DEVELOPING A CLINICAL SUPPORT TOOL OF SUBOPTIMAL CAREGIVER
BEHAVIOURS DURING VACCINATION: PRELIMINARY VALIDATION OF THE
OPPORTUNITIES TO UNDERSTAND CHILDHOOD HURT INOCULATION (OUCHI)
TOOL

HANNAH G. GENNIS

A MASTER'S THESIS SUBMITTED TO THE FACULTY OF GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE MASTER OF ARTS

GRADUATE PROGRAM IN CLINICAL-DEVELOPMENTAL PSYCHOLOGY

YORK UNIVERSITY

TORONTO, ONTARIO

August 2016

© Hannah Gennis, 2016

ABSTRACT

The ability of an infant to regulate from his or her distress is heavily contingent on sensitive caregiver behaviours. Socioemotional development and mental health outcomes are strongly predicated on adequate abilities of the caregiver to soothe their infant, and model regulatory strategies that the infant learns to use during distress regulation throughout development. A child who does not receive adequate distress regulation support during infancy develops regulatory patterns that impact physical, cognitive, and emotional development. An ideal opportunity to support the infant, the parent, and the infant-caregiver relationship is embedded within the vaccination context. It provides primary pediatric care clinicians with a relatively standardized opportunity to support caregiver soothing of infant distress repetitively across childhood. However, there is no clinical tool or norms to identify dyads that may need support in this important area. The object of the present thesis was to develop a clinical support tool highlighting caregiver behaviours that increase infant distress during vaccination – the OUCHI Tool (Opportunities to Understand Childhood Hurt Inoculation Tool), and establish its preliminary psychometric properties (i.e., reliability and validity). The tool was developed and validated by synergizing extensive research experience in vaccination behaviours, clinician expertise in everyday practice, and archival vaccination data (n = 537). Our findings showed excellent interrater reliability, moderate test-retest reliability, as well as solid evidence reflecting ecological, content, face, convergent, and divergent validity. The OUCHI Tool is a promising tool that can help integrate infant mental health practices during pediatric well-baby visits. Key words: Vaccination, Pain, Infant, Caregiver, Behaviour, Clinician, Measure

ACKNOWLEDGEMENTS

I would first like to thank my supervisor and mentor, Dr. Rebecca Pillai Riddell, for her continued support, guidance, and allowing me to work by her side on the OUCHI Tool. I have learned so much from you, and approaching you at IFPP in 2013 was the best decision I have ever made. Thank you for allowing me to continue my passion for pediatric pain research, and helping me grow as an independent researcher. I would also like to thank Dr. Joel Katz, and my committee for their thoughtful feedback and advice throughout this project.

I am extremely grateful to the clinicians at the Black Creek Community Health Centre for working with us on the tool, and providing such thoughtful and important input.

Thank you to the OUCH lab! I am so fortunate to work with such a hardworking and intelligent group of individuals. Thank you to all past and present graduate students for your continued support, guidance, and laughter. Thank you to all of our wonderful lab coordinators, undergraduate students, research assistants, and volunteers for your hard work and dedication to the work that we do. A very special thank you goes out to Paula Tablon, my OUCHI Tool coding partner in crime, as well as Alessandro Perri for his help with coding. I would also like to thank those families who participated in the OUCH Cohort.

I would like to take the opportunity to thank those that have funded this work. I am extremely grateful to the Canadian Institutes of Health Research, the Lillian Meighen and Don Wright Foundation, and Pain in Child Health for their generous support of my work through graduate fellowships. Further, this work would not have been possible without the support of a TD Community Catalyst Grant, a Canadian Psychological Association Award for Innovative Access to Psychological Services, and a Children and Youth in Challenging Contexts Network Centres of Excellence Grant provided to Dr. Pillai Riddell.

Lastly, I would like to thank my friends and family for their continued support. Mom and Dad, I would not be at this point without your love, your wisdom, and your belief in me. There is not an acknowledgement section long enough to express my gratitude.

TABLE OF CONTENTS

Abstract	ii
Acknowledgements	iii
Table of Contents	v
List of Tables	vi
List of Figures	vii
Introduction	1
Methods	7
Participants	7
Measures	8
Procedure	12
Analyis Plan	14
Results	15
OUCHI Tool Descriptives	15
Reliability	16
Validity	16
Discussion	17
Interpretation of Findings	18
Clinical Implications	20
Research Implications	21
Limitations	21
Future Directions	22
Conclusion	23
References	24
Appendix A	35
Appendix B	37
Appendix C	38
Appendix D	40

LIST OF TABLES

Table 1. OUCHI Tool Development through Focus Groups	. 30
Table 2. Correlations of OUCHI Tool with Measures of Caregiver Behaviours and	
Infant Distress	. 32

LIST OF FIGURES

Figure 1. Final D	escriptions of OUCHI	Tool Caregiver Behaviours	
-------------------	----------------------	---------------------------	--

1. Introduction

When evaluating infant distress reactions, the caregiver is a critical contributor (Phillips & Best, 2007). Observation of infant behaviours (e.g., attachment seeking behaviours), parent behaviours (e.g., attitude toward the infant, sensitivity and responsiveness to infant cues), and dyadic behaviours (e.g., attachment relationship) are crucial to understanding the infant's social and emotional state (DC: 0-3R Task Force, 2005). The caregiver plays a particularly critical role in the development of early childhood distress regulation because they support and model the infant's regulation from distressing emotions when the infant does not possess the capacity to independently do so. After the first year of life, how an infant has learned to use their caregiver to regulate their distress is a central part of the attachment relationship (Bowlby, 1969/1982).

Thus, in early infancy, successful regulation from distressing events (e.g., fear, pain) relies heavily on contingent and sensitive caregiver support (Calkins & Fox, 1992; Kopp, 1982; Sroufe, 2000). Insensitive caregiver behaviours during times of high infant distress can contribute to the development of emotion regulation patterns that inhibit the development of appropriate skills needed for later developmental challenges (Cassidy, 1994). Through repeated pairings of external threat causing infant distress with sensitive and contingent caregiver soothing, the infant learns to effectively use the caregiver to regulate his or her distress. This in turn leads to a child's developmental trajectory towards healthy emotion-regulation across distress contexts (Schore, 2000).

Thus, while sensitive and contingent caregiver soothing (i.e., responses based on the infant's distress signalling) is important in the moment, these caregiver behaviours also have important implications for the child's future development. The way in which a caregiver soothes his or her highly distressed infant has important implications for the child's social and emotional

well being throughout development. In fact, it has been shown that as much as 75% of mental health diagnoses are linked with distress regulation (Werner & Gross, 2010). A young child who has been shown suboptimal or less optimal strategies for emotion regulation will have a higher chance of having challenges regulating distress throughout the lifespan (Bowlby 1969/1980). Therefore, finding a feasible way to support parents and infants who demonstrate poor distress regulation would be beneficial to integrate into primary pediatric care. Strategies and tools that support parent mental health and infant mental health optimize child development broadly (Kerker et al., 2016).

An ideal environment to support parents who have challenges with sensitively regulating their infants in high distress is during childhood vaccinations. Infant vaccination is an ecologically valid distress paradigm that allows health professionals to observe caregiver soothing during already existing primary care appointments ("well-baby visits"), at regular intervals across early childhood. However, in order for this to occur, medical professionals need a feasible way to determine whether or not the caregiver's behaviours are supporting the infant's regulation. The OUCHI Tool was designed to be a clinical support tool that assesses suboptimal caregiver behaviours during infant distress that can be feasibly incorporated into primary pediatric care.

In developing a checklist or tool to support medical care, there are five components described as necessary: context, content, structure, images, and usability (Hales, Terblanche, Fowler, & Sibbald, 2008). Context refers to the need to determine the setting in which the checklist will be used prior to development (e.g., use in primary pediatric care). Speaking to this point, the OUCHI Tool's initial item generation phase was based upon analyses of over 2000 vaccination appointments from 16 papers published on the OUCH Cohort using well-established

measures of caregiver soothing behaviours, emotional availability, and infant pain-related distress (Atkinson, Gennis, Racine, & Pillai Riddell, 2015; Campbell, Pillai Riddell, Garfield, Greenberg, 2013; Din, Pillai Riddell, & Gordner, 2009; Din Osmun, Pillai Riddell, & Flora, 2014; Hillgrove-Stuart, Pillai Riddell, Flora, Greenberg, & Garfield, 2015; Hillgrove-Stuart, Pillai Riddell, Horton, Greenberg, 2013; Horton, Din Osmun, Pillai Riddell, Stevens, & Greenberg, 2010; Horton & Pillai Riddell, 2010; Horton, Pillai Riddell, Flora, Moran, & Pederson, 2015; Horton, Pillai Riddell, Moran, & Lisi, 2016; Lisi, Campbell, Pillai Riddell, Garfield, & Greenberg, 2013; Pillai Riddell, Flora, Stevens, Greenberg, & Garfield, 2014; Pillai Riddell et al., 2011; Pillai Riddell et al., 2013; Racine, Pillai Riddell, Flora, Garfield, & Greenberg, 2012; Vinall, Pillai Riddell, & Greenberg, 2011). Thus, given the OUCHI Tool's firm roots in the infant vaccination appointment, this vaccination context was considered suitable to integrate supportive infant mental health practices into primary care.

To meet the requirement of content, a synthesis of evidence-based best practices and peer-reviewed resources must be undertaken when developing a medical tool, and the perspectives of all individuals using the tool should be considered. There currently exist no clinical support tools that have been designed for use in primary pediatric care that assess suboptimal caregiver soothing behaviours during infant pain-related distress. While there are some measures used as infant socioemotional screeners (American Academy of Pediatrics, 2012; Briggs et al., 2012, Weitzman & Leventhal, 2006), these are based solely on caregiver report. To our knowledge, only one measure has recently been developed to assess the caregiver-infant relationship in primary pediatric care (Moe, Siqveland, & Fredriksen, 2016). This tool is based on dyadic behaviours observed by health professionals, focusing on the child's emotional development in areas such as mutual engagement, two-way communication, abstract thinking,

etc. Although this tool also assesses regulation during a challenging task, it does not assess the parent's behaviour in a distress context. Parent-child behaviour during distress contexts is known to be a powerful predictor of child development (Ainsworth et al., 1978). Moreover, in the present thesis, we aimed to engage in focused discussions with a team of vaccinating physicians and nurses to help shape the content of the OUCHI.

With respect to the structure, the tool must be organized in a way that is logical, functional, and reflects the flow of clinician activity. Moreover, the images (i.e., the appearance) must be clear and appropriate for the parties using it and, when considering the tool's usability, the tool should not be too time-consuming that it does not fit in with the clinic flow. Current infant mental health primary care tools can be costly, and require an additional 10 to 15 minutes on average to administer (American Academy of Pediatrics, 2012). Considering an average well-baby visit is 10 to 15 minutes in duration (Canadian Pediatric Society, 2013), their use would require clinicians to double the time spent per patient, and thus these measures are less adapted for the primary care environment. Moreover, clinical tools should be concise yet support clinicians to make judgements about further intervention when needed, all members of the team should be able to use it, and the tool's validation should occur in the environment for its intended use (Hales et al., 2008). Taking these guidelines under consideration, our discussions with practicing immunizers in the present thesis was targeted to confirm the content, the images, the structure, and the usability of the OUCHI.

Present Study

To address the current gaps of integrating core infant mental health principles into primary care, the object of the present thesis was to develop a clinical support tool, the Opportunities to Understand Childhood Hurt Inoculation (OUCHI) Tool, with the five

components of tool development recommended by Hales and colleagues (2008) in mind. The purpose of developing the OUCHI Tool was to provide primary care clinicians (either physicians or nurses) a tool to use in the minutes following vaccination that would support identification of dyads that struggle with distress regulation. The novel approach of the OUCHI Tool is its focus on parent behaviours, easily identifiable to medical professionals that have been shown to consistently increase or maintain high infant distress in the vaccination setting.

It is critical to underscore that the OUCHI Tool is a support tool, and not a diagnostic tool. Each behaviour on the OUCHI Tool is associated with high distress levels, as they are all suboptimal behaviours to enact in the immediate post-vaccination period when the child is already in moderate to high distress. However, it was not designed to measure a central construct such as parental insensitivity. It is recognized that a variety of parental factors may contribute to OUCHI behaviours (e.g., time-shortage, insensitivity, depression, anxiety, lack of knowledge, personal beliefs about appropriate soothing) and it is up to mental health experts to determine the reason for the OUCHI behaviours. However, the OUCHI Tool was designed to be a starting point for medical professionals to integrate infant mental health principles into primary care by providing a structure regarding key behaviours that are associated with high infant distress levels, and difficulties with regulation.

Research Questions and Hypotheses

After independently generating the behavioural items with our research team based on several years of experience with caregiver and infant behavioural coding systems, the first goal was to answer the question: To ensure that the context, structure, images, usability and content of the tool is appropriate for clinical practice, what is the perspective of vaccinating clinicians on the validity (content validity, face validity, ecological validity) of the OUCHI Tool behaviours?

This goal was achieved through in-lab item generation, as well as a series of focused discussion groups (Wilkinson, 1998). It was hypothesized that at the end of the three separate group meetings, after presentation of initial items and their modification, clinicians and researchers would come to a consensus on a list of behaviours and a format to present these behaviours that not only reflected their shared experience with suboptimal caregiver soothing behaviours post-vaccination, but a format that can be easily integrated in primary care. Outlines of the three focus group meetings, as well as the corresponding changes made to the tool are displayed in Table 1.

Once we had settled on the final structure of the OUCHI, the second goal of the study was answer the question: What is the reliability and validity of the OUCHI Tool in the vaccination context? Archival video footage of 537 vaccinations in 12-month old infants was coded using the final version of the OUCHI Tool in order to assess preliminary reliability and validity of the tool. This age was chosen as previous work in both developmental (Ainsworth et al., 1978) and pediatric pain literatures (Pillai Riddell et al., 2011) suggest that this is the age at which relationships between suboptimal caregiver behaviours and infant distress regulation can be first reliably discerned.

It was hypothesized that the OUCHI Tool would demonstrate strong interrater reliability, and moderate test-retest reliability between 6-month and 12-month OUCHI Tool scores (n= 136). Moderate test-retest reliability was hypothesized, as we would expect some temporal stability in caregiver behaviours; however, it was recognized that the caregiver and infant relationship is not reliably measured until 12 months of age (Ainsworth, Blehar, Waters, & Wall, 1978). As a clinician support tool, internal consistency of items or factor structure analyses were not deemed appropriate.

Lastly, it was hypothesized that the OUCHI Tool would demonstrate strong convergent and divergent validity with gold standard measures of infant pain related distress, and caregiver emotional availability and soothing behaviours, respectively. As a measure of caregiver behaviours post-vaccination related to higher levels of infant distress, one of the primary requirements of the OUCHI Tool was that it demonstrates convergent validity with infant distress measures. Both facial expression and more complex behavioural measures have been shown to be associated with infant distress during painful procedures. Both types of measures were used to determine convergent validity, and both were coded from videotapes obtained during the vaccination appointment. While not a measure of insensitivity, it was hypothesized that the OUCHI Tool should demonstrate divergent validity with validated measures of sensitivity/emotional availability (clinical judgment measure), and proximal soothing (frequency count of behavioural occurrence). Both measures were coded from video footage from the vaccination. Higher scores reflect greater emotional availability to the child and greater frequency of soothing behaviours that require proximity.

2. Methods

2.1. Participants

The present thesis builds on a larger program of research based on data from a longitudinal study that began in 2007 (The Opportunities to Understand Childhood Hurt Cohort or OUCH Cohort). Initially, 760 infant-caregiver dyads were followed throughout the first year of life at their 2-, 4-, 6-, and/or 12-month vaccinations.

This study utilized data from dyads that participated at the 12-month wave (n = 548). Due to video footage limitations in 11 dyads, a total of 537 dyads were included in the analyses. The average age of participating caregivers in the vaccination videos was 34.09 years (SD = 5.16),

and 86.9% of caregivers were mothers. They self-reported a number of cultural backgrounds (37.6% European, 16.1% Asian, 12.1% North American, 7.6% Jewish, 6.5% Middle Eastern/African, 3.2% Latin/South American, 8.2% Other, and 8.7% Mixed). The caregiver sample was well-educated (32.9% completed graduate school/professional training, 40.9% completed four years of university, 4.7% partially completed university, 15.3% completed trade school/community college, 5.6% completed high school, 0.4% partially completed high school, and 0.2% completed junior high school).

Eleven vaccinating clinicians who were not involved in the original OUCH cohort data collection or analyses (four physicians and seven nurses) provided input on the OUCHI Tool. Clinicians were from the Black Creek Community Health Centre in the Jane-Finch neighbourhood of North-Western Toronto. Recognizing the majority of the data from the OUCH Cohort was from largely mid-to-high socioeconomic neighbourhoods, it was considered important to cross-validate our observations with clinicians from a neighbourhood considered at potentially higher risk of difficulties due to lower socioeconomic status (e.g., higher parental stress).

2.2. Measures

Parent demographic information. During the 12-month vaccination visit, caregivers completed a short demographic questionnaire inquiring about their relationship with the infant, education level, self-reported heritage culture, as well as infant age, sex, and medical conditions since their last vaccination appointment.

OUCHI Tool. The final version of The Opportunities to Understand Childhood Hurt – Inoculation Tool (OUCHI Tool) was developed through this study. After the initial item generation period by the research team, three focused group discussions were conducted with

vaccinating clinicians (see outline of meetings and corresponding changes to the OUCHI Tool in Table 1). The final tool contains eight caregiver behaviours identified by expert researchers and clinicians as increasing infant distress in the three minutes post-vaccination. It is not purported to be a measure of parental insensitivity, but rather a list of behaviours post-injection that are associated with higher infant distress, such that the more behaviours that are seen, the more distress the infant will be in post-needle. The OUCHI Tool was designed as a clinical support tool to help primary care clinicians assess caregiver behaviours that might suggest challenges within how the parent soothes the child during distressing situations. The three-minutes post-vaccination were specifically chosen for OUCHI coding/scoring because the ambiguity of the child's needs through an infant mental health lens is considered low in this time period. This is a particularly critical time when almost all infants need appropriate soothing. The OUCHI Tool is predicated on the developmental principle that infants who are in pain and are in moderate to high distress require contingent and proximal soothing behaviours from a parent or caregiver (Pillai Riddell & Racine, 2009).

Figure 1 provides a picture of the final (i.e., post focus group changes) formatted OUCHI Tool with behavioural descriptions. The OUCHI Tool total score ranges from 0 to 8. The higher the score, the higher the number of suboptimal parent behaviours that were seen in the first three minutes post-needle. The summary score from the final tool is what was used for reliability and validity analyses.

Infant pain-related distress and regulation.

The Modified Behavior Pain Scale (MBPS) (Taddio, Nulman, Koren, Stevens, & Koren, 1995) uses the sum of three behavioural scales: facial expression (0-3), cry (0-4), and body movement (0-3) to depict the degree of infant pain-related distress on a scale of 0-10. Higher

scores indicate greater pain. For study purposes, we looked at MBPS scores from three different time points: for 15 seconds one minute after an initial 15 second epoch (MBPS 1min), 15 seconds two minutes after the initial 15 second epoch (MBPS 2min), and 15 seconds three minutes after the initial 15 second epoch (MBPS 3min). The MBPS has demonstrated strong concurrent and construct validity, as well as item-total and interrater reliability within the immunization context (Ipp, Cohen, Goldbach, & Macarthur, 2004; O'Brien, Taddio, Ipp, Goldbach, & Koren, 2004; Pillai Riddell et al., 2013; Taddio et al., 1995). In the present study, interrater reliability ranged from .93 to .96. Reliability training was conducted and supported by the scale's creator. See Appendix A for the coding system.

The Neonatal Facial Coding System (NFCS) (Grunau & Craig, 1987) is a well-validated measure of facial responses to painful stimuli. It uses brow bulge, eye squeeze, nasolabial furrow, open lips, vertical stretch mouth, horizontal stretch mouth, and taut tongue to create a facial pain score. Each facial action is coded as 0 (present), or 1 (not present) (Grunau, Oberlander, Holsti, & Whitfield, 1998). Pain scores were obtained calculating the proportion of time the facial actions were present for every second in a 10 second epoch one minute after last needle (NFCS 1 min), 10 seconds two minutes after last needle (NFCS 2 min), and 10 seconds three minutes after last needle (NFCS 3 min). Scores range from 0 to 1, with higher scores indicating greater facial pain expression. Reliability training was conducted and supported by staff in the original lab that created the measure. In the present study, interrater reliability ranged from .85 to .97 for each facial action. Strong relationships were seen between the MBPS and NFCS at all three time points (see Table 2). See Appendix B for the NFCS coding system.

Caregiver emotional availability and proximal soothing.

Emotional availability, measured using the Emotional Availability Scales – 4th Edition (EAS) (Biringen, 2008), is a clinical measure of the quality of caregiving behaviours. It examines caregiver behaviours on four different subscales: sensitivity, structuring, non-intrusiveness, and non-hostility. While it is a caregiver measure, the subscales take into account the interaction between caregiver and infant. Caregivers receive a total score by combining the four subscales (28-116) based on caregiver behaviour and how the infant responds to those behaviours. The EAS has been validated in numerous distressing non-pain contexts (Biringen, 2000) and subsequently in pain contexts through our work with the OUCH Cohort. All EAS coders were trained by the scale's creator to ensure validity in a pain context. In the present study, interrater reliability for the total EAS scores ranged from .88 to .93. See Appendix C for the coding system.

The Measure of Adult and Infant Soothing and Distress (Cohen, Bernard, McClelland, & MacLaren, 2005) is a reliable and valid behavioural observation scale developed to evaluate behaviours of children, parents, and nurses during painful medical procedures. For the purposes of the present study, we were interested in examining the relationship with parental proximal soothing behaviours (i.e., rocking and physical comfort). These behaviours, when done sensitively (i.e., following the child's lead), have consistently been shown to reduce infant distress (Lisi et al., 2013). Rocking and physical comfort were coded as present (1) or absent (0) in 5-second epochs for the one-minute period after the last needle (MAISD Rock 1min, MAISD Phys Comf 1min), the two-minute period after the last needle (MAISD Rock 2min, MAISD Phys Comf 2min), and the three-minute period after the last needle (MAISD Rock 3min, MAISD Phys Comf 3min). Index scores were calculated based on the proportion of time each behaviour was

present out of the total number of epochs that were codeable in a time period. Index scores ranged from 0 to 1, with higher scores indicating greater frequency. Seven coders were trained in MAISD for this study, and the lab originally worked with the tool's creator to establish reliability (ranging from .91 to .95 for rocking, and .75 to .88 for physical comfort). See Appendix D for the coding system.

2.3. Procedure

Ethics Approval. Ethics approval was obtained from both York University and the Hospital for Sick Children for the original OUCH Cohort study. These methods are described extensively elsewhere (Atkinson, et al., 2015; Campbell et al., 2013; Din et al., 2009; Din Osmun et al., 2014; Hillgrove-Stuart et al., 2013; Hillgrove-Stuart et al., 2015; Horton et al., 2010; Horton & Pillai Riddell, 2010; Horton et al., 2015; Horton et al., 2016; Lisi, et al., 2013; Pillai Riddell et al., 2011; Pillai Riddell et al., 2014; Racine et al., 2012; Vinall et al., 2011). Subsequent ethics approval for the clinician discussion groups for the present study was obtained from York University.

Present study. An initial set of behavioural items was generated from coding vaccination footage across the first year of life. Item generation discussions by the senior author were held with six reliable coders with training in the use of "gold standard" measures of caregiver emotional availability, caregiver soothing, and infant pain-related distress reactivity and regulation. Coding of the final OUCHI Tool on the archival video footage for the current study was conducted by one graduate student (HG; not involved in the initial item generation) and two undergraduates with two or more years of experience in acute pediatric pain coding.

Establishing content, face, and ecological validity with practicing clinicians. To establish content, face, and ecological validity, HG and RPR led focused discussion groups with practicing

clinicians. These groups are commonly used to generate hypotheses during measure development (Wilkinson, 1998). They work well when they are a manageable size (no more than 12 individuals), and when members are encouraged to elaborate on and defend their opinions when challenged (Wilkinson, 1998). In line with this methodology, group sizes were kept manageable (less than 12), and open debate and discussion throughout our different group meetings were encouraged. The three group meetings were held between July and September 2014 and each was between 60 and 75 minutes in duration.

In the first focus group meeting (See Table 1), a presentation was given on the importance of parental sensitivity and soothing, as well as the importance of having a feasible checklist of parent behaviours post-vaccination that increased pain-related distress. Clinicians were asked about this premise and the need for a tool to support their practice during vaccination. In this initial meeting, the original OUCHI Tool, which included ten behaviours (face out, flake out, frustration, fearful/distressed, flat face, fathom wrong, face cover, fashion first, fork over, flit away), was brought forward by the research team. All ten behaviours were seen as related to strongly distressing caregiver behaviours or simply being strongly distressing caregiver behaviours. At each meeting, clinicians were asked to watch vaccination videos with these original ten behaviours in mind, and to discuss their opinions on the presented behaviours as well as the way they were defined based on their own clinical experience. Also, they were asked if there were other 'easily recognizable' caregiver behaviours that generally increased infant distress in their vaccination setting that we had not seen in our original cohort of infants.

During the second meeting, an updated list of behaviours with improved explanations was presented (see Table 1). Clinicians were encouraged to suggest further improvements to the structure and images of the tool to make it more user-friendly. Subsequent to these discussions, a

tip sheet was created, and the coding sheet was reorganized to improve usability. In the third meeting, a finalized version of the OUCHI Tool was presented based on feedback. Clinicians and researchers came to consensus about the final items for inclusion. The participants agreed that the final content of the OUCHI did reflect suboptimal soothing behaviours (face and content validity) that are commonly seen during routine vaccination across their practices (ecological validity) and believed that the final OUCHI Tool was usable, with a clear structure and images. As saturation (i.e., no new ideas were being generated) had been achieved, no further meetings occurred after the third meeting (See Table 1). The final OUCHI Tool is provided in Figure 1.

Establishing reliability, convergent, and divergent validity. For reliability purposes, videos from 30% of the entire 12-month sample were coded by three separate raters using the OUCHI Tool (n = 161). As well, using a stratified random sampling method, we coded 6-month vaccination footage from 25% of our 12-month sample (n = 136) to assess the OUCHI's test-retest reliability. We used stratified random sampling to ensure that we coded 6-month data from an equal number of dyads with high and low OUCHI Tool scores at 12 months. Six-month coders were blind to the 12-month OUCHI Tool scores. Measures of infant distress reactivity and regulation (NFCS, Grunau & Craig, 1987; MBPS, Taddio et al., 1995), caregiver emotional availability (EAS – 4^{th} Edition, Biringen, 2008) and proximal soothing (MAISD, Cohen et al., 2005) which had already been coded from the footage in previous work on the cohort were used for the present purposes of establishing convergent and divergent validity of the OUCHI Tool.

2.4. Analysis Plan

To answer our two primary research questions, the outcomes of our focused discussions with clinical experts regarding the content, structure, images and usability of the measure were qualitatively tracked in a chart that assessed the items, structure, and key changes proposed to the

tool. To further examine the content of the measure, quantitative validity and reliability statistics were run.

Validity. Establishing content, face, and ecological validity was described above in the study's procedure (i.e., creating initial items through our extensive coding with the OUCH cohort and our discussion with 11 practicing clinicians with experience in post-vaccination infant distress regulation [who were not involved in the original cohort study]). To determine convergent validity, Pearson correlation coefficients were used to assess the relationship between the OUCHI Tool total scores and the MBPS and NFCS scores at one-, two-, and three minutes post-vaccination. To determine divergent validity, Pearson correlation coefficients were conducted with EAS scores, and MAISD (rocking and physical comfort) scores one-, two-, and three minutes post-vaccination.

Reliability. Intraclass correlations were used to determine interrater agreement for total OUCHI Tool scores, and a Pearson correlation coefficient was used to determine test-retest reliability between 6-month and 12-month OUCHI Tool scores.

3. Results

3.1. OUCHI Tool Descriptives

In terms of content, structure, images, usability, the progression of the measure is tracked in Table 1 and final behaviours are listed and briefly described in Figure 1. The mean caregiver OUCHI Tool score was 1.47 (SD = 1.10). The observed scores had a range of 5 (min = 0, max = 5; Total possible was 8). Of the entire sample, 22.5% had a score of 0, 30.7% had a score of 1, 26.3% had a score of 2, and 18.2% had a score of 3, 2% had a score of 4, and 0.2% had a score of 5. Of the eight behaviours on the OUCHI Tool, the most commonly coded behaviour was

Fathom Wrong (53.8%), and the least common behaviour was Flat Face (occurring in only 1% of the sample).

3.2. Reliability

The OUCHI Tool demonstrated excellent interrater reliability between the three independent coders (Averaged ICC = .92, p < .001). Lastly, using Pearson's correlation, the OUCHI Tool demonstrated moderate test-retest reliability between 6-month and 12-month OUCHI Tool scores (r = .36, p = < .001), with a medium effect size (d = .77).

3.3. Validity

To determine convergent validity, the total score of the OUCHI Tool was correlated with the MBPS and NFCS at one-, two-, and three minutes post-vaccination. Moderate to strong positive relationships were seen between the OUCHI Tool and the MBPS one minute post-vaccination [r = .42, p < .001; large effect size (d = .93)], two minutes post-vaccination [r = .46, p < .001; large effect size (d = 1.04)] and three minutes post-vaccination (r = .33, p < .001; medium effect size (d = .70)]. Moderate positive relationships were seen between the OUCHI Tool and NFCS one minute post-vaccination [r = .36, p < .001; medium effect size (d = .77)], and two minutes post-vaccination [r = .30, p < .001; medium effect size (d = .63)].

Divergent validity was determined using Pearson's correlations between the OUCHI Tool score and EAS and MAISD (rocking and physical comfort subscales). A strong negative relationship was seen between the OUCHI Tool and EAS [r = -.40, p < .001; large effect size (d = .87)]. Significant relationships were not seen between the OUCHI Tool and the MAISD caregiver proximal soothing and rocking subscales at any time point. Table 2 displays all intercorrelations between measures.

4. Discussion

Infants do not possess the ability to regulate their own distress; they rely heavily on their caregiver's contingent and sensitive soothing to do so. By pairing infant distress with contingent caregiver soothing, infants learn regulatory strategies from their caregiver, which sets up an optimal trajectory for their own distress regulation throughout development. In absence of this, infants may develop maladaptive self-regulatory behaviours that can lead to difficulties throughout development and beyond. This is concerning, as some researchers estimate that approximately 75% of mental health diagnoses have been connected to difficulties in emotion regulation (Werner & Gross, 2010), and there exist well-established links between child distress and health (e.g., Winning, Glymour, McCormick, Gilsanz, & Kubzansky, 2015).

An ideal context to support the caregiver-infant relationship and the way caregivers soothe and model distress regulation is during vaccination appointments. It is an ecologically valid distress paradigm, and provides primary care clinicians an opportunity to observe caregiver soothing behaviours during pre-existing appointments at regular intervals across early childhood. The overall objective of this study was to create a support tool for clinicians to help them assess infant-parent dyads in need of support during vaccinations, based on the presence of particular suboptimal caregiver soothing behaviours. There are currently no clinical support tools available for use in primary pediatric care that focus on suboptimal caregiver soothing behaviours during infant distress, and current socioemotional measures have several limitations regarding validity and feasibility (American Academy of Pediatrics, 2012; Briggs et al., 2012; Weitzman & Leventhal, 2006).

To address the need for this type of tool in primary care, the OUCHI Tool was created during the present thesis to provide a count of easily identifiable, suboptimal caregiver soothing

behaviours that are associated with high levels of infant distress post-vaccination. The OUCHI Tool includes eight key post-vaccination caregiver behaviours that are associated with high infant distress, which are tallied during the minutes immediately following the injection. The results of the present study indicated that the more of these OUCHI Tool behaviours that are seen, the greater the infant distress and thus the more support the parent may require in knowing how to adequately support their child's distress regulation.

4.1. Interpretation of Findings

The two goals of this thesis were to describe the OUCHI's development and establish its basic psychometric properties. Since the OUCHI Tool was developed to be a clinical support tool for use in primary pediatric care, we followed guidelines for medical care tool development. Guidelines by Hales and colleagues (2013), suggest that five critical components of a tool in any medical setting are context, content, structure, images, and usability.

Our first goal was to establish the content, face, and ecological validity of the measure with practicing clinicians. This was accomplished through focused group meetings with physicians and nurses. After three meetings, psychology researchers, primary care nurses, and primary care physicians agreed on a checklist of behaviours that reflected shared perspectives about parent behaviours in the infant vaccination context to comprise the final OUCHI Tool. The generalizability of the OUCHI items was bolstered because this specific group of clinicians was not involved in the study on which the initial OUCHI items were generated.

To establish preliminary reliability, convergent validity, and divergent validity of the measure, a team coded a substantial sample of archival video footage of 12-month infant vaccinations using the final version of the measure. The OUCHI Tool demonstrated strong interrater reliability among trained research assistants, and moderate test-retest reliability. There

was high agreement on the total number of OUCHI Tool behaviours present between coders. Examining reliability over time, the moderate relationship between OUCHI Tool scores at 6- and 12 months is important for two reasons. First, this was found despite knowledge that the caregiver-infant relationship is not reliably measured until 12 months. This suggests that there is stability in less optimal parent soothing behaviours over the first year of life. Further, in terms of generalizability, 12-month vaccinations tend to cause more pain in the majority of infants than the 6-month vaccinations. Thus, the same infant would react with differing levels of intensity at these two time points, suggesting the OUCHI may be valid across different levels of distress.

The OUCHI Tool also demonstrated moderate to strong convergent and divergent validity, confirming the primary purpose of this measure. Convergent validity was demonstrated by moderate to strong relationships between the OUCHI Tool and two separate measures of infant pain-related distress post-vaccination. Converting to effect sizes, the magnitude of the relationships ranged from *d*'s of .63 to 1.04. The higher the score on the OUCHI Tool (i.e., more suboptimal behaviours present), the greater the infant's pain-related distress. These relationships were strongest at one-minute and two-minutes post vaccination, and while still significant, were lower at three-minutes. This confirms the importance of coding OUCHI Tool caregiver behaviours when the infant is in moderate to high distress. Many of the OUCHI Tool behaviours would not have the same meaning when the infant is in no or low distress. For example, if a caregiver dresses a non-distressed baby, this is not viewed in the same way as a caregiver who is trying to dress a highly distressed infant.

Divergent validity was demonstrated by showing a strong negative relationship between the OUCHI Tool and caregiver emotional availability, suggesting that the more OUCHI Tool behaviours present, the less emotionally available and sensitive the caregiver is in the minutes following the needle puncture. No relationships were seen between the OUCHI Tool and caregiver proximal comforting or rocking. This may be because the measure used simply counting the occurrence of proximal soothing and rocking. High quantities of either proximal soothing or rocking can be either very effective in reducing distress or very distressing dependent on the infant's needs. Thus, because the OUCHI tool was created based on behaviours that have a generally linear positive relationship with infant distress, correlations with MAISD behaviours (rocking and proximal soothing) may not have been seen.

The structure and images of the tool were determined through discussions with primary care clinicians on how the tool could be clearer in practice. With respect to its usability, once the clinician is trained to be reliable, the OUCHI Tool should take no more than 30 seconds to complete (after observing approximately three minutes immediately following the needles), a timeline that should fit well with the patient-allotted time in primary care.

4.2. Clinical Implications

These findings suggest that the OUCHI Tool is a promising clinician support tool that contains content appropriate to the vaccination context and has been deemed to have a structure, images, and usability that fits into primary pediatric care. It was developed by researchers in conjunction with health professionals, and reflects a shared experience between researchers and clinicians of suboptimal caregiver behaviours that increase infant distress post-vaccination. The current study on the preliminary psychometrics of the OUCHI Tool is a promising starting point for incorporating supportive mother-infant mental health into primary care. As a support tool, the OUCHI Tool shows potential to assist clinicians in observing whether certain infant-caregiver dyads are in need of support. It has been established that the higher the OUCHI scores, the lower the parent sensitivity and the higher the infant distress. Therefore, over vaccination

appointments, the more OUCHI behaviours that are seen, the higher the likelihood a clinician should provide the parent with greater support on how to sensitively soothe their distressed infant (e.g., parent coaching of optimal soothing strategies, orienting the parent to online resources, etc.) or even suggest follow up recommendations for more intensive mental health services.

4.3. Research Implications

The value of the OUCHI Tool is also seen in its potential as a research tool. It has become increasingly clear that infant pain-related distress cannot be understood outside of the caregiver context (Pillai Riddell & Racine, 2009). However, some disciplines that study pediatric pain may not have resources and expertise to adequately incorporate the caregiver context. Behavioural scientists have been studying the way the caregiver can influence pain for decades (e.g., Campos, 1994; Cohen et al., 2005; Gunnar, Connors, Isensee, & Wall, 1988; Jahromi, Putnam, & Stifter, 2004; Lewis & Ramsay, 1999). However, many of the measures in use are time-consuming to learn, costly to maintain reliability and often require a specific level of health professional graduate training. More work should be conducted to better understand the possibilities of the OUCHI Tool as a broad research tool of the caregiver context for pain-related distress.

4.4. Limitations

There are two situations where the OUCHI will have trouble capturing the nuanced nature of the impact of caregiver behaviours on infant pain-related distress. Past research by our lab (Horton et al., 2015; Horton et al., 2016) has shown that there are infants who do not respond as vigorously to pain-related distress as other infants because of insecure attachments (i.e., they have learned that distress signalling to their caregiver will not result in a reduction of their own distress). Mounting a pain-related distress display is adaptive, and we would expect an infant to

demonstrate some level of distress post-needle. The cases where moderate-to-high distress is not displayed (or displayed for a much shorter time) due to significantly maladaptive infant-caregiver behavioural patterns suggest a challenge for the OUCHI Tool because OUCHI behaviours are intended to only be coded when the infant is in moderate to high distress. Future work should be done with the OUCHI Tool on large subgroups of insecurely attached infants in order to establish norms within this population.

Finally, it is important to comment that the OUCHI Tool does not have particular diagnostic cutoffs regarding total scores. This is based partly on our observation that while generally speaking, higher OUCHI Tool scores suggest a dyad in need of more support, on occasion the presence of a single behaviour may be severe enough to reflect more intervention is necessary. For example, a parent who is very forceful with their child on a number of occasions throughout the vaccination would only receive a score of one on the OUCHI. Yet, this is a behaviour that should be a red flag for a medical professional. The OUCHI Tool is meant to be a support tool for primary care clinicians, providing a feasible structure to orient them to concerning caregiver behaviours to support both maternal and child mental health.

4.5. Future Directions

Upon establishing the initial value of the OUCHI Tool, the next phase of development will be to conduct a demonstration project that assesses its reliability and validity when used invivo during infant vaccination appointments by physicians and nurse practitioners. This addresses the recommendation that medical care tools should be further piloted by individuals in actual clinical practice (Hales et al., 2008).

Our research team also hopes to look at the relationships between OUCHI Tool scores and subsequent scores on parent mental health (e.g., depression, anxiety, parenting stress) and

infant developmental measures (e.g., socioemotional, cognitive, motor and language development) in order to assess the checklist's concurrent and predictive validity of constructs that are related to distress regulation.

4.6. Conclusion

Infants heavily rely on their caregivers' contingent and sensitive soothing to help them learn how regulate from distress (Calkins & Fox, 1992; Kopp, 1982; Sroufe, 2000). Regulatory strategies that infants learn from their parents set up the trajectory for distress regulation throughout the lifespan. Distress regulation is a key developmental skill associated with physical and mental health. The OUCHI Tool was designed as a tool to support primary care medical professionals become aware of key caregivers behaviours occurring post-vaccination that increases infant distress (3-minutes) and therefore pay attention to parents who may require more support in scaffolding their infant's distress regulation. Using the concepts of context, content, structure, images, and usability, the OUCHI Tool has demonstrated that it is a promising new clinical support tool that could benefit primary pediatric care practitioners.

References

- Ainsworth, M., Blehar, M., Waters E., & Wall, S. (1978). *Patterns of Attachment*. Hillsdale, NJ: Erlbaum.
- American Academy of Pediatrics. Mental Health Screening and Assessment Tools for Primary Care. Downloaded on December 8, 2015 from: https://www.aap.org/en-us/advocacy-and-policy/aap-healthinitiatives/Mental-Health/Documents/MH_ScreeningChart.pdf.
- Atkinson, N., Gennis, H., Racine, N., Pillai Riddell, R., Garfield, H., & Greenberg, S. (2015). Caregiver emotional availability, caregiver soothing behaviors, and infant pain during immunization. *Journal of Pediatric Psychology*, 40(10), 1105-1114.
- Biringen, Z. (2000). Emotional availability: Conceptualization and research findings. The American Journal of Orthopsychiatry, 70(1), 104–114.
- Biringen, Z. (2008). The EA Professionals and Parent Curricula. Available at http://www.emotionalavailability.com. And The Emotional Availability Scales, 4th ed.
- Bowlby, J. (1969/1982). Attachment and loss: Vol. 1. Attachment. New York, NY: Basic Books.
- Briggs, R. D., Stettler, E. M., Silver, E. J., Schrag, R. D., Nayak, M., Chinitz, S., & Racine, A. D. (2012). Social-emotional screening for infants and toddlers in primary care. Pediatrics, 129(2), e377-e384.
- Calkins, S.D., & Fox, N.A. (1992). The relations among infant temperaments, security of attachment, and behavioral inhibition at twenty-four months. *Child Development*, *63*(6), 1456-1472.
- Campbell, L., Pillai Riddell, R., Garfield, H., & Greenberg, S. (2013). A cross-sectional examination of the relationship between caregiver proximal soothing and infant pain over the first year of life. *Pain*, *154*(6), 813-823.

- Campos, R. G. (1994). Rocking and pacifiers: Two comforting interventions for heelstick pain.

 *Research in Nursing and Health, 17, 321–331.
- Canadian Pediatric Society. (2013, August). You and your child's doctor. Retrieved from http://www.caringforkids.cps.ca/handouts/your_childs_doctor.
- Cassidy, J. (1994). Emotion regulation: Influences of attachment relationships: In N. Fox (Ed.),

 The development of emotion regulation. *Monographs of the Society for Research in Child Development*, 59(2-3, Serial No. 240), 228-249.
- Cohen, L. L., Bernard, R. S., McClelland, C. B., & MacLaren, J. E. (2005). Assessing medical room behavior during infants' painful procedures: The measure of adult and infant soothing and distress (MAISD). *Children's Health Care*, *34*(2), 81-94.
- Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood: Revised edition (DC: 0-3R; 2005). Washington, DC: Zero to Three Press.
- Din, L., Pillai Riddell, R., & Gordner, S. (2009). Brief report: Maternal emotional availability and infant pain-related distress. *Journal of Pediatric Psychology*, *34*, 722-726.
- Din Osmun, L., Pillai Riddell, R., & Flora, D. B. (2014). Infant pain-related negative affect at 12 months of age: Early infant and caregiver predictors. *Journal of Pediatric Psychology*, 39(1), 23-34.
- Grunau, R. V. E., & Craig, K. D. (1987). Pain expression in neonates: Facial action and cry. *Pain*, 28, 395-410.
- Grunau, R. E., Oberlander, T., Holsti, L., & Whitfield, M. F. (1998). Bedside application of the neonatal facial coding system in pain assessment of premature infants. *Pain*, *76*(3), 277-286.

- Gunnar, M. R., Connors, J., Isensee, J., & Wall, L. (1988). Adrenocortical activity and behavioural distress in human newborns. *Developmental Psychobiology*, *21*(4), 297-310.
- Hales, B., Terblanche, M., Fowler, R., & Sibbald, W. (2008). Development of medical checklists for improved quality of patient care. *International Journal for Quality in Health Care*, 20(1), 22-30.
- Hillgrove-Stuart, J., Pillai Riddell, R., Flora, D. B., Greenberg, S., & Garfield, H. (2015).
 Caregiver soothing behaviors after immunization and subsequent infant attachment style:
 A longitudinal analysis. *Journal of Developmental and Behavioral Pediatrics*, 36(9), 681-689.
- Hillgrove-Stuart, J., Pillai Riddell, R., Horton, R., & Greenberg, S. (2013). Toy-mediated distraction: Clarifying the role of distraction agent and preneedle distress in toddlers. *Pain Research and Management, 18*(4), 197-202.
- Horton, R. E., Din Osmun, L., Pillai Riddell, R. R., Stevens, B., & Greenberg, S. (2010).

 Maternal relationship style, paediatric health care use and infant health. *Pediatrics & Child Health*, *15*(7), 432-436.
- Horton, R. E., & Pillai Riddell, R. R. (2010). Mothers' facial expressions of pain and fear and infants' pain response during immunization. *Infant Mental Health Journal*, *31*(4), 397-411.
- Horton, R. E., Pillai Riddell, R., Flora, D., Moran, G., & Pederson, D. (2015). Distress regulation in infancy: Attachment and temperament in the context of acute pain. *Journal of Developmental & Behavioral Pediatrics*, 36(1), 35-44.

- Horton, R., Pillai Riddell, R., Moran, G., & Lisi, D. (2016). Do infant behaviors following immunization predict attachment? An exploratory study. *Attachment & Human Development*, 18(1),
- Ipp, M., Cohen, E., Goldbach, M., & Macarthur, C. (2004). Effect of choice of measles-mumpsrubella vaccine on immediate pain in infants. *Archives of Pediatrics and Adolescent Medicine*, 158, 323-326.
- Jahromi, L. B., Putnam, S. P., Stifter, C. A., (2004). Maternal regulation of infant reactivity from 2 to 6 months. *Developmental Psychology*, 40(4), 477-487.
- Kerker, B. D., Storfer-Isser, A., Stein, R. E. K., Garner, A., Szilagvi, M., O'Connor, K. G., ... McCue Horwitz, S. (2016) Identifying maternal depression in pediatric primary care.

 *Journal of Developmental & Behavioral Pediatrics, 37(2), 113-120.
- Kopp, C. (1982). Antecedents of self-regulation: A developmental perspective. *Developmental Psychology*, *18*, 199-214.
- Lewis, M., & Ramsay, D. S. (1999). Effect of maternal soothing on infant stress response. *Child Development*, 70(1), 11-20.
- Lisi, D., Campbell, L., Pillai Riddell, R., Garfield, H., & Greenberg, S. (2013). *Pain*, *154*(8), 1245-1253.
- Moe, V., Siqveland, T., & Fredriksen, E. (2016). The Relational Health Screen a new screening method for assessing parent-child relationships. Master class lecture conducted at the 15th World Congress of the World Association of Infant Mental Health, Prague, CZ.
- O'Brien, L., Taddio, A., Ipp, M., Goldbach, M., & Koren, G. (2005). Topical 4% amethocaine gel reduces the pain of subcutaneous measles-mumps-rubella vaccination. *Pediatrics*, 114, e720-724.

- Phillips, S., & Best, M. L. (2007). Early recognition of infant mental health concerns. *BC Medical Journal*, 49(3), 121-125. Retrieved from: http://www.bcmj.org/article/early-recognition-infant-mental-health-concerns.
- Pillai Riddell, R., Campbell, L., Flora, D. B., Racine, N., Din Osmun, L., Garfield, H., & Greenberg, S. (2011). The relationship between caregiver sensitivity and infant pain behaviors across the first year of life. *Pain*, *152*(12), 2819-2826.
- Pillai Riddell, R., Flora, D. B., Stevens, S., Greenberg, S., & Garfield, H. (2014). The role of infant pain behaviour in predicting parent pain ratings. *Pain Research and Management*, 19(5), e124-e132.
- Pillai Riddell, R., Flora, D. B., Stevens, S. A., Stevens, B., Cohen, L. L., Greenberg, S., & Garfield, H. (2013). Variability in infant acute pain responding meaningfully obscured by averaging pain responses. *Pain*, *154*(5), 714-721.
- Pillai Riddell, R., & Racine, N. (2009). Assessing pain in infancy: The caregiver context. *Pain Research Management*, 14, 27-32.
- Racine, N., Pillai Riddell, R., Flora, D., Garfield, H., & Greenberg, S. (2012). A longitudinal examination of verbal reassurance during infant immunization: Occurrence and examination of emotional availability as a potential moderator. *Journal of Pediatric Psychology*, *37*(8), 935-944.
- Schore, A. (2000). Attachment and the regulation of the right brain. Attachment & Human Development, 2, 23-47.
- Sroufe, L. A. (2000). Early relationships and the development of children. *Infant Mental Health Journal*, 21, 67-74.

- Taddio, A., Nulman, I., Koren, B. S., Stevens, B., & Koren, G. (1995). A revised measure of acute pain in infants. *Journal of Pain and Symptom Management*, 10, 456-463.
- Vinall, J., Pillai Riddell, R., Greenberg, S. (2011). The influence of culture on maternal soothing behaviours and infant pain expression in the immunization context. *Pain Research and Management*, 16(4), 234-238.
- Werner, K., & Gross, J. J. (2010). Emotion Regulation and psychopathology: A conceptual framework. In A. M. Kring & D. M. Sloan (Eds.), *Emotion regulation and psychopathology: A transdiagnostic approach to etiology and treatment* (pp. 13-37). New York, NY: Guilford Press.
- Weitzman, C. C., & Leventhal, J. M. (2006). Screening for behavioural health problems in primary care. *Current Opinion in Pediatrics*, *18*(6), 641-648.
- Wilkinson, S. (1998). Focus group methodology: A review. *International Journal of Social Research Methodology, Theory, and Practice*, 1, 181-204.
- Winning, A., Glymour, M. M., McCormick, M. C., Gilsanz, P., & Kubzansky, L. D. (2015).

 Psychological distress across the life course and cardiometobolic risk: Findings from the 1958 British Birth Cohort Study. *Journal of the American College of Cardiology*, 66(14), 1577-1586.

Table 1. OUCHI Tool Development through Focus Groups

	Items	Structure of Checklist	Key changes that were discussed
Focus Group 1 (Original Meeting)	Caregiver and Infant Behaviours:	One page behavioural checklist, with a separate page of brief behaviour	One behaviour added – <i>Flee the Scene</i> : Parent not present at any time during the needle
O)	 Face Out Flake Out Frustration 	descriptions	Group caregiver behaviours into meaningful subcategories so easier to understand
	4. Fear/Distress5. Flat Face		Item descriptions required greater detail
	6. Fathom Wrong7. Face Cover8. Fashion First		Focus clarified that infant had to be in high distress post-needle; 3 minutes post-needle
	9. Flit Away 10. Fork Over		Remove infant behaviours (not valid), and focus solely on the caregiver behaviours
Focus Group 2	Caregiver Behaviours: 1. Frustration 2. Fear/Distress	Caregiver behaviours grouped into 3 subcategories with more-detailed definitions:	Have the separate sheet with extended (but not too long) item descriptions to keep handy prior to coding
	3. Flat Face4. Fathom Wrong5. Face Cover	Face-related (Frustrated, Fearful)	One behaviour added – <i>Forceful</i> - when you note a parent is 'too' rough with their child post-needle.
	6. Fashion First7. Flit Away8. Fork Over9. Flee the Scene	Face, Flat Face) 2. Saying/Doing to the infant (Fathom Wrong, Face Cover, Fashion First) 3. Distance (Flit Away, Fork Over, Flee the Scene)	Condensed all <i>Distance</i> behaviours into one OUCHI Tool behaviour because they don't occur: <i>Flit Away</i>

		Small Pictures added for each subcategory
Focus Group 3 (Final	Caregiver Behaviours:	"Cheat Sheet" with extended definitions provided
Consensus)	 Frustration Fear/Distress Flat Face Fathom Wrong Face Cover Fashion First Forceful Flit Away 	

Table 2. Correlations of OUCHI Tool with Measures of Caregiver Behaviours and Infant Distress

	OUCHI	MBPS 1min	MBPS 2min	MBPS 3min	NFCS 1min	NFCS 2min	NFCS 3min	EAS	MAISD Rock 1min	MAISD Rock 2min	MAISD Rock 3min	MAISD Phys Comf 1min	MAISD Phys Comf 2min	MAISD Phys Comf 3min
OUCHI	-													
MBPS 1min	.42***	-												
MBPS 2min	.46***	.52**	-											
MBPS 3min	.33***	.38**	.51***	-										
NFCS 1min	.36***	.51***	.38***	.25***	-									
NFCS 2min	.30***	.28***	.41***	.26***	.34***	-								
NFCS 3min	.20***	.25***	.36***	.51***	.28***	.23***	-							
EAS	40***	21***	23***	22***	20***	18***	15**	-						
MAISD Rock 1min	.02	.17***	.18***	.14**	.09*	.11*	.08	.09*	-					
MAISD Rock 2min	05	.19***	.14**	.18***	.10*	.09*	.13**	.01	.55***	-				

MAISD Rock 3min	05	.14**	.09	.14**	.11*	.09*	.05	02	.37***	.62***	-			
MAISD Phys Comf 1min	.02	.14**	.04	.01	.03	.07	.02	.14**	.35***	.24***	.09	-		
MAISD Phys Comf 2min	.04	.18***	.13**	.13**	.14**	.14**	.09	.05	.26***	.40***	.27***	.43***	-	
MAISD Phys Comf 3min	01	.09*	.07	.07	.10*	.11*	.09	.06	.17***	.27***	.35***	.29***	.27***	-

Note. The correlations of interest in this table are those assessing the relationships between the OUCHI Tool and measures of caregiver soothing behaviours (MAISD), emotional availability (EAS), and infant pain-related distress (MBPS, NFCS). Further, correlations below r = .30 are considered weak, regardless of statistical significance due to the large sample size in this study.

^{***} p < .001 ** p < .01 * p < .05

Figure 1. Final Description of OUCHI Tool Caregiver Behaviours

OUCHI POST-IMMUNIZATION

□ NP	□ MD	□ RN	TIME STARTED FORM:
□ IS T	HE INFA	ANT IN LOW DISTRESS QUICKLY AFTER	R NEEDLE? (i.e., WITHIN 30 SECONDS OF LAST NEEDLE)
POST-	NEEDLE	PARENT BEHAVIOURS	

*HPs: If you are unsure if you saw the behaviour or not, just check it off.

** DO NOT DOUBLE CODE BEHAVIOURS! (E.G., FASHION FIRST AND FLIT AWAY AT SAME EXACT MOMENT)

I. SAYING/DOING TO INFANT



□ **FATHOM WRONG** – When baby in high distress: Parent says something to indicate she/he does not get that baby is in pain. Saying "It's ok", "You're ok/fine" *repetitively (do not code if only happens a few times)*. Parent might also make a statement such as, "That wasn't bad at all", or "Did that hurt?", or if parent laughing at baby. □ **FACE COVER** – When baby in high distress: Covers baby's face with blanket, hand, breastfeeding, pacifier, etc.

□ **FASHION FIRST** – When baby in high distress: Dresses baby when baby is in high distress.

□ **FORCEFUL** – *Anytime in 3 minutes*: Parent is *rough* with child (e.g., roughly placing child on table, lifting child by arms, forcing child down on table).

II. FACE RELATED



□ FRUSTRATED – When baby is in high distress: Sighing; eye-rolling; "Just calm down so we can go"; "Why are you getting so upset?" Parent seems mildly angry, annoyed by infant (could be severe anger but this would be extremely rare)

□ FEARFUL FACE – When baby is in high distress: Shows fear/distress, Parent has scared face

□ FLAT FACE – When baby is in high distress: Noticeable lack of emotional expressiveness to infant's distress. Parent's face has no or muted expression for most of the three minutes post-needle. (i.e., zoned out, robotic)

III. PARENT DISTANCING HER/HI MSELF FROM CHILD IN HIGH DISTRESS POST-NEEDLE



□ FLIT AWAY – When baby is in high distress there is a lack of physical closeness between parent and child:

Examples could be puts baby down after needle OR despite baby in arms or on lap, lots of space between parent and baby OR parent hands baby over to someone else OR parent chooses not to be the room for entire immunization.

*WERE THERE ANY OTHER BEHAVIOURS YOU SAW THAT MADE YOU THINK THIS PARENT-INFANT DYAD COULD USE SUPPORT?

APPENDIX A

Infant Position during I	mmunization	Modified Behavioral Pain Scale (Longitudinal Study)						
1 = Infant lying on doctor's ta	able	Coder Name:	Codi	Coding Time:				
2 = Infant Held in mother's a		Date:	Particij	pant ID:				
3 = Infant Held in Mother's a	rms - mother sitting Cl	ip Start:	Clip Fi	nish:				
4 = Infant standing in betwee	n mother's legs - mother s	sitting						
5 = other: Specify				T	T			
	BASLINE	POST-NEEDLE	RECOVERY 1	RECOVERY 2	RECOVERY 3			
Needle #1 Time:	(15 sec. before	(15 sec. after the	(75 sec. after last	(135 sec. after last	(195 sec. after last			
	Needle #1)	last needle)	needle for 15 sec.	needle for 15 sec.	needle for 15 sec.			
Needle #2 Time:	START:	START:	period)	period)	period)			
	FINISH:	FINISH:	START:	START:	START:			
			FINISH:	FINISH:	FINISH:			
FACIAL								
EXPRESSION								
0- definite positive expression								
(smiling)								
1- neutral expression								
2- slightly negative expression								
(grimace; BB; NLF)								
3- Definite neg. exp. (BB,								
NLF, EC, open lips, maybe RF)								
CRY								
0- laughing or giggling								
1- not crying								
2- moaning, quiet vocalizing,								
gentle or whimpering cry								
3-full lunged cry or sobbing								
4-full lunged cry, more than								
baseline cry (only if infant crying during baseline)								
crying during buseline)				1				

MOVEMENTS			
0- usual movements/activity			
or resting /relaxed			
2 – partial movement or			
attempt to avoid pain by			
withdrawing the limb from			
puncture (squirming, arching,			
limb tensing/clenching)			
3- Agitation with complex			
movements involving the head,			
torso OR the other limbs OR			
rigidity (generalized limb			
and/or body movements, or			
rigidity)			

APPENDIX B

Modified Neonatal Facial Coding System

Facial Action	Description
Brow Bulge (BB)	Bulging, creasing and vertical furrows above and between brows occurring as a result of the lowering and drawing together of the eyebrows.
Eye Squeeze (ES)	Identified by the squeezing or bulging of the eyelids. Bulging of the fatty pads about the infant's eyes is pronounced.
Nasolabial Furrow (NLF)	Primarily manifested by the pulling upwards and furrow deepening of the naso-labial furrow (a line or wrinkle that begins adjacent to the nostril wings and runs down and outward beyond the lip corners).
Open Lips (OL)	Any separation of the lips.
Vertical Stretch Mouth (VSM)	Characterized by a tautness at the lip corners (vertical) coupled with a pronounced downward pull of the jaw. Often stretch mouth is seen when an already wide open mouth is opened a fraction further by an extra pull at the jaw.
Horizontal Stretch Mouth (HSM)	Appears as a distinct horizontal pull at the corners of the mouth.
Lip Purse (LP) Taut Tongue (TT)	The lips appear as if an 'oo' sound is being made. Characterized by a raised, cupped tongue with sharp tensed edges. The first occurrence of taut tongue is usually easy to see, often occurring with a wide open mouth. After this first occurrence, the mouth may close slightly. Taut tongue is still scoreable on the basis of the still-visible tongue edges.
Chin Quiver (CQ)	An obvious high-frequency, up-down motion of the lower jaw.
Tongue Protrusion (TP)	Tongue visible between the lips extending beyond the mouth.

Possible range of scores for individual facial actions is 0 to 10 for each 10 second epoch. Possible range of scores for total NFCS is 0 to 100 for each 10 second epoch.

APPENDIX C

Modified Emotional Availability Scales (EAS) – 4th Edition

Participant ID:
Date:
Rater:
Observation time:
Observation time.
Describe who is in the immunization room:

Clinical Screener Clinical Screener

EA Adult Sensitivity

#	Subscale	Range	Score
1	Affect	1-7	
2	Clarity of perceptions	1-7	
3	Awareness of timing	1-3	
4	Flexibility, variety, and	1-3	
5	Acceptance	1-3	
6	Amount of Interaction	1-3	
7	Conflict Situations	1-3	
-	Total	-	

EA Adult Structuring

#	Subscale	Range	Score
1	Provides appropriate guidance	1-7	
2	Success of attempts	1-7	
3	Amount of Structure	1-3	
4	Limit setting, setting boundaries.	1-3	
5	Remaining firm in the face of	1-3	
6	Verbal vs. nonverbal structuring	1-3	
7	Peer vs. adult role	1-3	
_	Total	-	

EA Adult Nonintrusiveness

#	Subscale	Range	Score
1	Follow child's lead:	1-7	
2	Non-interruptive ports of entry	1-7	

3	Commands, directives:	1-3	
4	Adult talking:	1-3	
5	Didactic teaching:	1-3	
6	Physical vs. verbal interferences	1-3	
7	The adult is made to "feel" or	1-3	
-	Total	-	

EA Adult Nonhostility

#	Subscale	Range	Score
1	Adult lacks negativity in face or	1-7	
2	Lack of mocking, ridiculing, or	1-7	
3	Lack of threats of separation:	1-3	
4	Does not lose cool during low	1-3	
5	Frightening behavior/tendencies:	1-3	
6	Silence	1-3	
7	Themes or play themes hostile	1-3	
-	Total	-	

EA Child Responsiveness

#	Subscale	Range	Score
1	Affect/emotion regulation/	1-7	
2	Responsiveness:	1-7	
3	Age-appropriate autonomy-	1-3	
4	Positive physical positioning	1-3	
5	Lack of role reversal/over-	1-3	
6	Lack of avoidance	1-3	
7	Task oriented/concentrate	1-3	
_	Total	-	

EA Child Involvement

#	Subscale	Range	Score
1	Simple Initiative:	1-7	
2	Elaborative initiative:	1-7	
3	Use of adult:	1-3	
4	Lack of over-involvement	1-3	
5	Eye contact, looking, postural	1-3	
6	Verbal involvement:	1-3	
7	Body positioning	1-3	
-	Total	-	

$\mathbf{E}\mathbf{A}$	Dimensional	sum:

APPENDIX D

Modified MAISD Coding Sheet

Adult Behaviour	Definitions and Examples
Physical Comfort	Any physical (ie. nonverbal) behavior conducted in an attempt to comfort the child. This may
	include rubbing, massaging, or patting (on any body part), kissing the child, or a comforting hug.
	if the adult is simply holding the child so that the procedure may be performed, do not code hug.
	This has to be an obvious blatant squeeze.
	-Physical comfort can also be coded when a child is being held closely in (e.g. hand pulling head
	into mom with mom's cheek or chin resting on baby).
	-it is also coded if the child is picked up right after the needle (unless the doctor tells the parents
	to pick up the baby)
Rocking	If the parent remains in the chair and begins to sway, rock, or bounce the child. When the adult
	stands up and rocks, sways, or bounces, or when the adult moves around the room while holding
	the child.
	-needs to be purposeful- not just walking around the room to get something or adjusting baby's
	position.