentation systems, documentation of pain scores and PPM should be considered at the outset as one of the documentation priorities. While electronic documentation is currently used in the Urgent Care and ED at KHSC, there has been no indication at this time that KHSC is planning to implement this system hospital-wide. Therefore, in future documentation development and planning, pediatric nurses and managers must advocate for strategies that allow nurses to thoroughly and

clearly document PPM and pain-related constructs.

Study Strengths

Unlike many previous pain management studies that utilized only a chart review data collection method which is known to be lacking in comprehensiveness (Harrison et al., 2014), the current study combined chart review and child-caregiver survey data to obtain a more inclusive and objective overview of the current PPM practices at the study site. The use of an approach similar to previously conducted pain surveys (Harrison et al., 2014; Harrison et al., 2019; Wilding et al., 2019) allowed for comparison of current results to findings from other study centres. Additionally, nearly all eligible participants who were approached for this study consented to participate. This high rate of consent suggests that the data collected is likely representative of the current practices at KHSC, rather than based on the perceptions and experiences of a select number of inpatients.

Study Limitations

This study was conducted with a small sample size of 50 children who were all recruited from the single inpatient unit at KHSC over a three-week period. Data collected for this study most often occurred within the first 24 hours of a child's admission and only collected data about the most recent blood testing needlestick. The findings therefore do not provide a true overview of the number of painful procedures occurring for pediatric inpatients at KHSC as some children may have experienced more than one needlestick prior to or following study enrolment. This was especially relevant for all newborns who are required to have Ontario newborn screening completed within the first 48 hours of life (Newborn Screening Ontario, 2019). In the case of this study, only one of three newborns had undergone a needlestick as the others were enrolled too early in the post-partum period. Capturing data for a small sample of 50 children therefore only

provides a glimpse of current PPM use and needlestick frequency occurring at KHSC.

Another limitation to this study was that there was no evaluation of nurses', children's, or caregivers' preferences for PPM practices or their perceptions of barriers inhibiting compliance with best practice PPM guidelines. The current study found that PPM practices varied between units, type of needlestick, and child age. The cause for these variations was not investigated but may have been attributable, at least in part, to practitioner, child, and caregiver preferences; unit practices; available resources; and perceived barriers. While some qualitative feedback was collected during the child-caregiver surveys, it was insufficient to fully capture the experiences of these children and their caregivers.

Survey responses were based on child and caregiver recollection of a previously completed needlestick. While the cross-sectional approach used for the current study was beneficial in identifying which procedures occurred, it provided insufficient evidence to determine the efficacy of specific pain management interventions beyond the perceived benefit as reported by children and their caregivers. Caution must therefore be taken in interpreting the results describing PPM effectiveness because effectiveness was not measured using validated or age-appropriate assessment tools.

Nursing documentation has repeatedly found to be variable and incomplete, and may not provide a true reflection of actual nursing practices (Novelo & Mann, 2012). Although the use of a child-caregiver survey provides a clearer picture of PPM interventions used during needlesticks, the reports were subject to participant recall and may not have provided a complete overview of all PPM practices used at KHSC. The current study also did not make note of who employed each PPM intervention (child, caregiver, nurse, or other hospital staff). It is therefore possible that some non-pharmacological interventions were parent-led rather than nurse-initiated

and results likely do not solely reflect nurse-initiated PPM practices. Caution must also be taken in comparing the results of the current study to previously conducted studies due to differences in definition of painful procedure (all painful procedures or needle procedures), study methodology (chart review and/or survey/interview), and the time period captured in data collection (single procedure verses 8-or-24-hour recall).

Recommendations for Future Research

This was the first known study about pediatric PPM to have been conducted at KHSC. As such, these findings have illuminated potential ways to improve PPM practices. Once practice change initiatives have been implemented, the current study should be repeated and the current results can act as baseline data for monitoring the effectiveness of practice and policy changes. Future researchers should consider exploring the experiences of children, their caregivers, and nurses regarding PPM practices, barriers, and effectiveness of these interventions to develop tailored knowledge translation interventions for use in local practice (Harrison, Légaré, Graham, & Fervers, 2010; Marshall, 2018).

As demonstrated by both the proposed and actual study, rates of venipuncture for the toddlers at KHSC were low and no identified studies have explored venipuncture or painful procedure rates in different age groups at hospital outpatient- or community-based pediatric clinics. Furthermore, no data regarding age-specific rates of venipuncture were available at KHSC or reported in previous epidemiological studies of painful procedures. The lack of available age- and procedure-specific data must therefore be considered when designing future study protocols with age restrictions for enrolment for studies in both in- and outpatient settings.

It is generally accepted that interventions that are considered clinically effective for neonates, infants, and older children are not always efficacious for toddlers (Harrison et al.,

2014; Stevens et al., 2011; Zhu et al., 2012). This knowledge gap may be in part attributable to the fact that toddlers are not often studied separately, and their data is frequently integrated with either younger or older counterparts. Of the studies reviewed in preparation for this research, few explored intervention efficacy solely for toddlers. Future studies aiming to quantitatively assess the effectiveness of PPM interventions should consider separating the toddler age group for statistical analysis.

Conclusion

Pain management during painful procedures has been an ongoing concern for over 20 years. The results of the current study demonstrate that while small improvements in PPM practices and a slight decrease in the number of painful needlesticks have occurred, procedural pain was still undertreated despite the abundance of high-quality evidence, PPM strategies, and existing knowledge surrounding PPM. However, despite the small size of the pediatric program at KHSC and absence of local policy to guide PPM practices, rates of local PPM interventions were consistent with those found at larger Canadian pediatric centres. Although low rates of PPM interventions were observed, both perceived intervention effectiveness and satisfaction with pain management at KHSC were found to be relatively high.

Poor nursing documentation of pain management interventions is an ongoing problem for nursing practice and research purposes, but the use of child-caregiver surveys helped to provide a more comprehensive understanding of the strategies that nurses were using to manage procedural pain. To improve PPM practices, the development of local practice guidelines and pain management policies was suggested, and the adoption of pain management as a priority for leaders and front-line staff was recommended. Implementation of pre-selected orders and medical directives for pharmacological PPM, a pain management toolkit, and the development of

a standardized procedure documentation tool could be used as initial interventions to improve availability, awareness, and use of PPM interventions at KHSC. The barriers and facilitators affecting the use of existing PPM interventions should be studied and subsequently considered to successfully integrate these recommendations into local practice. More research is needed to explore the experiences of children, their caregivers, and nurses in relation to PPM practices and satisfaction with pain management. Due to difficulty with recruitment for the initially proposed study, the effectiveness of PPM interventions for toddlers remains unclear and warrants future research. Despite these knowledge gaps, the findings from this study can be used to inform efforts that aim to improve procedural pain management practices for all hospitalized children.

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Appendices

Appendix A: Proposed Methods & Results from Originally Proposed Protocol

An Observational Study of Nursing Pain Management Practices and Responses of Hospitalized Toddlers during Venipuncture

Little empirical evidence exists to support pain management practices for toddlers undergoing painful procedures. At the time of study proposal, no policy existed to guide nurses' use of PPM practices. To accurately identify current nursing PPM practices and toddler responses to pain during venipuncture in the KHSC hospital system, a structured observational study design was proposed.

Methodology

Observation-based research allows researchers to capture human activities when, where, and how they are occurring by providing direct, unaltered access to the behaviours being studied (Polit & Beck, 2012). Observational research can produce both qualitative and quantitative data depending on the researcher's questions (Polit & Beck, 2012). This methodology allows for a rich and unaltered perspective of the phenomenon being studied which is usually unobtainable through participant surveys or interviews alone (Salmon, 2015). Checklists, rating scales, and a structured approach are the preferred methods for quantitative observations to be recorded as measurable data (Polit & Beck, 2012). Using a structured observational methodology aimed to help to bridge the gap between what nurses thought they were doing and what they were actually doing (Salmon, 2015). Using an external observer to carry out the observations instead of a staff member had the added benefit of capturing processes that may be missed due to the routines and preconceived perceptions ingrained in an internal observer (one who works on the unit being observed) (Salmon, 2015).

For this study, PI, JR, was to act as an observer only. Being a non-participant observer allowed subjectivity to be removed from observations, which would have resulted in more quantifiable and less biased observations (Twycross, 2002). Although JR, as an adult intensive care Registered Nurse employed by KGH, could have participated in some activities on the unit, her role was to be strictly limited to non-interference observation to prevent participation from acting as a distractor to data collection thereby ensuring the objectivity of the data collected (Polit & Beck, 2012; Salmon, 2015).

One disadvantage to using an observational approach to data collection was the potential for a Hawthorne effect; one in which participants' behaviour may change in an attempt to 'look good' and due to their awareness of being observed (Polit & Beck, 2012; Salmon, 2015). However, this effect was aimed to be minimized by limiting the observer's presence as much as possible during painful procedures (Polit & Beck, 2012). Furthermore, participants have been found to more closely resemble their normal activities as they grow accustomed to an observer's presence (Polit & Beck, 2012) and this study was predicted to occur over at least a four-month period.

Setting

KGH is a tertiary care teaching hospital in Southeastern Ontario. The pediatrics unit at KGH is a Level III inpatient pediatric care unit that employs 30 Registered Nurses and consists of ten medical-surgical beds and four PCCU beds. KGH is included in the KHSC network of hospitals that services a catchment area of over 20,000 square kilometres, including many rural northern communities (KGH, 2018). KGH is also one of five tertiary care members of the Ontario Pediatric Critical Care Network (KGH, 2018). In one year, the pediatrics unit at KGH admits an average of 1700 children, of which approximately 200 are toddlers.

After initial piloting of the study on the pediatrics inpatient unit, the study was extended to include the COPC and the pediatric division of the Cancer Centre of South-Eastern Ontario (CCSEO). The COPC operates out of the HDH site and serves patients 0-18 years of age through the combination of a specialized pediatric walk-in emergency service and clinics, Monday to Friday, 0900 to 1600 (HDH, 2019). The CCSEO is located within the KGH campus and provides cancer care services from diagnosis, treatment, monitoring, and palliative care for patients throughout the KHSC catchment area (KGH, 2019). There is a special unit within the CCSEO that is staffed by dedicated pediatric-oncology physicians and registered nurses to ensure consistency in care delivery.

At the time of study extension into the outpatient clinics, nursing staff on the pediatric inpatient unit indicated that many children were having peripheral IV cannulation and/or venipuncture completed in peripheral hospitals or the KGH Emergency Department (ED) prior to admission to the pediatric unit. The decision to not expand the study into the ED was made as the ED staff at KGH do not receive any pediatric-specific training.

Sample

Due to the strictly observational and descriptive nature of this initial study, a convenience sample of 50 participants was proposed. This sample size was based on the assumption that an annual average of 200 toddler admissions would continue to occur, allowing for the expected 50 toddlers per fiscal quarter in conjunction with the assumption that general pediatric research follows the 15-20% non-consent rate found in pediatric critical care research (Menon et al., 2012). Due to the PI's schedule, it was predicted that these 50 observations could have occurred over a four-month period. Venipuncture/blood specimen testing rates were unable to be provided

by the pediatrics unit or core lab at KGH, but both the unit manager and nursing staff believed the study to be feasible based on perceived recent venipuncture rates.

Eligible participants were defined as toddlers who were receiving medically necessary, physician-ordered blood work either through direct venipuncture or simultaneously with IV cannulation. This blood work must have been performed by a member of the health care team. To be eligible, a caregiver of the child must have understood English and been able to provide informed consent. Toddlers were to be deemed ineligible if they were intubated or demonstrated decreased levels of consciousness, if a diagnosis of developmental delay or neurological abnormalities has been made, or if the child's MAR noted receipt of a muscle relaxant, sedative, or opioid analgesic in the previous 24 hours.

Recruitment & Study Promotion

Although hospital staff were not actively involved in the study, their role in identifying potential participants was predicted to support study success. The unit census was reviewed by the PI on each data collection day to identify all toddlers on the unit, and communication with staff was planned to help identify which toddlers were scheduled to undergo bloodwork. Potential participants were to be approached by the pediatric nursing staff who provided the caregiver(s) of potential participants with a printed study recruitment poster (Appendix A1). Once identified and interest had been expressed by the caregiver, the PI would have reviewed the child's Medication Administration Record (MAR) (if the participant was an inpatient) and demographics to confirm eligibility. Once deemed eligible, the PI was to meet with the caregiver(s) of potential participants to explain the study purpose and procedure, and to review the study consent form (Appendix A2). Caregivers were to be reassured that participation was voluntary, and the risks and benefits of their child's participation were to be restated. A signed

informed consent form from the caregiver was to be obtained at this time. Caregivers were also to be given the opportunity to sign a media release consent form to allow for use of recordings in future research and presentations (Appendix A3). Signed copies of these consent forms were to be left with the caregivers, and a second set kept by the PI to satisfy the ethics requirements.

Once approval from the unit and clinic managers as well as the required ethics boards had been received, the PI visited the inpatient unit and outpatient clinics to generate awareness about this study and to acquaint the unit staff with the study protocol. An e-mail was sent to the pediatrics staff to capture those who were not present on the unit at the same time as the PI (Appendix A4). Follow-up reminder emails were sent as deemed necessary. Being present on the nursing unit allowed for the unit staff to become familiarized with the PI and her upcoming role on the unit while ongoing presence on the unit during the study period was useful in reminding staff of the ongoing study. Study recruitment posters were made available on all involved nursing units for easy distribution to potential participants. Weekly e-mails were used to communicate with the staff in the CCSEO where visits are by appointment only, and twice-daily phone calls were used for the in-patient unit as a method of participant identification on days when the PI was unable to be present on the unit.

Data Collection

Event sampling was to be used as JR had knowledge regarding the occurrence of routine venipuncture events and was in a position to wait for an event to occur (Polit & Beck, 2012). Use of this method reduced the chance of events being missed but did have the risk of missing events that occurred outside the pre-designated time periods of the investigator's availability (Polit & Beck, 2012). When unable to be physically present on the unit, the PI informed the nursing staff that she could be contacted by phone if a data-collection event presented itself. Data collection

was to occur on weekdays and weekends, with the PI being available 24-hours per day by phone to the inpatient unit, and weekdays 0900-1600hrs based on the outpatient clinic hours, subject to the availability of the PI. The PI had planned to be present at times most likely to present an opportunity for venipuncture observation for a period of approximately four months (January 1 to April 30, 2019) or until 50 venipuncture procedures have been observed, whichever came first.

Once informed consent had been obtained, participants were to be assigned a randomly generated identification number. Demographic data to be collected included age in months, sex, reason for hospital admission, hospital admission history, and the sex of all other persons in the room (the PI excluded). Once enrolled, each participant's MAR was to be photocopied for proof of study eligibility by confirming there had been no administration of muscle relaxants, sedatives, or opioid analgesics in the previous 24 hours. The MAR was also to be used to determine if and when topical anesthetic and oral sucrose were used in preparation for the procedure. All identifying factors were to be removed from the MAR and the MAR and signed consent forms would have been coded with the participant's corresponding identification number.

A structured data collection method, in-line with the positivist research paradigm, requires "structured, descriptive, inferential observation and 'standing apart' from that which is being observed" (Salmon, 2015, p. 37). 'Standing apart' from participant activities was essential as to not interfere with the activities being observed. This approach would have allowed for quantification of specific behaviours related to the phenomenon being studied while preventing data contamination based on the researcher's preconceived beliefs and biases (Salmon, 2015; Twycross, 2002). Using only a structured data tool based on the researcher's preconceived

beliefs for data collection increased the likelihood of components of the environmental context and participant behaviours being missed (Salmon, 2015). As there was no policy to guide nurses in the use of PPM at KHSC, the PI may have observed participants engaging in unexpected PPM strategies. Therefore, a field notes section was included for use as needed in the data collection sheet to allow for unexpected observations to be included in the data set (Polit & Beck, 2012).

Data Collection Tools

A categorical and rating scale data collection tool designed specifically for this study was to be used to collect all research data as no existing tool was able to capture and measure all of the desired outcomes (see Appendix A5; Polit & Beck, 2012). The data collection tool for this study used an exhaustive system; one in which all behaviours of a certain type fell into a set of predefined categories (physical, psychological, or pharmacological interventions; Polit & Beck, 2012). The use of clearly defined categories was used so as to require minimal inference during data collection (Polit & Beck, 2012). Inclusion of field notes and an “other” category in each section allowed for unpredicted behaviours to be categorized and included in the data set. Use of an exhaustive system with an additional “other” category therefore reduced the risk of unexpected PPM strategies not being categorized (Polit & Beck, 2012).

Behavioural observation of pain is considered to be the standard pain assessment method for infants and toddlers who are too young to understand and operationalize self-report pain scales (Thrane et al., 2016). Young children also tend to estimate pain at the extreme ends of scales with minimal variability as a result of their dichotomous thinking (St. Laurent-Gagnon et al., 1999). This pattern of thinking often skews self-reported pain scores to appear higher in the toddler age group when compared to older children. The FLACC pain assessment tool, developed by Merkel et al. (1997), provides a simple and rapid assessment tool to assess and

document pain and distress in children ages 2 months to 7 years (see Appendix A6). Pain is assessed through the observation of five pain-related behaviours: facial expression, leg movement, activity, cry, and consolability (Merkel et al., 1997). Scores for each behaviour are recorded on a scale from 0 (no response/normal) to 2 (extreme response) and summated for an overall score from 0 to 10 (Merkel et al., 1997).

FLACC was initially deemed valid and reliable for use with toddlers in the post-operative setting (Merkel et al., 1997) but has since been validated for the assessment of post-operative, traumatic, disease-induced (Crellin, Harrison, Santamaria, Huque, & Babl, 2018; Gomez et al., 2013) and procedural pain (Crellin, Harrison, Santamaria, & Babl, 2015). While some concerns related to the validity, internal consistency, and feasibility for use in procedural pain do exist (Crellin et al., 2015), no better alternative scale existed at the time of study proposal. The combination of ease and speed of use and high inter- and intra-rater reliability (Gomez et al., 2013; Thrane et al., 2016) has resulted in the FLACC being recommended by the RNAO as a suitable pain assessment tool for young children who are experiencing acute pain (RNAO, 2013). FLACC assessment by a single researcher further enhances consistency of the required pain measurements while the use of a commonly used tool would have facilitated comparison between other studies also operationalizing the FLACC scale (Crellin et al., 2018). While the use of FLACC to assess procedural pain has recently been supported (Polit & Beck, 2012), researchers much continue to consider the inability of FLACC to distinguish between pain- and non-pain related distress in all settings and circumstances (Crellin et al., 2015).

Study Procedure

Each venipuncture was to be observed by the PI and was to be videotaped to capture complex behaviours that are difficult to assess or may be missed due to the volume of data to be

collected (Polit, 2010). The PI planned to set up an audio-visual recording device once informed consent has been obtained, and the video and audio recording would have started when the staff member performing the venipuncture indicated readiness for the procedure. The PI planned to be in the room but removed from the child's immediate vicinity to allow for a more natural environment and would not interact with anyone involved in the procedure after commencement of audio-visual recording. Study measurements were to be documented on the standardized data collection form. All PPM interventions observed were to be recorded on the data collection form. Audio-video recording was planned to be stopped two minutes post-procedure or two minutes after two attempts have been made and the procedure deemed unsuccessful as defined by this study protocol. The conclusion of video recording after two minutes was designed to allow for observation of PPM interventions used in the post-procedure period. Demographic data and a photocopy of the child's MAR were to be obtained when feasible, either pre- or post-procedure.

Recordings were to be transferred from the recording device to a secure data storage device and then erased from the recording device to ensure confidentiality. The recordings were then planned to be reviewed post-procedure to measure procedure length, to determine FLACC scores, and to measure crying duration and proportion of crying time through the procedure and in the two minutes following procedure completion. The data collection form was also going to be reviewed at this time to ensure completeness of the data. Data was to be entered into an electronic data management system, and hard copies retained in a locked office. The electronic data set and audio-video recording files were going to be stored on a password-protected computer and an encrypted memory stick that could only have been accessed by the research team members. Data was to be securely conserved for five years after the conclusion of the study period and then destroyed as per the requirements of the ethics boards approving this study.

Data Analysis

Data was going to be entered into Microsoft Excel, cleaned, and then imported into the IBM SPSS 25.0 data analysis program. FLACC scores were to be obtained at pre-determined times to ensure consistency in scoring across all participants. To ensure rigor and inter-rater reliability, 10% of all procedures were to have FLACC scores measured by both the PI and by a second researcher. Inter-rater reliability was to be measured using an intraclass correlation coefficient. The FLACC training tool that was being developed by Dr. Harrison and Brenda Martelli at the Children's Hospital of Eastern Ontario was to be completed by all parties measuring FLACC scores for this study. If any one component of a FLACC score was missed, imputation was to be employed. Imputation was not going to be used for cry times due to variation in procedural period lengths. If more than one component of any measurement was missing the scores were to be omitted from the data set. Analysis of continuous and frequency data was going to include descriptive statistics (means, standard deviations, medians, and interquartile ranges) based on normality or non-normality of data distribution (Polit, 2010).

Demographic Analysis

Analysis of demographic data was to be completed using descriptive statistics (Polit, 2010). At the time of this study there was no validated scale for assessing the severity of illness in children beyond the neonatal period. Therefore, severity of illness was not to be measured or included in data analysis.

Procedure and PPM Analysis

Planned procedure descriptions were to include the number of people present and their roles, procedure site(s) selected, average length of procedure from tourniquet application to the application of a bandage or dressing, procedure success rates, presence or absence of PPM

interventions, duration of crying time, and proportion of crying time. PPM interventions were to be analyzed for frequency of individual intervention use, “3-P” approach frequency, and to explore which PPM interventions were employed in each procedure phase. The “pre-procedure 1” time was defined as the time from procedure readiness to when the tourniquet is applied. The FLACC score and crying status were to be noted at the time of procedure readiness. The “pre-procedure 2” time period was to be measured from the moment at which the tourniquet was applied to just before the moment of first skin-break. FLACC scores were to be measured once the tourniquet had been fully applied. The “procedure” time was to be measured from the moment of first skin-break to the moment of needle withdrawal. For this period, FLACC score was to be calculated one minute after the first skin break. The “post-procedure” period was defined as the time from needle withdrawal to application of a bandage with FLACC score being determined at the time of bandage application. The “recovery” period was an observed two-minute period, at which time a final FLACC score will be calculated, and recording would have been ceased. Duration of crying would have been measured for each time period. Duration and proportion of crying were also to be calculated for the entire procedure.

Associations and Correlations

When possible, additional comparisons would have evaluated the relationship between the use and non-use of individual PPM interventions used and both pain, using FLACC, and distress, using duration of crying and proportion of crying time. The total number of PPM interventions used were also to be compared to pain and distress measurements. This would have been completed using bivariate descriptive statistics such as cross-tabulations using contingency tables, and correlations to explore the relationships between these variables (Polit, 2010).

Ethics

The pediatrics unit manager at KGH was approached and granted support and permission to carry out this observational study. This proposal was first submitted for approval to the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, which represents the KGHRI, and then to the University of Ottawa Research Ethics Board (Appendix A7). The PI also obtained a Hospital Research Appointment through KGHRI, as per KGH requirements. Ethics amendments were obtained when the study was expanded into the KHSC outpatient clinics (Appendix A8).

Once identified as potential research participants, caregivers of eligible toddlers were to be given an explanation of the purpose of the study, participant requirements, and disclosure of any potential risks of study involvement. One caregiver per child being observed was to be asked to sign a consent form that included information about the study, a guarantee of confidentiality, and the right to terminate study participation at any time without consequence to them or their child. Caregivers were also to be asked to sign a media consent form. No compensation was to be provided for study participation. Upon study completion, a summary of the results was to be available to all participants upon request.

Hospital staff involved in the procedures would have been reminded that data would only be collected for the predetermined procedure variables and not on the performance of the involved staff member(s). If a caregiver consented to future use of their child's procedure recording, the face and voice of the hospital staff were to be blurred out unless express consent to leave these identifying factors in place could have been obtained from the staff member(s) involved in the procedure.

If unsafe practices had been observed during the study, the PI, as a Registered Nurse, was under a legal obligation to report such behaviours to the unit manager. If the participant was noted to deteriorate, the PI would have been obligated to intervene or acquire the necessary resources to ensure the participant's safety and well-being.

Results

Data collection was initially proposed to begin on January 1, 2019 but was delayed due to extended wait times for ethics clearance processing. Both overseeing ethics boards had granted ethics clearance for this study by January 15, 2019, and the Hospital Research Appointment was granted for commencement on January 30, 2019. As of February 20, 2019 no participants had been enrolled in this study due to a perceived reduced frequency of venipuncture procedures occurring on the inpatient pediatrics unit. At this time, the PI approached the pediatrics unit manager who recommended expansion of the study into the CCSEO and COPC. A study amendment was submitted to the required ethics boards and was approved on March 15 for expansion into relevant outpatient clinics within the KHSC system. The study protocol then ran simultaneously in the clinics and inpatient unit from March 15 until April 9.

Study recruitment reminders were posted in locations around the unit and clinics that were deemed relevant to venipuncture processes by the PI, nursing staff, and managers, and in areas that were frequently visited by unit/clinic staff. These locations included computers where bloodwork requisitions are entered, beside printers where bloodwork labels are obtained by staff, in supply rooms, near phlebotomy totes that staff bring to the bedside when performing venipuncture, on the cupboards in the COPC procedure room, and in staff break rooms. Posters were also prominently displayed at nursing desks for easy distribution to the caregivers of

toddlers. Due to an ongoing commitment to other research projects and hospital initiatives, posters were unable to be placed on the walls in patient care rooms.

On days when the PI was able to be present on-site, she was available at the out-patient clinic location as the unit manager suggested this was the location most likely to present potential study recruitment. On these days, the PI called the in-patient unit charge nurse to remind them of the researcher's availability, and short travel time required to travel from the HDH to the KGH hospital site. When the PI was unable to actively wait on-site, twice-daily phone calls were made to the in-patient unit at 0800 and 2000hrs, corresponding with the beginning of each nursing shift, to identify any scheduled bloodwork for inpatient toddlers. At this time, the nursing staff were reminded that the PI was readily available by phone should an enrolment opportunity present itself. Due to concerns with the unpredictability of patient visits and overall clinic flow, it was requested the no phone calls be made to the COPC. At the request of the pediatrics CCSEO nursing co-ordinator because CCSEO visits were by appointment only, an email was sent weekly on Monday morning before 0900hrs to request a review for any potential participant appointments for the upcoming week. This nursing co-ordinator was also agreeable to phoning the PI should a last-minute appointment be added. As of April 9, nearly 10 weeks after the initial commencement of the study, no toddlers had been screened or enrolled in the study. After consultation with the unit managers and thesis committee members, the study methods were revised and subsequently amended. Discussion of possible explanations for recruitment difficulties are addressed in the discussion chapter of this thesis.

Appendix A1: Proposed Methods - Recruitment Poster for Caregivers



Research Participants Needed!

"An observational study of nursing practices and toddler responses during venipuncture in hospital"

What is the study about?



This research will look at how toddlers respond when having blood work drawn in the hospital. We are also looking to see how nurses decrease pain during blood work.

Who can participate?

Toddlers between the ages of 12 and 36 months who are having blood work drawn in hospital will be eligible for participation. A parent or guardian must be present to talk to the researcher before being enrolled.

What is involved in participating?

Toddlers will be observed during routine blood work that has been ordered by their doctor. No changes to the procedure will happen while participating in this study. Parents and guardians are welcome to be present and involved as always!



Where will the study take place?

The study will take place on the pediatrics in-patient unit (Kidd 10), at the Kingston General Hospital.

Contact information:

If you are interested in participating in this study, please contact:

Jennifer Peters

XXX-XXX-XXXX

XXXXXXXXX@uottawa.ca

No compensation will be provided for participation.

This study has been approved by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board and UOttawa Research Ethics Board

Appendix A2: Proposed Methods - Caregiver Consent Form

**Kingston Health
Sciences Centre**

Centre des sciences de
la santé de Kingston

Caregiver Consent Form.

Title of the study: An Observational Study of Nursing Practices and Toddler Responses to Venipuncture in Hospital

Principal Investigator

Jennifer Peters, BScN, MScN(c), RN
Graduate Student, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Research Supervisor

Denise Harrison, PhD, RN
Associate Professor, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Invitation to Participate: I am invited to participate in the abovementioned research study conducted by Jennifer Peters under the supervision of Dr. Denise Harrison.

Purpose of the Study: The purpose of the study is to identify the strategies nursing staff are using to help manage pain for toddlers (ages one to three years) who are having blood work drawn at Kingston Health Sciences Centre. Toddler responses will be used to gain insight into the effectiveness of pain management strategies that nurses are using.

Participation: My participation will consist essentially of my child having medically necessary blood drawn during which the researcher will observe the procedure and make notes about what happens during the procedure. The procedure will also be videotaped for further analysis after the procedure. No unnecessary blood work will be drawn for the purpose of this study.

Risks: My participation in this study will entail that my child will have medically required blood work drawn. This may cause them to feel the normal discomfort associated with this procedure. I have received assurance from the researcher that every effort will be made to minimize these risks through nurses' use of usual pain management strategies as deemed necessary by the nurse, myself, or my child. No change to usual care will occur as a result of participating in this study.

Benefits: My participation in this study will help researchers and the Kingston Health Sciences Centre pediatrics nursing staff to learn how nurses are managing pain and how toddlers respond to having blood work done in hospital. Learning about these practices and responses will help to develop education, policies, and procedures for nurses to better manage a toddler's pain when they are having blood work drawn. Research findings will be available upon request after the final thesis submission and approval at the conclusion of the study period.

Confidentiality and anonymity: I have received assurance from the researcher that the information I will share will remain strictly confidential. I understand that the contents will be used only for this study and that my

76 Stuart Street, Kingston, Ontario, Canada K7L 2V7
Tel: 613.549.6666 www.kgh.on.ca www.hotelldieu.com



Kingston Health Sciences Centre

Centre des sciences de
la santé de Kingston

confidentiality and anonymity will be protected by assigning randomly generated code numbers for all research participants. These numbers will be used on all research notes and documents. All identifying information, including notes and observational data, will be kept in a locked cabinet in the personal possession of the researcher. Approving Research Ethics Boards may review the research data files for auditing and quality assurance purposes.

Conservation of data: The data collected on paper will be entered into an electronic data management system. The electronic data set will be stored on a password protected computer and an encrypted memory stick that can only be accessed by the primary researcher. Data will be conserved for 5 years after the conclusion of the study period, and then destroyed.

Voluntary Participation: I am under no obligation to participate and if I choose to participate, I can withdraw my child from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If I choose to withdraw, all data gathered until the time of withdrawal will be destroyed and not included in the research report. Not consenting to participate or withdrawing consent will have no impact on any current or future health care services at the Kingston Health Sciences Centre.

Acceptance: I, _____, agree to participate in the above research study conducted by Jennifer Peters of the School of Nursing, Faculty of Health Sciences, University of Ottawa, which research is under the supervision of Dr. Denise Harrison.

If I have any questions about the study, I may contact the researcher or his supervisor.

If I have any questions regarding the ethical conduct of this study, I may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5

Tel.: (613) 562-5387

Email: ethics@uottawa.ca

The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Call 1-844-535-2988 (toll free in North America) or email the HSREB Chair at clarkaf@queensu.ca.

AND/OR

Kingston General Health Research Institute, 76 Stuart Street, Kingston, ON, K7L 2V7

Tel: (613) 549-6666 x 8171 (7 am-3 pm) or x 3344 (3 pm-6 pm)

Email: kghri@kingstonhsc.ca

There are two copies of the consent form, one of which is mine to keep.

Date:

Date:

Participant's signature:

Researcher's signature:

Appendix A3: Proposed Methods - Media Release Consent Form

**Kingston Health
Sciences Centre**

Centre des sciences de
la santé de Kingston

Media Release Consent Form

Title of the study: An Observational Study of Nursing Practices and Toddler Responses to Venipuncture in Hospital

Principal Investigator

Jennifer Peters, BScN, MScN(c), RN
Graduate Student, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Research Supervisor

Denise Harrison, PhD, RN
Associate Professor, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

On-Site Supervisor

Susan Vasily, MScN, NP
Acute Pain Management Service, Kingston General Hospital

I, _____ hereby grant permission to Jennifer Peters, the
(Parent/Guardian/Patient)
principal investigator, and any other person authorized by the hospital to take and produce photographs, film, sound recordings and any other audio and/or visual reproductions of myself or my child. Formats may include, but are not limited to: television, print, and internet (web).

I consent to these video recordings being used for:

- ☐ This study only
- ☐ Education/training purposes (i.e. conferences, presentations)
- ☐ Promotion for public related events (i.e. pediatric pain public awareness)

Participant ID Number: _____

Name of Parent/Guardian (print): _____

Parent/Guardian Signature : _____ Date : _____

Research Representative: _____ Date : _____

NOTES:

76 Stuart Street, Kingston, Ontario, Canada K7L 2V7
Tel: 613.549.6666 www.kgh.on.ca www.hoteldieu.com



Appendix A4: Proposed Methods - Sample Staff Recruitment Email

Dear KGH pediatrics nurses!

My name is Jenn Peters; I am an MScN student and an RN in the Cardiac Sciences Unit at KGH. Some of you may remember me from the epidural, PCA pump, and lidocaine infusion in-services I provided in early 2018.

I am very excited to be conducting a study in the near future that will observe toddler responses to venipuncture done in-hospital. The study will also make note of the strategies that you, as nurses, are using to help minimize the pain that toddlers are experiencing during venipuncture. The study involves no changes to usual care and has been cleared by Queens University, KGH, and UOttawa ethics. Currently, the study is scheduled to start in the next two weeks, but I will send a follow-up email when data collection will begin.

This work is being conducted under the supervisions of Dr. Harrison (University of Ottawa) and Susan Vasily (Nurse Practitioner for APMS at KGH). Kerri-Lee has also expressed interest in this study, as the findings will directly benefit the nurses and children admitted to our hospital!

Attached to this email you will find the recruitment poster that will be used for this study. I will bring more posters that can be handed out to parents of toddlers who are admitted to the unit.

Once the study begins, if you are taking care of a toddler who will be undergoing venipuncture and has parents present who can discuss the study further I would appreciate your assistance in contacting me by phone or text at 613-XXX-XXXX. I will also be on the unit on research days and will try and touch base with the charge nurses in order to capture as many cases as possible. If you have any questions about the research or the data collection process please do not hesitate to reach out to either myself or Susan Vasily from APMS.

I sincerely look forward to working with you all!

Warmest wishes for the New Year,

Jenn Peters

Appendix A5: Proposed Methods - Data Collection Form

Pediatrics Venipuncture Study: Data Collection Form

1

Eligibility

Does the child meet inclusion eligibility criteria? ☐ Yes ☐ No

If No, specify: _____

Does the child meet any exclusion criteria? ☐ Yes ☐ No

If No, specify: _____

Consent Obtained? ☐ Yes ☐ Refused

Media Release Signed? ☐ Yes ☐ Refused

Demographics

Randomized 6-digit ID: _____

Year & Month of Birth (Y/M): _____

Today's Date (Y/M/D): _____

Date of Admission (Y/M/D): _____

Gender: ☐ Male ☐ Female

MAR Reviewed: ☐ Yes ☐ No

First Hospitalization: ☐ Yes ☐ No

Location: _____

Reason for Admission

- ☐ elective surgical ☐ trauma ☐ respiratory (non-infectious)
☐ respiratory (infections) ☐ gastrointestinal (non-infectious) ☐ gastrointestinal (infectious)
☐ cardiovascular ☐ neurological ☐ endocrine
☐ acute exacerbation of chronic condition ☐ other

Procedure Data:

Procedure Start Time: _____ (considered time 0m:0sec)

Time of tourniquet application (min:sec): _____ Time of first skin break (min:sec): _____

Time of bandage Application (min:sec): _____ Total Time (min:sec): _____

Number of Attempts: _____ Procedure Successful: ☐ Yes ☐ No

Characteristic	Pre-Proc. 1	Pre-Proc. 2	Procedure	Post-Procedure	Recovery
Length (secs)					
FLACC					
Cry Time (secs)					
Crying At Start of Time Period?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Pre-procedure 1: before the tourniquet is applied.

Pre-procedure 2: the moment at which the tourniquet is applied to just before the moment of first skin-break. Measure once the tourniquet has been fully applied.

Procedure: the moment of first skin-break to the moment of needle withdrawal. Measure at one minute after the first skin break.

Post-procedure: needle withdrawal to application of a bandage. Measure at the time of bandage application.

Recovery: observed for two-minutes. Measure at 2-minutes after bandage application

Pediatrics Venipuncture Study: Data Collection Form

2

People Present in Room

Role/Position	Gender & Number Present	Involved in procedure	Role/Position & Gender	Number Present	Involved in procedure (Y/N)
Caregiver	☐ M ____ ☐ F ____	☐ Y ☐ N	Nurse	☐ M ____ ☐ F ____	☐ Y ☐ N
Physician	☐ M ____ ☐ F ____	☐ Y ☐ N	Child Life Specialist	☐ M ____ ☐ F ____	☐ Y ☐ N
Phlebotomist	☐ M ____ ☐ F ____	☐ Y ☐ N	Sibling	☐ M ____ ☐ F ____	☐ Y ☐ N
Other (Specify)	☐ M ____ ☐ F ____	☐ Y ☐ N	Other (Specify)	☐ M ____ ☐ F ____	☐ Y ☐ N

Use of Comfort Measures

Pharmacological Comfort Measures		
Strategy	When Used	Comments
Topical Anesthetic	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	☐ EMLA ☐ AMETOP ☐ Other _____ Site(s) _____ ☐ Application Time _____ ☐ Procedure Time _____
Sucrose	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Pre-analgesia	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	☐ Acetaminophen ☐ Ibuprofen ☐ Other _____ ☐ Administration Time _____ ☐ Procedure Time _____
Non-nutritive Sucking	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Other	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	

Physical Comfort Measures		
Strategy	When Used	Comments
Cuddling / Holding	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	☐ Facing Holder ☐ Away From Holder ☐ Side-Sitting ☐ Other _____
Positioning & Restraint	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	☐ Upright ☐ Supine ☐ Restrained
Other	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	

Pediatrics Venipuncture Study: Data Collection Form

3

Psychological Comfort Measures		
Strategy	When Used	Comments
Distraction	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Verbal Support	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Explanations & Procedural Preparation	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Breathing Techniques	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	
Other	☐ Pre 1 ☐ Pre 2 ☐ Proc. ☐ Post. ☐ Recov.	

Notes

Appendix A6: The FLACC Pain Assessment Tool

FLACC Characteristic	Score
FACE 0 - No particular expression or smile 1 - Occasional grimace or frown, withdrawn, uninterested 2 - Frequent to constant quivering chin, clenched jaw	
LEGS 0 - Normal position or relaxed 1 - Uneasy, restless, tense 2 - Kicking, or legs drawn up	
ACTIVITY 0 - Lying quietly, normal position, moves easily 1 - Squirming, shifting, back and forth, tense 2 - Arched, rigid or jerking	
CRY 0 - No cry (awake or asleep) 1 - Moans or whimpers; occasional complaint 2 - Crying steadily, screams or sobs, frequent complaints	
CONSOLABILITY 0 - Content, relaxed 1 - Reassured by occasional touching, hugging or being talked to, distractible 2 - Difficult to console or comfort	
TOTAL	

(Merkel et al., 1997; Merkel & Malviya, 2000)

Appendix A7: Initial Ethics Approval



QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD (HSREB)

HSREB Initial Ethics Clearance

November 15, 2018

Jennifer Peters
University of Ottawa

ROMEO/TRAQ #: 6025147

Department Code: NURS-456-18

Study Title: "An observational study of nursing practices and toddler responses during venipuncture in hospital"

Supervisor: Dr. Denise Harrison

Review Type: Delegated

Date Ethics Clearance Issued: November 15, 2018

Ethics Clearance Expiry Date: November 15, 2019

Dear Peters:

The Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB) has reviewed the application and granted ethics clearance for the documents listed below. Ethics clearance is granted until the expiration date noted above.

- Data Collection Form: 2018NOV09
- Consent Form: 2018NOV09
- Recruitment Poster: 2018OCT01
- Caregiver Media Release Form: 2018OCT04

Documents Acknowledged:

- Thesis Committee Approval (uploaded 2018OCT04)
- Core Certificate – J. Peters

Amendments: No deviations from, or changes to the protocol should be initiated without prior written clearance of an appropriate amendment from the HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involve(s) only

administrative or logistical aspects of the trial.

Renewals: Prior to the expiration of your ethics clearance you will be reminded to submit your renewal report through ROME0. Any lapses in ethical clearance will be documented on the renewal form.

Completion/Termination: The HSREB must be notified of the completion or termination of this study through the completion of a renewal report in ROME0.

Reporting of Serious Adverse Events: Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after study team members have become aware of the information.

Reporting of Complaints: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of study team members becoming aware of the complaint.

Note: All documents supplied to participants must include the contact information for the Research Ethics Board. Investigators: please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete.

Yours sincerely,


Albert F. Clark, PhD
Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

The HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations, and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP). Federalwide Assurance Number: FWA#:00004184, IRB#:00001173

HSREB members involved in the research project do not participate in the review, discussion or decision

Université d'Ottawa

Bureau d'éthique et d'intégrité de la recherche

University of Ottawa

Office of Research Ethics and Integrity

15/01/2019

CERTIFICAT D'APPROBATION ÉTHIQUE | CERTIFICATE OF ETHICS APPROVAL

Numéro du dossier / Ethics File Number

H-11-18-1418

Titre du projet / Project Title

An observational study of nursing practices and toddler responses during venipuncture in hospital.

Type de projet / Project Type

Thèse de maîtrise / Master's thesis

Statut du projet / Project Status

Approuvé / Approved

Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)

15/01/2019

Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)

15/11/2019

Équipe de recherche / Research Team

Chercheur / Researcher Affiliation

Role

Jennifer PETERS

École des sciences infirmières / School of Nursing

Chercheur Principal / Principal Investigator

Denise HARRISON

École des sciences infirmières / School of Nursing

Superviseur / Supervisor

Conditions spéciales ou commentaires / Special conditions or comments

550, rue Cumberland, pièce 154 550 Cumberland Street, Room 154
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada

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www.recherche.uottawa.ca/deontologie | www.recherche.uottawa.ca/ethics

Appendix A8: Ethics Amendment #1



QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD (HSREB)

HSREB Amendment Acknowledgment/Ethics Clearance

February 22, 2019

Jennifer Peters
School of Nursing
University of Ottawa

TRAQ #: 6025147

Department Code: NURS-456-18

Study Title: "An observational study of nursing practices and toddler responses during venipuncture in hospital"

Review Type: Delegated

Date Ethics Clearance Issued: February 22, 2019

Dear Jennifer:

The Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB) has reviewed the amendment application and granted ethics approval/acknowledgement for the documents listed below.

- Caregiver Consent Form v.2019FEB20
- Data Collection Form v.2019FEB20
- Recruitment Poster v.2019FEB20
- Request to expand study to include recruitment from beyond the KGH in-patient pediatrics unit. Once approved, recruitment will take place at Kingston Health Sciences Centre out-patient clinics with approval from the associated managers (ie: ER, COPC, cancer-clinic).

Yours sincerely,

Albert F. Clark, PhD

Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

The HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH), and is constituted in accordance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations; and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is qualified through the CYO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP), Federalwide Assurance Number: FWA00004184, IRB#00001173

HSREB members involved in the research project do not participate in the review, discussion or decision.

Université d'Ottawa

Bureau d'éthique et d'intégrité de la recherche

University of Ottawa

Office of Research Ethics and Integrity

H-11-18-1418 - MOD1-1418 - Modification approuvée / Modification Approved

(English message follows)

Cher/Chère Jennifer Peters,

Merci d'avoir soumis une demande de modification pour votre projet de recherche intitulé «An observational study of nursing practices and toddler responses during venipuncture in hospital.».

Ces modifications ont été approuvées et sont assujetties au certificat d'approbation éthique, valide jusqu'au 15-11-2019.

Recruitment Process:

Participants from outpatient clinics within the same facility, Kingston Health Sciences Centre, will be recruited. Revised copies of research instruments and consent forms have been submitted.

Si vous avez des questions, n'hésitez pas à communiquer avec le Bureau d'éthique au ethique@uottawa.ca ou au 613-562-5387.

Vous pouvez voir votre demande en vous connectant à votre compte [eReviews](#).

Cordialement,

Ethics Coordinator
 Coordonnateur de l'éthique
 Président(e) : Daniel Lagarec
 CÉR : Comité d'éthique de la recherche en sciences de la santé et sciences / Health Sciences and Sciences Research Ethics Board

Ceci est une réponse automatisée, merci de ne pas répondre à ce courriel.

Dear Jennifer Peters,

Thank you for submitting a modification request for your research project titled "An observational study of nursing practices and toddler responses during venipuncture in hospital."

These modifications are now covered under the certificate of ethics approval, valid until 15-11-2019.

Recruitment Process:

Participants from outpatient clinics within the same facility, Kingston Health Sciences Centre, will be recruited. Revised copies of research instruments and consent forms have been submitted.

If you have any questions, please contact the Ethics Office at ethics@uottawa.ca or 613-562-5387.

You can view your project at any time by logging into [eReviews](#).

Best regards,

Ethics Coordinator
 Ethics Coordinator
 Chair: Daniel Lagarec
 REB: Comité d'éthique de la recherche en sciences de la santé et sciences / Health Sciences and Sciences Research Ethics Board

550, rue Cumberland, pièce 154 550 Cumberland Street, Room 154
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Appendix B: Consent and Assent Forms



Kingston Health
Sciences Centre

Centre des sciences de
la santé de Kingston

Caregiver Consent Form

Title of the study: Pediatric Procedural Pain Management Practices: A Chart Review and Patient-Caregiver Survey

Principal Investigator

Jennifer Peters, BScN, MScN(c), RN
Graduate Student, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Research Supervisor

Denise Harrison, PhD, RN
Associate Professor, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Invitation to Participate: I am invited to participate in the abovementioned research study conducted by Jennifer Peters under the supervision of Dr. Denise Harrison.

Purpose of the Study: The purpose of the study is to identify the strategies nursing staff are using to help manage pain for pediatric inpatients (ages 0-18 years) who have had a needle procedure at Kingston Health Sciences Centre. Participant responses will be used to gain insight into the effectiveness of pain management strategies that nurses are using.

Participation: My participation will consist essentially of myself and my child (if able) responding to a short survey about my child's most recent needle procedure. This short survey should take less than 10 minutes to complete. The principal investigator will also review my child's medical chart to document the nursing interventions that were used for the same procedure. No needle procedures will be performed for the purpose of this study.

Risks: My participation in this study will only entail retelling of my child's most recent needle procedure. No risks are foreseen. No change to usual care will occur as a result of participating in this study.

Benefits: My participation in this study will help researchers and the Kingston Health Sciences Centre pediatrics nursing staff to learn how nurses are managing pain and how children respond to pain management approaches. Learning about these practices and responses will help to develop education, policies, and procedures for nurses to better manage a children's pain when they are having needle procedures performed. Research findings will be available upon request after the final thesis submission and approval at the conclusion of the study period.

Confidentiality and anonymity: I have received assurance from the researcher that the information I will share will remain strictly confidential. I understand that the contents will be used only for this study and that my confidentiality and anonymity will be protected by assigning randomly generated code numbers for all research participants. These numbers will be used on all research notes and documents. All identifying information, including notes and observational data, will be kept in a locked cabinet in the personal possession of the



**Kingston Health
Sciences Centre**

Centre des sciences de
la santé de Kingston

researcher. Approving Research Ethics Boards may review the research data files for auditing and quality assurance purposes.

Conservation of data: The data collected on paper will be entered into an electronic data management system. The electronic data set will be stored on a password protected computer and an encrypted memory stick that can only be accessed by the primary researcher. Data will be conserved for 5 years after the conclusion of the study period, and then destroyed.

Voluntary Participation: I am under no obligation to participate and if I choose to participate, I can withdraw my child from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If I choose to withdraw, all data gathered until the time of withdrawal will be destroyed and not included in the research report. Not consenting to participate or withdrawing consent will have no impact on any current or future health care services at the Kingston Health Sciences Centre.

Acceptance: I, _____, agree to participate in the above research study conducted by Jennifer Peters of the School of Nursing, Faculty of Health Sciences, University of Ottawa, which research is under the supervision of Dr. Denise Harrison.

If I have any questions about the study, I may contact the researcher or her supervisor.

If I have any questions regarding the ethical conduct of this study, I may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5

Tel.: (613) 562-5387

Email: ethics@uottawa.ca

The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Call 1-844-535-2988 (toll free in North America) or email the HSREB Chair at clarkaf@queensu.ca.

AND/OR

Kingston General Health Research Institute, 76 Stuart Street, Kingston, ON, K7L 2V7

Tel: (613) 549-6666 x 8171 (7 am-3 pm) or x 3344 (3 pm-6 pm)

Email: kghri@kingstonhsc.ca

There are two copies of the consent form, one of which is mine to keep.

Date:

Date:

Participant's signature:

Researcher's signature:



**Kingston Health
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la santé de Kingston

Consentable Pediatric Patient (Aged 14-18yrs) Consent Form.

Title of the study: Pediatric Procedural Pain Management Practices: A Chart Review and Patient-Caregiver Survey

Principal Investigator

Jennifer Peters, BScN, MScN(c), RN
Graduate Student, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Research Supervisor

Denise Harrison, PhD, RN
Associate Professor, School of Nursing Faculty of Health Sciences
Telephone: XXX-XXX-XXXX XXXXXXXX@uottawa.ca

Invitation to Participate: I am invited to participate in the above-mentioned research study conducted by Jennifer Peters under the supervision of Dr. Denise Harrison.

Purpose of the Study: The purpose of the study is to identify what nursing staff are doing to help manage pain for pediatric inpatients (ages 0-18 years) who have had a needle procedure at Kingston Health Sciences Centre.

Participation: My participation will consist of my answering a short survey about my most recent needle procedure. This short survey should take less than 10 minutes to complete. The researcher will also review my medical chart to review the strategies that were used for the same previous procedure. I will not be given a needle for the purpose of this study.

Risks: My participation in this study will only involve retelling of my most recent needle procedure. No risks are foreseen. No change to my care will occur as a result of participating or not participating in this study.

Benefits: My participation in this study will help researchers and the Kingston Health Sciences Centre pediatrics nursing staff learn how nurses are managing pain and how children respond to pain management approaches. Learning about these practices and responses will help to develop education, policies, and procedures for nurses to better manage a children's pain when they are having needle procedures performed. Research findings will be available upon request after the final thesis submission and approval at the conclusion of the study period.

Confidentiality and anonymity: I have received assurance from the researcher that the information I will share will remain strictly confidential. I understand that the contents will be used only for this study and that my confidentiality and anonymity will be protected by assigning randomly generated code numbers for all research participants. These numbers will be used on all research notes and documents. All identifying information, including notes and observational data, will be kept in a locked cabinet in the personal possession of the researcher. Approving Research Ethics Boards may review the research data files for auditing and quality

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Tel: 613.549.6666 www.kgh.on.ca www.hoteldieu.com





**Kingston Health
Sciences Centre**

Centre des sciences de
la santé de Kingston

assurance purposes.

Conservation of data: The data collected on paper will be entered into an electronic data management system. The electronic data set will be stored on a password protected computer and an encrypted memory stick that can only be accessed by the primary researcher. Data will be conserved for 5 years after the conclusion of the study period, and then destroyed.

Voluntary Participation: I am under no obligation to participate and if I choose to participate, I can withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If I choose to withdraw, all data gathered until the time of withdrawal will be destroyed and not included in the research report. Not consenting to participate or withdrawing consent will have no impact on any current or future health care services at the Kingston Health Sciences Centre.

Acceptance: I, _____, confirm that I am at least 14 years of age and agree to participate in the above research study conducted by Jennifer Peters of the School of Nursing, Faculty of Health Sciences, University of Ottawa, which research is under the supervision of Dr. Denise Harrison. If I have any questions about the study, I may contact the researcher or her supervisor.

If I have any questions regarding the ethical conduct of this study, I may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5
Tel.: (613) 562-5387
Email: ethics@uottawa.ca

The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. Call 1-844-535-2988 (toll free in North America) or email the HSREB Chair at clarkaf@queensu.ca.

AND/OR

Kingston General Health Research Institute, 76 Stuart Street, Kingston, ON, K7L 2V7
Tel: (613) 549-6666 x 8171 (7 am-3 pm) or x 3344 (3 pm-6 pm)
Email: kghri@kingstonhsc.ca

There are two copies of the consent form, one of which is mine to keep.

Date:

Date:

Participant's signature:

Researcher's signature:



**Kingston Health
Sciences Centre**

Centre des sciences de
la santé de Kingston

Child Assent Form

Title of the study: Pediatric Procedural Pain Management Practices: A Chart Review and Patient-Caregiver Survey

I agree to talk to Jennifer about my last needle stick. It is also okay if my mom/dad/caregiver talk(s) to Jennifer. We will talk about any pain I had during my last needle stick procedure. We will talk for about 10 minutes today.

Jennifer is also allowed to look at my nurses' notes to read what they wrote about my last needle stick and to learn more about why I am in the hospital.

I know she will not give me any needles today and talking to her will not hurt me.

I know I do not have to talk to Jennifer. I can choose to say yes or no. I can stop talking to her at any time.

☐ YES, I WILL TALK TO JENNIFER ☐ NO, I DO NOT WANT TO TALK TO JENNIFER

There are two copies of the consent form, one of which is mine to keep.

Date:

Date:

Caregiver's signature (witness):

Researcher's signature:

Appendix C: Data Collection Form

Pediatrics Needle Procedure Review Study: Data Collection Form

1

Eligibility

Does the child meet inclusion eligibility criteria? ☐ Yes ☐ No (specify: _____)

Does the child meet any exclusion criteria? ☐ Yes ☐ No (specify: _____)

Consent Obtained? ☐ Yes ☐ Refused ☐ Parent Unavailable

Tool 1: Chart Review

Demographics

Randomized 6-digit ID: _____

Year & Month of Birth (Y/M): _____

Today's Date (Y/M/D): _____

Date of Admission (Y/M/D): _____

Gender: ☐ Male ☐ Female

First Hospitalization: ☐ Yes ☐ No

Reason for Admission

☐ elective surgical

☐ trauma

☐ respiratory (non-infectious)

☐ respiratory (infections)

☐ gastrointestinal (non-infectious)

☐ gastrointestinal (infectious)

☐ cardiovascular

☐ acute exacerbation of chronic

☐ neurological

☐ endocrine

condition

☐ other _____

Procedure Data:

Pharmacological	☐ Topical Anesthetic (☐ EMLA ☐ AMETOP ☐ Other _____) ☐ Sucrose ☐ Pre-analgesia (noted as procedure-specific) ☐ Non-nutritive sucking ☐ Other _____
Physical	☐ Cuddling ☐ Kangaroo Care ☐ Swaddling ☐ Position of Comfort ☐ Breastfeeding ☐ Other _____
Psychological	☐ Distraction (☐ Not described ☐ Describe _____) ☐ Blowing Bubbles ☐ Verbal Support ☐ Guided Imagery ☐ Explanation & Preparation ☐ Breathing Technique ☐ Other _____
☐ None Documented ☐ N/A – no needle sticks	

If pre-analgesia used:

☐ Topical anesthetic (EMLA, Ametop)

☐ Acetaminophen

☐ Ibuprofen

☐ Morphine

☐ Fentanyl

☐ Hydromorphone

☐ Ketorolac

☐ N/A – nothing given

☐ Other: _____

Field Notes:

Pediatrics Needle Procedure Review Study: Data Collection Form

2

Tool 2: Parent-Child Survey

1. Most recent needle stick for blood draw (*select one only*):

- ☐ N/A – no painful needle procedures during hospitalization
☐ Venipuncture ☐ Blood draw with Peripheral IV start
☐ Heel lance ☐ Unsure
☐ Other (please specify): _____

2. Where was your last needle stick done?:

- ☐ Kidd 10 ☐ Emergency Department ☐ COPC ☐ Other (please specify): _____

3. During your last needle stick (or poke) for a blood draw, what sort of things did the nurse/doctors/blood collectors/child life specialists do to help you/your child? (*select all that apply*)

- | | |
|---|--|
| ☐ N/A – no needle sticks | ☐ Swaddling |
| ☐ Numbing cream (EMLA, Ametop) | ☐ Position of Comfort |
| ☐ Sucrose | ☐ Distraction (☐ Unsure ☐ Describe: _____) |
| ☐ Pain Medication | ☐ Blowing Bubbles |
| ☐ Sucking (ie: pacifier) | ☐ Verbal Support |
| ☐ Encourage breastfeeding during procedure | ☐ Guided Imagery |
| ☐ Cuddling | ☐ Explanation & Preparation |
| ☐ Kangaroo Care | ☐ Breathing Technique |
- ☐ Nothing specific ☐ Unsure ☐ Other (please specify) _____

0 = Not at all effective; 1 = Mildly effective; 2 = Moderately effective; 3 = Extremely effective

4. Overall, how effective was the strategy (or strategies) used (*as identified in question 2*) (0-3) :

- ☐ ___/3 ☐ Unsure ☐ N/A – no needle sticks ☐ N/A – nothing specific used

0 = Very dissatisfied; 1 = Somewhat dissatisfied; 2 = Somewhat satisfied; 3 = very satisfied

5. Please rate your satisfaction with procedural pain management for your last needle stick on a 0-3 scale:

- ☐ ___/3 ☐ N/A – no needle sticks

6. Please rate your current overall satisfaction with procedural pain management at KGH on a 0-3 scale:

- ☐ ___/3 ☐ N/A – no needle sticks

Field Notes:

Appendix D: Ethics Amendment #2



QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD (HSREB)

HSREB Amendment Acknowledgment/Ethics Clearance

April 25, 2019

Jennifer Peters
School of Nursing
University of Ottawa

TRAQ #: 6025147

Department Code: NURS-456-18

Study Title: "An observational study of nursing practices and toddler responses during venipuncture in hospital"

Review Type: Delegated

Date Ethics Clearance Issued: April 25, 2019

Dear Jennifer:

The Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB) has reviewed the amendment application and granted ethics approval/acknowledgement for the documents listed below.

- Notification that the study arm observing nursing practices and toddler responses to venipuncture in the hospital has been closed due to unforeseen complications with participant recruitment. In order to continue to develop an awareness of these PPM practices, a new descriptive, cross-sectional study has been proposed.
- Protocol- Updated Methods v.2019APR11
- Caregiver Consent Form v.2019APR24
- Data Collection Form v.2019APR09

Yours sincerely,

Albert F. Clark, PhD

Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

The HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonization Good Clinical Practice Consolidated Guideline (ICH), and is constituted in accordance with the requirements of the Tri-Council Policy Statement: Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations; and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is qualified through the CYO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP), Federalwide Assurance Number: FWA#00004184, IRB#00001173

HSREB members involved in the research project do not participate in the review, discussion or decision.

Université d'Ottawa

Bureau d'éthique et d'intégrité de la recherche

University of Ottawa

Office of Research Ethics and Integrity

H-11-18-1418 - MOD2-1418 - Modification approuvée / Modification Approved

(English message follows)

Cher/Chère Jennifer Peters,

Merci d'avoir soumis une demande de modification pour votre projet de recherche intitulé «Pediatric Procedural Pain Management Practices: A Chart Review and Patient-Caregiver Survey. ».

Ces modifications ont été approuvées et sont assujetties au certificat d'approbation éthique, valide jusqu'au 15-11-2019.

1) Research design: The observation of nursing practices and toddler responses to venipuncture in the hospital has been abandoned due to unforeseen complications with participant recruitment.

* A new approach is undertaken. It will provide a snapshot of the PPM strategies nurses are using for all pediatric patients.

* This study includes a brief caregiver-child survey addressing aspects of their most recent blood-draw needle procedure and a chart-review assessing the nursing documentation of PPM strategies for the same procedure.

2) Inclusion criteria: The age inclusion criterion is now newborn to 18 years of age.

3) Recruitment process: Participants will be identified by their primary assigned nurse who will ask if the potential participant/their caregiver (if <14 years of age) is willing to be approached by a researcher. If a potential participant is 14 years of age or older, the researcher will approach the participant directly to discuss the study and recruit them.

4) Research instruments: A new data collection tool to capture the new data set is used.

5) Consent documents: New consent and assent forms are used.

Si vous avez des questions, n'hésitez pas à communiquer avec le Bureau d'éthique au ethique@uottawa.ca ou au 613-562-5387.

Vous pouvez voir votre demande en vous connectant à votre compte [eReviews](#).

Cordialement,

Germain Zongo

Responsable d'éthique en recherche

Président(e) : Daniel Lagarec

CÉR : Comité d'éthique de la recherche en sciences de la santé et sciences / Health Sciences and Sciences Research Ethics Board

Ceci est une réponse automatisée, merci de ne pas répondre à ce courriel.

Dear Jennifer Peters,

Thank you for submitting a modification request for your research project titled "Pediatric Procedural Pain Management Practices: A Chart Review and Patient-Caregiver Survey. ".

These modifications are now covered under the certificate of ethics approval, valid until 15-11-2019.

1) Research design: The observation of nursing practices and toddler responses to venipuncture in the hospital has been abandoned due to unforeseen complications with participant recruitment.

* A new approach is undertaken. It will provide a snapshot of the PPM strategies nurses are using for all pediatric patients.

* This study includes a brief caregiver-child survey addressing aspects of their most recent blood-draw needle procedure and

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www.recherche.uottawa.ca/deontologie | www.recherche.uottawa.ca/ethics

Université d'Ottawa

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University of Ottawa

Office of Research Ethics and Integrity

a chart-review assessing the nursing documentation of PPM strategies for the same procedure.

2) Inclusion criteria: The age inclusion criterion is now newborn to 18 years of age.

3) Recruitment process: Participants will be identified by their primary assigned nurse who will ask if the potential participant/their caregiver (if <14 years of age) is willing to be approached by a researcher. If a potential participant is 14 years of age or older, the researcher will approach the participant directly to discuss the study and recruit them.

4) Research instruments: A new data collection tool to capture the new data set is used.

5) Consent documents: New consent and assent forms are used.

If you have any questions, please contact the Ethics Office at ethics@uottawa.ca or 613-562-5387.

You can view your project at any time by logging into [eReviews](#).

Best regards,

Germain Zongo

Protocol Officer

Chair: Daniel Lagarec

REB: Comité d'éthique de la recherche en sciences de la santé et sciences / Health Sciences and Sciences Research Ethics Board

This is an automated message. Please do not reply directly to this email.

Attachement(s) / Attachment(s)

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QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD (HSREB)

HSREB Amendment Acknowledgment/Ethics Clearance

May 22, 2019

Jennifer Peters
University of Ottawa

TRAQ #: 6025147

Department Code: NURS-456-18

Study Title: "An observational study of nursing practices and toddler responses during venipuncture in hospital"

Review Type: Delegated

Date Ethics Clearance Issued: May 22, 2019

Dear Peters:

The Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB) has reviewed the amendment application and granted ethics approval/acknowledgement for the documents listed below.

- Consent v.2019MAY14
- Assent v.2019MAY14

Yours sincerely,

Albert F. Clark, PhD

Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

The HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the international Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 3 of the Food and Drug Regulations; Part 4 of the Natural Health Product Regulations; Part 3 of the Medical Devices Regulations, and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP). Federalwide Assurance Number: FWA#: 00004184, IRB#: 00001173. HSREB members involved in the research project do not participate in the review, discussion or decision.