

Pain Management for Infants during Vaccination: Evaluation of Online Resources and Pilot
Testing of Parent-Targeted Interventions

Shokoufeh Modanloo, BScN, MScN

A thesis submitted to
Faculty of Health Sciences, School of Nursing in partial fulfillment of the requirements
for the Doctorate in Philosophy degree in Nursing

Faculty of Health Sciences
School of Nursing
University of Ottawa

© Shokoufeh Modanloo, Ottawa, Canada, 2020

Abstract

The overall aim of this thesis was to improve the use of recommended pain management strategies during infant vaccination by investigating the quality and use of evidence-based online parent resources.

Study 1: A two-armed pilot randomized control trial (RCT) was conducted to evaluate the feasibility, acceptability and preliminary efficacy of two interventions, delivered online, aimed at improving the use of recommended pain management strategies during infant vaccination. Parents of infants < six months old were randomized to 1) Be Sweet to Babies videos and tip sheet; and 2) Be Sweet to Babies videos, tip sheet and Motivational Interviewing-informed Affirmative Statements and Questions (AS&Q). Results showed it was feasible to recruit parents via online means (201 eligible respondents recruited in a week, 170, 85% provided written consent, and 89, 59% completed all data collection. From these 89 participants, there was high acceptability of the study, 84 (94%) were satisfied with study processes, and 78 (88%) intended to recommend the strategies to others. For preliminary efficacy, almost all participants used at least one of the pain management strategies in the subsequent vaccination (Intervention 1 (49, 98%); Intervention 2 (38, 95%)). There were no significant differences in the use of pain management strategies between the two study groups.

Study 2: To investigate the quality of online parent resources about vaccination pain management, an environmental scan of Google and Social Media networks (i.e. Facebook, YouTube, and Twitter) was conducted. The quality of resources was evaluated using the Center for Diseases Control and Prevention (CDC) Clear Communication Index. 65 resources (55 written, 10 videos), were included. The mean quality score was $60\% \pm 0.19$. Only 5% of resources scored an acceptable quality of >90%. Only 30 (46%) resources included evidence-

based content on pain management strategies during vaccination, which included breastfeeding (24, 37%), holding (27, 42%), and sweet solutions (22, 34%).

Most publicly accessible online parent-targeted vaccination resources were of poor to moderate quality and did not contain pain management information during vaccination. The study was shown to be feasible and acceptable to those parents who completed the study. The Internet is an efficient way to recruit parents for trial participation and to disseminate knowledge.

Keywords: childhood vaccination, pain management, parents, knowledge translation

Acknowledgments

I cannot express my gratitude enough for what this journey brought me to. This Ph.D. is not only an academic degree to me, but it is also the product of my personal growth, self-reflection, and finding the passion and purpose in my life. I am genuinely blessed to have the opportunity to study, live and work in Canada, where I can happily call it “home” now. Canada, you were good to me and I do my best not to take my privileges for granted and never forget how lucky I am.

When I look back at my journey, it has had a lot of ups and downs. Because of those experiences I am now an advocate for what I have been through; my heart goes out to all people who are dealing with mental health problems in their life. I will do my best to be real, supportive and fight against the existing stigma. Further, I would like to express my respect to all women and children of vulnerable populations, I will never stop fighting for attaining their rights in health equity and social justice.

However, this journey was not a solo mission by any means,

I would like to thank my supervisor Dr. Denise Harrison for the excellent knowledge and expertise in the field of infant pain management. I could not complete this program without her great mentorship, ongoing support, and generous guidance throughout the journey. I truly admire her strong leadership skills that taught me how to be the voice of my research in the academic world. Thank you, Denise, for providing this learning opportunity and being incredibly patient with me. Most importantly, I am also thankful for my research committee members, Drs Stacey and Dunn, for their great advice, valuable time, and knowledge provided to me. Their excellent expertise in the field of knowledge translation and implementation science shed light on my path at different levels to complete this dissertation.

I would like to thank all the parents who participated in this dissertation. I also acknowledge the financial support I received from the University of Ottawa, International Doctoral Scholarship and International Admission Full Scholarship. The university support helped me gain experience as a teaching assistant in seven nursing courses at undergraduate and graduate levels during the last four years. I also would like to acknowledge the travel awards and grants I received from the University of Ottawa, the Pain in Child Health (PICH) trainee consortium, along with my supervisor's support. Their generous supports helped me participate and present ten study abstracts in different national conferences and networking events across Canada. This opportunity helped me connect with many amazing researchers, mentors, and trainees in the field of pediatric pain research nationally and internationally. As a result, I have contributed to seven academic publications during the last four years in addition to my Ph.D. studies.

Last but not the least, I would like to thank my beloved ones (Maman, Baba, and my beautiful sister Bahar), whom I could have not been here without their ongoing emotional support, they were always there for me and never stopped believing in me. Love you to the moon and back!

Shokoufeh,

26.09.2019

Preface

This dissertation is presented as a thesis with the two studies written as manuscripts formatted for the target journals. Both manuscripts are included as result chapters.

Co-Authorship:

- Denise Harrison, RN, Ph.D. School of Nursing, University of Ottawa and Children's Hospital of Eastern Ontario (CHEO) Research Institute.

As the Ph.D. supervisor, Dr Harrison co-authored each manuscript of this dissertation. She provided guidance and support throughout this dissertation.

- Dawn Stacey, RN, Ph.D. School of Nursing, University of Ottawa, Ottawa Hospital Research Institute, Ontario, Canada.
- Sandra Dunn, RN, Ph.D. Children's Hospital of Eastern Ontario (CHEO) Research Institute, and Better Outcomes Registry & Network (BORN), Ontario, Canada.

As my dissertation committee members, Drs. Stacey and Dunn co-authored the manuscripts and provided support and guidance on the studies' design, progress, and reporting the results, and contributed greatly to the development and completion of this dissertation.

- Juliana Choueiry, BScN, Children's Hospital of Eastern Ontario (CHEO) Research Institute, Ottawa, Ontario, Canada.

Juliana co-authored the second manuscript of this dissertation. She helped as a second screener in the quality appraisal of online resources and proofreading the final manuscript.

List of Abbreviations

AS&Q: Affirmation Statements and Questions

CHEO: Children's Hospital of Eastern Ontario

CIHR: Canadian Institutes of Health Research

CDC: Center for Diseases Control and Prevention

CNICS: Childhood National Immunization Coverage Survey

HELPinKIDS: Help Eliminate Pain in Kids

HCP: Health Care Providers

IASP: International Association for the Study of Pain

ICN: International Council of Nursing

IQR: Inter Quartile Range

KT: Knowledge Translation

KTA: Knowledge to Action

MI: Motivational Interviewing

RCT: Randomized Controlled Trial

REDCap: Research Electronic Data Capture

SKIP: Solutions for Kids in Pain

WHO: World Health Organization

Table of Contents

Abstract.....	ii
Acknowledgments.....	iv
Preface.....	vi
List of Abbreviations	vii
Table of Contents	viii
List of Figures	xv
List of Tables	xvi
Chapter 1 – Introduction and Background.....	1
Introduction	2
Significance of the Issue	2
Background	8
Childhood Vaccination	8
Vaccination Pain.....	9
Recommended Pain Management Strategies during Vaccination.....	11
Breastfeeding for reducing pain during needle-related procedures	12
Sweet solutions	15
Upright secure holding.....	16
HCPs’ Use of Pain Management Strategies during Vaccination	17
Parents’ Role in Pain Management during Vaccination.....	19
Motivational Interviewing (MI) as a Self-advocacy Strategy	21

Use of Online Platforms for Engaging Parents in Research.....	23
Parent-targeted KT Interventions in Vaccination Pain Management.....	24
Summary	28
References	29
Chapter 2 - Theoretical Framework and Methods	42
Purpose	43
Aim.	43
Objectives.	43
Theoretical Framework	44
Methods of Study 1: Feasibility, Acceptability and Preliminary Efficacy Evaluation of a Parent-targeted Intervention.....	47
Study design.	47
Objectives.	47
Research questions.	48
Participants.	48
Recruitment process	49
Interventions.	50
Outcome.....	52
Development and modification of surveys.....	54
Sample size.	54
Randomization.....	54
Allocation concealment mechanism.	55

Blinding.....	55
Statistical methods.....	55
Ethical considerations.....	55
Methods of Study 2: Parent Resources for Infant Vaccinations: A Cross-Canada	
Environmental Scan	57
Objectives.....	57
Research questions.....	57
Study design.....	57
Search strategy.....	58
Selection of eligible resources.....	59
Data collection.....	59
Quality appraisal.....	60
Scoring.....	61
Data analysis.....	62
References	63
Chapter 3 -The Feasibility, Acceptability, and Preliminary Efficacy of Parent-targeted Interventions in Vaccination Pain Management of Infants: A Pilot Randomized Control Trial (RCT).....	
Abstract	69
Introduction	71
Materials and Methods	73
Trial design	73

Participants.....	74
Recruitment process	74
Interventions.....	74
Outcome measurements.....	75
The primary outcome.....	75
The secondary outcome	76
Additional study outcomes	76
Development and modification of surveys.....	76
Sample size.....	77
Randomization.....	77
Blinding.....	77
Statistical methods.....	78
Ethical considerations.....	78
Results.....	78
Study participants	78
Demographic characteristics.....	79
Baseline knowledge and previous use	79
Feasibility and acceptability	80
Preliminary	81
Discussion	82
Strengths and Limitations.....	85
Conclusion.....	87

References	88
Figure 1. Affirmative Statements and Questions (AS&Q) Tool.....	93
Figure 2. CONSORT Flow Diagram.....	94
Table 1. Characteristics of Respondents to Baseline Demographic Survey	95
Table 2. Knowledge and Use of Pain Management Strategies in Respondents to Baseline Knowledge Survey	97
Figure 3. Affirmative Statements and Questions (AS&Q)	98
Table 3. Acceptability of Study Tools, Procedure, and Interventions	99
Table 4. Knowledge Utilization Information after Subsequent Vaccination	100
Chapter 4 -Parent Resources for Early Childhood Vaccination: An Online Environmental Scan	101
Abstract	102
Introduction	104
Methods.....	106
Study design	106
Search strategy.....	106
Selection of eligible resources	107
Data collection.	107
Quality appraisal.....	108
Scoring	109
Data analysis.....	110

Results	110
Search strategies	110
Quality appraisal.....	111
Pain management strategies.....	112
Discussion	112
Strengths and Limitations.....	115
Conclusion.....	116
References	118
Figure 1. PRISMA flow diagram	123
Figure 2. Vaccination Pain Management Strategies Addressed in Resources	124
Table 1. Characteristics of Resources	125
Chapter 5 - Integrated Discussion.....	128
Key Findings of Study 1.....	129
Key Findings of Study 2.....	131
Unplanned Outcome: The Impact of Anti- or Pro-Vaccination Movement.....	140
Summary	141
Implications of Findings.....	144
Implications for practice	144
Implications for future research.....	145
Implications for policy.....	146
Implications for education	146

Conclusion.....	147
References	149
Appendices.....	161
Appendix A. Knowledge to Action Framework	161
Appendix B. Advertisements Scripts	162
Appendix C. Consent Form.....	163
Appendix D. Demographic Survey	168
Appendix E. Baseline Knowledge Survey	171
Appendix F. AS&Q.....	173
Appendix G. Reducing Pain during Vaccination Tip Sheet	174
Appendix H. Knowledge Utilization Survey	175
Appendix I. Acceptability Survey	177
Appendix J. CDC Clear Communication Index Tool	178
Appendix K. CDC Social Media Guideline and Best Practice	185

List of Figures

Figure 3.1. Affirmative Statements and Questions (AS&Q) Tool.....	93
Figure 3.2. CONSORT Flow Diagram.....	94
Figure 3.3. Affirmative Statements and Questions (AS&Q).....	98
Figure 4.1. PRISMA flow diagram.....	123
Figure 4.2. Vaccination Pain Management Strategies Addressed in Resources.....	124

List of Tables

Table 3.1. Characteristics of Respondents to Baseline Demographic Survey.....	95
Table 3.2. Knowledge and Use of Pain Management Strategies in Respondents to Baseline Knowledge Survey.....	97
Table 3.3. Acceptability of Study Tools, Procedure, and Interventions.....	99
Table 3.4. Knowledge Utilization Information after Subsequent Vaccination.....	100
Table 4.1. Characteristics of Resources.....	125

Chapter 1 – Introduction and Background

Introduction

In this chapter, the research problem, study goals, and objectives are identified. This is followed by an overview of background information relating to childhood vaccination in Canada, infant pain during vaccination, effective pain management strategies for childhood vaccination, healthcare providers (HCPs) and parent-targeted and mediated knowledge translation (KT) interventions, motivational interviewing (MI) approach and the role of parents in improving the use of recommended pain management strategies during infant vaccination. This chapter aims to present an overview, synthesis, and critique of the relevant research in line with the research question. This review was not intended or conducted as a systematic review.

Significance of the Issue

Early childhood vaccination is the most important public health intervention against life-threatening infectious diseases worldwide (Centers for Disease Control and Prevention, 2017). However, vaccinations are painful and result in distress for infants and, in many cases, their parents (Taddio, McMurtry, Shah, et al., 2015). The early childhood vaccination schedule requires approximately 20 separate injections in the first year of life (Government of Canada, National Advisory Committee on Immunization, 2017). If vaccination pain is not addressed, this pain can lead to a fear of needles, subsequent non-adherence with vaccination schedules, and avoidance of health care (Taddio et al., 2015).

Clinical practice guidelines (Taddio et al., 2015) and high-quality synthesized evidence show that breastfeeding (Harrison, Reszel, et al., 2016), sucrose (Chen et al., 2016; Harrison et al., 2010; Kassab, Foster, Foureur, & Fowler, 2012), and upright secure holding (Taddio et al., 2015) reduce pain during vaccination in infants (Shah et al., 2015). In addition, the World Health Organization (WHO) position statement, recommends breastfeeding during infant vaccinations and the

administration of vaccinations with sucrose content (i.e. oral liquid rotavirus and oral polio vaccine) before injectable vaccines (World Health Organization, 2015). Despite the evidence, these strategies are not consistently used in practice highlighting an important gap in translating this knowledge into practice (Taddio et al., 2015). This suboptimal use of recommended pain management strategies was also highlighted in a systematic review of YouTube videos showing the vaccination of infants (Harrison, Sampson, et al., 2014) where effective pain management strategies were rarely used.

The current inconsistency in the use of effective pain management strategies may partly be due to HCPs being resistant and imposing barriers to using, and supporting parents to use, recommended pain management. However, research has traditionally targeted HCPs rather than consumers (Taddio, Shah, et al., 2013). Yet, the poor uptake of recommended pain management strategies shows that the education of HCPs alone is not sufficient to improve practices. Preparing parents in addition to clinicians may help to overcome this barrier, as parents can advocate for, and contribute to decreasing their infant's pain (Taddio, Ipp, et al., 2014). Parents have reported a lack of knowledge as the main barrier to advocate for the use of effective pain management strategies for their infant's pain care, but they have also indicated an interest to learn more about effective pain care during painful procedures (Franck et al., 2015). The use of recommended pain management strategies requires the involvement of parents in pain care by sharing responsibility through a partnership with physicians and nurses during early childhood vaccination (Axelin, et al., 2010, Franck, Berberich, & Taddio, 2015). This shows the importance of supporting parents to access high-quality educational resources about vaccination pain management and empowering them to advocate for effective pain care of their infant during painful procedures.

The advent of the internet has increased public access to online health information. In 2010, Statistics Canada reported that 70% of Canadians used the internet to search for medical or health-

related information at home (Statistics Canada, 2010). In all likelihood, this proportion has risen since this time. Social media platforms such as Facebook and Twitter are popular platforms for exchanging health information among parents (Sampson et al., 2013). YouTube is also commonly used by parents of infants and young children to access and share online videos (Sampson et al., 2013).

This access to online information, with the potential to improve knowledge, and subsequently, confidence, can be applied to online parent-targeted vaccination resources available to the public, in order to empower parents in the use of pain management strategies. Parent-targeted online resources may be effective informational tools in increasing the confidence of parents. More confident parents may be more likely to communicate their needs to HCPs and be more confident to advocate for a change in HCP's behaviors (McMullan, 2006; Sampson et al., 2013). However, parents seeking online vaccination information, including pain management during vaccination of their infant, are likely to find thousands of web pages and videos in their online search which may make it difficult for them to distinguish between accurate and reliable information and difficult to understand, or inaccurate and misleading information (Farkas et al., 2015). Parents may find online information conflicting, overwhelming and confusing, leading to a lack of confidence in trusting these online information resources (Dol, Richardson, Boates, & Campbell-Yeo, 2018; McMullan, 2006).

Little is known of the extent to which evidence-based pain management strategies for infants during vaccinations are included in parent-targeted online information. The degree of accessibility and user-friendliness of this information is also unknown. Therefore, it is important to identify and critically appraise online publicly available resources regarding early childhood vaccination and to evaluate their content and accuracy regarding evidence-based pain management strategies. Including credible parent-targeted informational resources about vaccination pain management on accessible

educational platforms may empower parents to comfort their infants during vaccination and to advocate for the use of effective pain management strategies during vaccination. On the other hand, it is not yet understood if parent-targeted educational resources by themselves can lead to an increase in the use of evidence-based recommended pain management strategies. It is also not known if additional approaches can further help parents to advocate for the pain care of their infants during vaccination.

A series of brief parent-targeted and parent-mediated videos named ‘Be Sweet to Babies’ has been co-produced professionally with parents of infants, clinicians and researchers at the Children’s Hospital of Eastern Ontario (CHEO) and the Carlington Community Centre. These videos were produced with the aim of making them available and accessible to parents with the goal of targeting both parents’ behaviors directly (patient-directed) and through the mediation of HCPs’ behavior (patient-mediated) (Stacey & Hill, 2013). These videos demonstrate to parents how they can work with physicians and nurses to reduce their babies’ vaccination pain by breastfeeding, or giving a small volume of a sweet solution, and holding their infants during vaccinations. A similar video by the Be Sweet to Babies research team demonstrating pain management during the newborn screening was previously pilot tested and showed a high rate of feasibility and acceptability for parents (Harrison et al., 2017).

KT interventions such as these videos may empower parents and motivate them to use these pain management strategies during their infant’s vaccination. However, it is not yet known if the videos, which are freely available on social media platforms, lead to increased use of pain management strategies during infant vaccination, or whether additional strategies such as motivational interviewing, can further support parents to advocate for their infant’s pain management. Motivational Interviewing (MI) is a patient-centered (in this case, parent) method that

presents the process of getting ready for a change in order to improve health outcomes (Rollnick, Miller, Butler, & Aloia, 2008). The use of this strategy on health behavior change is supported in systematic reviews (Gayes & Steele, 2014; Lundahl, Kunz, Brownell, et al., 2010), but has not been tested in the area of infant pain management. Motivational statements and questions delivered online informed by the MI approach, may further support parents to advocate for use of effective and recommended pain management strategies during vaccination. It is therefore important to evaluate the potential impact of the videos and additional strategies (such as a MI-based approach) in supporting parents to advocate for their choices of pain management strategies to HCPs at the time of their infants' vaccination.

In summary, despite high quality evidence of effective ways to reduce infants' pain during vaccination, and this knowledge has not been translated into consistent clinical practice despite availability of synthesized evidence and guidelines for HCP. No research has been identified which that focuses on evaluating visual, parent-targeted and mediated interventions, coupled with affirmation statements and questions based on MI. To address this research gap, an important first step is to understand the extent to which recommended pain management strategies for infants during vaccinations are included in publicly available parent-targeted online resources. A second step is to develop and pilot test KT interventions which may result in improved pain management practices by increasing the uptake of recommended pain management strategies during infant vaccination.

Therefore, this dissertation aims to improve the use of recommended pain management strategies during infant vaccination by investigating the use and quality of evidence-based online parent resources in order to i) determine if parent-targeted and mediated interventions (the publicly available *Be Sweet to Babies* videos and information tip sheet on children's vaccination pain management) with or without additional MI-based Affirmation Statements and Questions (AS&Q),

delivered to parents are feasible, acceptable and potentially effective in increasing the uptake of recommended pain care strategies during infant vaccination and, ii) identify and critically appraise the quality of online parent-targeted resources. In the next section of this chapter, an overview of the literature about vaccination pain management in infants is presented.

Background

This section presents an overview of background information in the context of vaccination pain management in infants. This section focuses on knowledge creation of recommended pain management strategies, parents' role in vaccination pain management, KT resources and interventions targeted at parents of infants, and motivational interviewing as an advocacy strategy in supporting parents' behavior change in infant vaccination pain management.

Childhood Vaccination

Vaccines are one of the most important achievements of public health. Vaccines have contributed greatly to increasing the life span of humans by almost 30 years, by widespread eradication of infectious diseases in the 20th century (Centers for Disease Control and Prevention, 2017). During infancy, in which a child is less than 12 months of age, a healthy infant undergoes almost 20 vaccine injections (Public Health Agency of Canada, 2019). These vaccinations are vital for human body immunization processes (Centers for Disease Control and Prevention, 2017). Immunization is the process in which a body becomes resistant to a life-threatening infectious disease by the administration of a vaccine. Vaccines contain agents that stimulate the immune system to protect the body against subsequent infections (World Health Organization, 2015).

According to the 2013 Childhood National Immunization Coverage Survey (CNICS), Canada has reported 84% coverage of vaccines in 2013, which ranked 28th out of 29 countries with vaccine coverage below 90%. This is the percentage of children between 12 and 23 months old who received recommended scheduled vaccinations according to the province where they live (Public Health Agency of Canada, 2019; Ismail et al., 2010). Vaccination programs also rely on population or "herd" immunity to be effective. Herd immunity occurs when large portions of the population get vaccinated and as a result, they protect the unprotected individuals by decreasing the number of

vulnerable hosts to a level less than the transmission threshold called “Herd immunity threshold”.

The value of this threshold varies with some related factors such as type of virus, the transmissibility of the disease, and vaccination coverage among the population. However, eradication for poliovirus and smallpox has been achieved in many countries when the vaccination coverage was above 90-95% (World Health Organization, 2019).

In Canada, public availability and funding of vaccines are determined at the provincial/territorial level and all provinces provide free routine childhood vaccines for infectious diseases such as, hepatitis B, diphtheria, Haemophilus influenza type b, tetanus, pertussis, meningococcal disease, measles, poliomyelitis, pneumococcal disease, mumps, rubella and varicella (Public Health Agency of Canada, 2019). Canada does not have a national registry system for vaccination records, however since 1994 the rates and coverage of routine childhood immunizations are estimated via the Childhood National Immunization Coverage Survey (CNICS), and the National Advisory Committee on Immunization every two years (Public Health Agency of Canada, 2019). Despite the benefits of immunization, vaccination injections are painful, and the most commonly occurring painful medical procedure in early childhood. This highlights the importance of improving pain management during vaccination, which can benefit both parents and their infants and children (Taddio et al., 2015).

Vaccination Pain

Childhood vaccinations, although necessary for public health, are associated with pain and distress (Centers for Disease Control and Prevention, 2017). According to the International Association for the Study of Pain (IASP), pain is a subjective experience and is defined as “an unpleasant sensory and emotional experience resulting from actual or potential tissue damage” (International Association for the Study of Pain Website, 2012). The International Council of Nursing’s (ICN) Code of Ethics addressed pain relief as an important nursing responsibility to reduce

suffering, especially in vulnerable groups such as infants (International Council of Nurses (ICN), Code of Ethics for Nurses, 2017).

The pain associated with vaccination is due to different phases of the injection process (Taddio, Manley, et al, 2007, Taddio, Chambers, et al., 2009). First, acute nociceptive pain is experienced when the skin is punctured by the needle, and then the pain continues when the vaccine solution is injected into the subcutaneous or muscle tissues. Next, post-injection pain is followed due to inflammation in the skin that might last several days (Taddio, Manley, et al, 2007, Taddio, Chambers, et al., 2009).

When no pain management is used, infants' reactions to a vaccine injection, typically include immediate behavioral responses including facial grimacing, body movements, and crying (O'Neill, Ahola Kohut, et al., 2019). Studies on specific pain expression in infants during two- and four- month vaccinations show that most infants demonstrate deep vertical furrow between the brows, nasolabial furrow, shutting eyes tightly, wide-open mouth, high-pitched cry and rigidity in their arms and torso muscles (O'Neill, Ahola Kohut, et al., 2019). These pain expressions in infants may be influenced by many individual and clinical factors such as age, sex, use of any pain relief interventions, injection technique, and caregiver behavior (DiLorenzo, Riddell, et al., 2018; Fitzgerald & Walker, 2009).

Painful experiences in early childhood may impact the development of the nervous system and ultimately lead to altered long term behaviors (Axia & Bonichini, 2005; Fitzgerald & Walker, 2009). A systematic review of 13 neonatal studies aimed to investigate the long-term developmental consequences of early pain experience during the neonatal period. Findings showed that untreated needle-related pain put preterm infants at risk of subsequent fear of injections, elevated pain responses to painful triggers later in life, being uncooperative in future painful procedures and adulthood fear of medical events and clinical settings, which can lead to avoidance behavior of health

care and vaccination in future (Valeri, Holsti, & Linhares, 2015). Although this systematic review by Valeri et al. (2015) was focused on neonatal intensive care unit (NICU) settings and the included population was preterm infants, the results have clinical implications for healthy newborn and young infants who are exposed to painful procedures with no, or ineffective pain treatment that may influence their vaccination experience.

During the first year of life, vaccination pain is the most common experience of acute pain in infants (Taddio, Chambers, et al., 2009). Poorly treated pain during vaccination may have both short- and long-term consequences. In the short term, untreated or poorly treated pain can result in behavioral and physiological changes such as facial grimacing, crying, and withdrawal of limbs, elevated heart rate, blood pressure, and oxygen desaturation (Fitzgerald & Walker, 2009). Long term effects include the risk of development of needle fear and fear of medical procedures (Valeri, Holsti, & Linhares, 2015). In a cross-sectional study of 1907 children and parents in Canada, 63% of children and 24% of parents reported a fear of needles (Taddio, Ipp, et al., 2012). Furthermore, 7% of parents and 8% of children stated that needle fear is the primary reason for vaccination non-compliance (Taddio, Ipp, et al., 2012). Vaccination pain may also disrupt parent-infant bonding and feeding schedules in infants (Fitzgerald & Walker, 2009).

There are, however, effective evidence-based strategies which can be used to reduce vaccination pain, which are cost-effective and safe, including breastfeeding, sweet solutions, and upright secure holding (Chen et al., 2016; Harrison, Reszel, et al., 2016; Shah et al., 2015; Taddio et al., 2015).

Recommended Pain Management Strategies during Vaccination

Pain management is a basic human right, and a priority identified by health care agencies, researchers, and parents of infants (World Health Organization, 2015). In terms of vaccination pain

management for infants and children, in 2008, a cross-Canada multidisciplinary team was established, named Help Eliminate Pain in Kids (HELPinKIDS), which aimed to reduce vaccination pain in children (Chan et al., 2013; Taddio, et al., 2015). In 2009 a clinical practice guideline on pain reduction during vaccination for different age categories (infants and young children, children, adolescents, and adults) was published, which was subsequently updated in 2015 (Taddio, McMurtry, et al., 2015). The quality of this clinical guideline was evaluated by the Registered Nurses' Association of Ontario (RNAO) (Registered Nurses' Association of Ontario, 2013) using the appraisal of Guideline for Research and Evaluation Instrument II (AGREE II) (Brouwers et al., 2010). The guideline was considered to be of high quality, and subsequently included as a resource in the RNAO's Pain assessment and Management Best Practice Guideline (Registered Nurses' Association of Ontario, 2013). In addition, in 2015 the WHO released the first position statement recommending the use of various evidence-based interventions for vaccination pain management (World Health Organization, 2015). For infants, recommendations included breastfeeding, administration of oral sweet-tasting vaccinations prior to injections, and holding by caregivers (Taddio, et al, 2015; World Health Organization, 2015). The evidence for these recommended pain management strategies of breastfeeding, sweet solutions, and upright secure holding is discussed in the following section. Other strategies including topical anesthesia, such as EMLA or Ametop, were not recommended during infant vaccination in the WHO position statement (World Health Organization, 2015). Although there is evidence of efficacy, especially in older children, the use of local anesthetics requires additional costs and extra time for application and is not readily available in health settings around the world (World Health Organization, 2015).

Breastfeeding for reducing pain during needle-related procedures. High quality synthesized evidence shows that breastfeeding reduces pain during vaccination in infants (Harrison,

Reszel, et al., 2016; Shah et al., 2015). In addition, as stated above, WHO recommends the use of breastfeeding during infant vaccinations (World Health Organization, 2015). To use breastfeeding as a pain management strategy, it is important to look at breastfeeding rates and acceptability in general. Exclusive breastfeeding is recommended by the WHO (World Health Organization, 2015) for the first six months of life, and continuation to two years with complimentary food. One of the Healthy People 2020 goals is to increase the rates of exclusive breastfeeding to 25.5% of infants for the first six months of life. In 2006, the rate of exclusive breastfeeding up to six months of age in the United States of America (USA), was 14.1% and the rate in 2015 was 24.9% according to the National Immunization Survey (NIS) 2016 (Center for Disease Control and Prevention, 2019, U.S Department of Health and Human Services, Healthy People 2020, 2019). In Ontario, Canada, the rate of exclusively breastfeeding at discharge reported 62%, however only 33% continue for six months (BORN Ontario, Better Outcomes Registry and Network, 2016).

In addition to nutritional and other health-related short- and long-term benefits of breastfeeding (Anderson, Johnstone, & Remley, 1999), breastfeeding infants during vaccination effectively reduces acute pain (Harrison, Reszel, et al., 2016; Shah et al., 2015). The analgesic mechanisms of breastfeeding include the touch, smell and sight of the mother, positioning of the infant, sucking, distraction, physical comfort, slightly sweet taste of human milk and, possibly, endorphins present in breastmilk (Harrison et al., 2016).

Results of synthesized evidence show that breastfeeding effectively reduces pain in infants aged one-12 months of age, during vaccination (Harrison et al., 2016). A Cochrane systematic review of ten randomized controlled trials (RCTs) including 1066 infants showed a statistically significant benefit of breastfeeding during vaccination, in terms of reduced behavioral pain responses (cry time and pain scores) compared to no treatment, placebo, maternal cuddling, topical anesthetic, oral

glucose, massage, and cold spray (Harrison et al., 2016). A meta-analysis including data on duration of a cry from six studies (547 infants) showed breastfeeding significantly reduced crying time during vaccination by 38 seconds (MD -38, 95% CI -50 to -26; $P < 0.00001$), compared to no treatment or water. In addition, a meta-analysis of standardized mean pain scores from five studies (310 infants) showed breastfeeding statistically significantly reduced pain scores by 1.7 points in standardized pain scores (SMD -1.7, 95% CI -2.2 to -1.3) (Harrison et al., 2016).

In addition, the analgesic effects of breastfeeding full-term newborn infants during acute painful procedures such as venipuncture, heel lance, and intramuscular injection have been shown in systematic reviews (Benoit, Martin-Misener, Latimer, et al., 2017; Shah et al., 2012). Breastfeeding compared to conditions such as infants being positioned on the examination table, being held or given small volumes of water or expressed breast milk to suck, resulted in reduced crying time, reduced facial expressions of pain, reduced body movements and decreased heart rate (Benoit, Martin-Misener, Latimer, et al., 2017; Shah et al., 2012).

Breastfeeding during vaccination and other painful procedures, when it is feasible and culturally acceptable, can be easily used by mothers who are breastfeeding, is cost-effective and safe (Harrison et al., 2016). However, there are barriers to facilitating the use of breastfeeding as a pain management strategy including lack of awareness in both parents and HCPs, the required time for the infant to latch on prior to the procedure, and HCPs' fears that breastfeeding during painful procedures, including vaccination, will result in choking, gagging, or coughing (Saarinen, 2010; Shah et al., 2015; Tansky & Lindberg, 2010). In addition, a misbelief exists that breastfeeding infants during painful procedures may result in infants associating feeding with the painful stimuli, impacting the mother-infant relationship as a result (Parikh, 2014; Saarinen, 2010; Shah et al., 2015; Tansky & Lindberg, 2010). However, no research has confirmed these perceptions, and no adverse

effects such as choking, gagging or aspiration is reported (Harrison, Reszel, et al., 2016). In addition, environmental factors may be viewed as barriers to breastfeeding during vaccination, such as a lack of privacy and lack of comfortable chairs for the mothers (Leite et al., 2009; Shah, Herbozo, et al., 2012).

Cultural and social support systems in a society can also impact breastfeeding practices. For example, breasts may be considered more of a sexual object rather than a nourishment source for infants (Saarinen, 2010), which may make public breastfeeding (including in a public vaccination clinic with no private room) difficult for mothers. Saarinen et al. (2010) highlighted the need for a cultural climate change for public breastfeeding. They reported this change needs to not only focus on educating parents about breastfeeding but also supporting breastfeeding practices in public by shaping the cultural norms surrounding women in society and making efforts to correct misperceptions around public breastfeeding (Saarinen, 2010). Wide-scale promotion of the use of breastfeeding during vaccination as an effective pain management strategy for infants may benefit not only individual infants and mothers but support a cultural norm of breastfeeding in public places.

Sweet solutions. In addition to breastfeeding, there is abundant evidence that small volumes of sweet solutions reduce pain during vaccinations and other needle-related procedures in infants. Since 1980, more than 200 studies have been conducted on the calming effects of sweet solutions during painful procedures in newborns, infants and young children (Harrison et al., 2010). A meta-analysis of 168 studies showed the effectiveness and safety of sweet solutions for pain management during painful procedures in newborn infants (Harrison et al., 2017). Further systematic reviews show that the analgesic effects extend beyond the neonatal period, specifically for the reduction of vaccination pain in infants up to 12 months (Chen et al., 2016; Kassab, Sheehy, et al., 2012; Shah et al., 2015). The use of sweet solutions is recommended as a standard of care in clinical practice

guidelines for immunization practices (Taddio, McMurtry, et al., 2015) and the WHO recommends oral sweet vaccination solutions to be administered prior to vaccine injections (World Health Organization, 2015).

Oral sucrose (Stevens, Yamada, Ohlsson, et al., 2016) and glucose (Bueno et al., 2013) are the most widely studied sweet solutions (Harrison et al., 2017). Sucrose significantly reduced behavioral responses of crying duration and facial expressions during painful procedures compared to water, no treatment, non-nutritive sucking or small volume of breast milk or formula in diverse populations of infants up to 12 months of age (Harrison et al., 2010). Although the actual mechanisms of analgesic effects of sweet-tasting solutions are poorly understood, it is believed to be due to an initial distraction response, due to the strong sweet taste, followed by an orally sweet-taste-mediated endogenous opioid effect, probably involving β -endorphins (Harrison, Beggs, & Stevens, 2012). These analgesic effects last for approximately one to five minutes in healthy infants (Harrison, Beggs, & Stevens, 2012). For the maximum effect, it is recommended that small amounts of a 24% to 50% of sucrose or glucose solutions be given to the infants orally, via a pacifier, syringe or dropper, about one to two minutes before the injections and repeated prior to each injection (Kassab, Foster, et al., 2012; Shah, et al., 2015). If the infant uses a pacifier, the additive effect of sucrose or glucose and pacifier may be more beneficial than sweet taste alone (Kassab, Foster, et al., 2012). Manufactured 24% sucrose is available in different pre-packaged brands at commercial pharmacies without a prescription. Sweet solutions for reducing pain during painful procedures are simple to use and cost-effective, and analgesic effects are rapidly achieved (Harrison et al., 2011; Shah, 2008).

Upright secure holding. Holding infants securely during vaccination injection may decrease their distress and fear and gives them a better sense of control (Taddio, McMurtry, et al., 2015). Pillai Riddell et al. (2015), in a systematic review of 63 studies on psychological interventions (non-

nutritive sucking, swaddling/facilitated tucking, rocking/holding, touch or massage, environmental modification, simulated rocking and water, simulated mother's voice, swallowing water, rocking, toy distraction, video distraction, parent presence, structured parent involvement, familiar odor, co-bedding, heel warming, sucrose) during vaccination of young children suggested the use of holding an infant in the caregivers' arms as the optimal position for distraction (Riddell et al., 2015). In addition, the HELPinKIDS' clinical practice guideline recommends secure holding by a caregiver as opposed to positioning the infants supine on an examination table during vaccination (Taddio, McMurtry, et al., 2015).

Despite the recommendations in the HELPinKIDS guidelines (Taddio, McMurtry, et al., 2015) and by WHO, to use breastfeeding, sweet solutions and upright secure holding during vaccinations in infants (World Health Organization, 2015), these strategies are not consistently used in practice (Harrison, Sampson, et al., 2014; Taddio, McMurtry, et al., 2015; (Harrison, Elia, Royle, & Manias, 2013). Moreover, the use of these effective pain management strategies during infant vaccinations remains largely unaddressed among parents (Harrison, Elia, Royle, & Manias, 2013; Harrison, Sampson, et al., 2014; Riddell, Taddio, et al, 2015).

HCPs' Use of Pain Management Strategies during Vaccination

This lack of use of evidence-based pain management strategies during vaccination of infants may be partly due to the existence of barriers imposed by HCPs or health organizations (Kikuta, et al. 2010 & 2011). Some of the reported barriers include lack of awareness, lack of enough time to allow mothers to breastfeed, lack of availability of resources such as privacy, sweet solutions, and the vaccinators' attitude towards parents attempting to use pain management strategies (Taddio, Ipp, et al., 2014; Taddio, Smart, et al., 2014, Taddio, Hogan, et al., 2012). HCPs may not support parental

contribution to comforting their infant or discuss the choice of pain management strategies with parents during the vaccination of their infants (Parvez et al., 2010; Taddio, Chambers, et al., 2009).

Traditionally, research and KT strategies have targeted HCPs rather than consumers to improve the uptake of evidence-based information. KT strategies used have included audit and feedback, KT resources, and in-service educational programs, however only small benefits have been shown in changing HCPs' behaviors and practice (Taddio, Shah, et al., 2013). Moreover, suboptimal use of recommended pain management has been reported in studies evaluating the HCPs' use of pain management strategies during vaccination (Harrison, et al., 2013; Russel and Harrison, 2015, Taddio, Chambers, et al., 2009). For example, Harrison et al conducted a survey of 125 nurses in the state of Victoria, Australia about pain management practices during vaccination, and showed the lack of use of effective pain management strategies among nurses. Less effective strategies such as distraction using bubbles, toys and talking were described as the most commonly used pain management strategies (Harrison, Elia, Royle, & Manias, 2013). Similar results were reported by Russel and Harrison (2015) in their study of 62 vaccination nurses' use of pain management strategies in New Zealand. Despite the evidence of demonstrated benefits of using effective pain management strategies, only occasional use of breastfeeding and sweet solutions was reported. In addition, findings of studies by Taddio, et al. (2009) and Riddell, et al. (2015) showed the lack of use of evidence-based pain management strategies among HCPs during the vaccination of infants. They reported the use of distraction and holding as the most used strategies to comfort infants during vaccination. Moreover, some misconceptions among HCPs were reported that led to this sub-optimal use of recommended pain management strategies, such as HCPs' concerns about parents' competency, or they believed the use of these pain strategies are not easy to accommodate in practice (Taddio, et al. 2009).

The poor uptake of recommended pain management strategies suggests that the education of HCPs alone is not sufficient to change practice. Partnering with, and informing parents in addition to clinicians, may be more effective, as parents can advocate for and contribute to decreasing their infant's pain. Taddio et al (2014) showed that providing information about vaccination pain management, on its own, resulted in increased attempts by mothers to use breastfeeding or sucrose during their infants' vaccination; however, these attempts were not always successful due to HCPs' resistance to the mothers' requests. More confident parents may, however, be more likely to communicate their needs to HCPs, and more confident to advocate for a change in HCP's behaviors (McMullan, 2006; Sampson et al., 2013). Shifting the focus to patients, or in this case, parents of infants, may be more effective in increasing the use of patient-targeted health information. However, practice-change is not guaranteed, and a partnership between parents and HCPs is required to facilitate the process (Franck, et al., 2015). Thus, there is a need to develop feasible and acceptable parent-targeted and mediated KT interventions, to help parents' partner with HCPs in improving pain management practices during vaccination (Schechter, et al. 2010). Therefore, evaluating whether an additional strategy that supports mothers to openly discuss their preferences for pain management with HCPs is important to understanding what strategies effectively increase the use of recommended pain management strategies. Such a strategy supported in the literature, but as yet untried in the area of infant pain management, is motivational interviewing (MI). If parents advocate for their infant's pain by sharing responsibility through a partnership with physicians and nurses, the use of effective pain treatment strategies may increase (Franck, Berberich, & Taddio, 2015).

Parents' Role in Pain Management during Vaccination

The inconsistency in the use of evidence-based recommended pain management strategies during infants' vaccination may partly be due to parents' knowledge or confidence in using the

strategies in medical care settings (Taddio et al., 2014). During vaccination, infants may be separated physically from their parents (Frank et al., 2015) and parents are often overlooked as a source of comfort for their infants. Yet parents have a unique contribution to make to infant pain management by providing effective interventions during vaccination (Frank et al., 2015). Some parents are confident in participating in the pain care of their infants, while other parents might be reluctant to be involved and reluctant to advocate for pain management for their infants during vaccination (Axelin, et al., 2010). Parents have expressed their dissatisfaction and a knowledge gap in their education as the main barrier to comforting their infants during painful procedures and they have reported a desire to learn more about effective vaccination pain management (Frank et al., 2015). Taddio et al. (2015), in a cross-sectional survey of 883 parents, and 1024 children aged between six and 17 years old about prevalence of immunization non-compliance behaviors reported that 70% (n= 618) of parents indicated that they never received any education on pain reduction and 79% (n= 698) reported they were interested to learn ways to reduce needle pain for their children (Taddio et al., 2012). The education of parents, in addition to HCPs, may result in increased use of effective pain management strategies during vaccination (Taddio, McMurtry, et al., 2015). When parents participated in pain management strategies during vaccination, they reported less anxiety and higher levels of satisfaction with health care practices (Schechter, Bernstein, & Zempsky, 2010). This highlights the importance of educating and empowering parents to effectively comfort their infants during vaccination (Taddio, Shah, Leung, & Wang, 2013).

It is crucial to engage parents in the pain management of their infants as early as possible, as they are in the best position to comfort their infants during painful procedures (Frank et al., 2015). To address this issue, strategies that can raise parents' awareness and knowledge of managing their infant's pain during immunizations and help them advocate for pain care of their infant in partnership

with nurses and other HCPs, may increase the use of recommended pain management strategies (Riddell et al., 2015).

Motivational Interviewing (MI) as a Self-advocacy Strategy

MI, a patient-centered method to support change behavior, was introduced by Rollnick & Miller in 1995 (Rollnick et al., 2008). MI is based on a theory of behavior change and the trans-theoretical model of change developed by Prochaska and DiClemente in the 1980s (Prochaska & DiClemente, 1982). MI approach presents the process of getting ready for a change in health planning. The process starts from a “pre-contemplation” step in which there is low readiness for change, to “contemplation” where the person is being informed of the ambivalence and feels a need to change, and then the “preparation” step, in which one develops an intention to change. Finally, there are “action and maintenance” steps where the person moves forward to make the changes, adapts to these new changes, and avoids going back to old behaviors. This model is based on the belief that people will have normal fluctuations in decision making and most of the participants would go through this process several times before a successful behavior change (Gance-Cleveland, 2007).

MI can be used as a patient counseling strategy, through supporting patients to become more confident and motivated to change or form a decision. MI research has primarily been conducted in the area of mental health, although recently it has been tested in other areas such as physical and mental health, substance abuse, adherence to medical treatment, weight loss, physical activity, symptoms of eating disorders and improved health-related quality of life (Carey, Scott-Sheldon, Carey, & DeMartini, 2007). This strategy supports the patient throughout the change process with a collaborative partnership between the patient and HCPs. Features such as reflection, collaboration, compassion, and acceptance build this technique, and the four guiding key criteria of MI is set based

on the acronym “RULE (Resist, Understand, Listen, and Empower)”. MI approach is based on positive affirmations in which patients reflect on their own thoughts (Johnson, 2017; Schumacher & Madson, 2014). This strategy aims to support the patient to realize their ambivalence and resistance to change and build trust and readiness for future new changes (Dunn, Deroo, & Rivara, 2001). The role of HCPs in MI is to help the patients to be informed about the implications of change and guide them to change in a non-judgmental way and let the patients explore their thoughts (Lundahl et al., 2010).

In a meta-analysis of 119 studies using MI, results showed that MI had statistically significant advantages in promoting behavior change in a wide range of health problems from substance use, health-related behaviors (diet, exercise, and safe sex), gambling and engagement in treatment (Lundahl et al., 2010). Conclusions were that MI interventions had a small to medium effect on improving health outcomes (Lundahl et al., 2010). In addition, a systematic review of 37 studies with a pediatric focus (asthma, HIV/AIDS, dental health, Type 1 diabetes, obesity, calcium intake, accident prevention, and sleep) found that MI techniques were effective compared to no treatment and other active treatments such as health education groups, modified versions of the intervention, nutrition counseling groups, in changing both parents’ (11 studies) and children’ (23 studies) health behaviors. They reported that MI interventions can be more effective if parents and children both participated in the research (3 studies) (Gayes & Steele, 2014). More importantly, the effect of MI was reported sustainable since there was no statistically significant decrease in effect size over time in the 16 studies which included follow-ups ranging from one month to two years (average 5.6 months) (Gayes & Steele, 2014). Thus, a motivational technique based on MI may further support parents to advocate for effective pain management, specifically, using breastfeeding or small volumes of sweet solutions and upright secure holding during vaccination of their infant. MI

interventions in all the included studies of Gayes & Steels (2014) and Lundahl et al. (2010) systematic reviews were all delivered by face-to-face in individual or group discussion. The results of these synthesized high-quality studies highlight the contribution and credibility of MI-based technique in behavior-changing interventions. In addition, a similar component of the MI technique was used by April et al. (2016) in the development of a decision aid tool for patients with osteoarthritis. The results of her study showed the tool helped participants reflect on their thoughts and as a result make an informed decision in the nonsurgical options for management of knee and hip osteoarthritis (April et al., 2016). However, no studies have evaluated MI-based intervention delivered to parents by online platforms.

Use of Online Platforms for Engaging Parents in Research

The use of the Internet and social media is rapidly growing amongst parents while traditional methods of communication such as in-person delivery of information for research purposes are decreasing (Jarrett, Wilson, O'Leary, et al., 2015). The Internet is an important influencer on parents' health behavior and beliefs. It is reported that 80% of Canadians, 16 years of age or older, use the Internet on the daily basis, and 64% of these users search for health-related information online (Statistics Canada, 2010). Social media networks are important sources of information since they allow for the rapid exchange of opinions or information by people who may have shared the same experiences in life (Schein, Wilson, & Keelan, 2011). Furthermore, virtual support groups may support users to be informed and subsequently empowered in the process of health care decision making (Larson, Cooper, Eskola, et al., 2011; Tustin et al., 2017).

In Canada, Facebook is the most popular social media venue that parents seek online health information from (Alshaikh, Ramzan, Rawaf, & Majeed, 2014). Facebook, as well as other popular social media venues such as Twitter, parent's forums and email lists, have recently been used as

pathways to approach parents of infants and children for research recruitment or for delivery of information in health research (Alshaikh et al., 2014; Tustin et al., 2017). These platforms provide easy access to diverse populations, allow for relatively simple data collection processes at low cost, and can successfully target large populations across wide geographical ranges, including vulnerable or isolated populations, as long as they have access to the Internet. Although methodological limitations exist for online studies, including validation of self-report findings, this is an issue in most studies using survey methods (Tustin et al., 2017; Tustin, Crowcroft, Gesink, et al., 2018).

In a systematic review of studies using social media for health research, Alshaikh et al. (2014) showed that popular online platforms are useful tools in health research (Alshaikh et al., 2014). In addition, Quach et al. (2013) showed that using multiple online recruitment strategies such as Facebook and Twitter to invite parents of infants and children to participate in vaccination programs, was a useful recruitment method as long as actions were taken to manage the potential risks of this strategy such as managing multiple response submissions (Quach et al., 2013). However, to the best of our knowledge, no studies have used popular online platforms to approach and deliver information to parents about vaccination pain management and no studies have evaluated the quality of existing educational online resources accessible to parents.

Parent-targeted KT Interventions in Vaccination Pain Management

Based on the Knowledge to Action (KTA) framework (informing this dissertation, and is explained further in the next chapter), an effective KT intervention needs to be tailored to the target knowledge users (Harrison, Graham, Fervers, et al., 2013), which, in the case of this study, are parents of infants. An accessible and understandable KT intervention (either written or audio-visual interventions, such as videos) can attract the audience and encourage the use of the knowledge in the local practice context (Brouwers, Stacey, & O'Connor, 2010). In addition, the increasing use of

social media in society is being capitalized on as a method of knowledge dissemination by health care researchers. For example, videos posted on YouTube may target both parents' behaviors (patient-directed) directly, and also be made available to parents with the goal of mediating health care providers' behavior (patient-mediated) (Stacey & Hill, 2013). Publicly accessible educational videos targeted at any consumers of healthcare knowledge, aim to promote engagement in health care by improving knowledge and experience. Such videos can subsequently, change health behavior and eventually improve health outcomes. An overview of systematic reviews shows that using patient-targeted interventions that actively engage patients in their care, improves knowledge, health outcomes and experiences of patients (Coulter & Ellins, 2007). In addition, informatics interventions such as using videos have been found to play a significant role in the timely and effective transfer of information to knowledge users (Gupta & McKibbin, 2013).

Educational interventions for parents in the form of printed tip sheets and videos have been produced, based on clinical practice guidelines on effective pain management strategies during vaccination, to facilitate uptake of knowledge (Taddio, et al., 2015). Several informative KT resources in forms of videos and websites focused on improving pain management during early childhood vaccination have been released by different reputable sources. For instance, the Canadian Institutes of Health Research (CIHR) funded the HELPinKIDS team in 2012. The team produced and posted a 20-minute video about vaccination pain management targeting HCPs and parents, onto YouTube. This video was updated in 2015 (13:08 minutes long) and includes explanations of different pharmacological and psychological strategies that parents can use during their child's vaccination (<https://www.youtube.com/watch?v=5Oqa1Fag5eQ>). The usefulness and efficacy of this video were evaluated as part of an educational package of materials, delivered face-to-face at prenatal sessions, to parents and was found to be successful in increasing the attempted use of recommended

pain management strategies during vaccination of infants (Chan, Pielak, McIntyre, Deeter, & Taddio, 2013; Taddio, Parikh, et al., 2015; Taddio, Smart, et al., 2014). In fact, the difference in the utilization rate of at least one of the effective pain management strategies at follow-up vaccination was reported to be 36% between study groups (intervention group 41 (68%) vs 21 (32%) control group, $p < 0.01$) (Taddio, Parikh, et al., 2015) and 17% (intervention group 30 (34%) vs 15 (17%) control group, $p < 0.01$) (Taddio, Smart, et al. 2014).

A parent targeted and mediated educational intervention, the first of the series of ‘Be Sweet to Babies’ videos, was developed and posted onto YouTube in 2013 (Harrison, Wilding, et al., 2016). This series of videos which were co-produced with parents of infants is targeted specifically at parents, to inform them about pain management during painful procedures during newborn blood work (showing breastfeeding, skin to skincare and sucrose), and infants during vaccination (showing breastfeeding and sucrose) (<https://www.youtube.com/playlist?list=PLIZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB>).

The first video, posted in 2013, demonstrated breastfeeding and sweet solutions for pain reduction during infant vaccination. This resulted in more than 65,000 views a year after release (Harrison, Wilding, et al., 2016). Following the evaluation, the Be Sweet to Babies was reproduced in three separate brief videos showing:

- i) Breastfeeding during 2-month vaccination

(<https://www.youtube.com/watch?v=FrKmAth4ZGc&list=PLIZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB&index=9>);

- ii) Breastfeeding during a 6-month vaccination

(<https://www.youtube.com/watch?v=55tejVjzzwE&list=PLIZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB&index=12>),

iii) Sucrose in infants less than 12 months of age during vaccination

(<https://www.youtube.com/watch?v=7NDJ463j2iI&list=PLIZczt8t4Ac8cW3pbuRKJAEs3SoC5y8MB&index=16>).

These videos produced by the HELPinKIDS and the Be Sweet to Babies teams are examples of KT resources disseminated using social media. It is not yet known if the videos themselves have resulted in increased use of breastfeeding or sweet solutions during infant vaccination, or whether additional strategies can further support parents to advocate for their infant's pain management.

In one study, parents of infants reported that if both pamphlets and videos were offered, this combination can increase the learning potential (Taddio et al., 2013). Another RCT study by Taddio et al. (2014) evaluated the effectiveness of educational materials for parents about vaccination pain management. After exposure to interactive presentation about vaccination pain management (intervention group) or general vaccination information (control group) in prenatal class, they showed an increased use of sweet solutions (10.5% vs. 0%; $p=0.005$) and topical anesthetics (5.3% vs. 0%; $p=0.049$) compared to the control group with no intervention (standard care). However, no difference was reported in the use of breastfeeding (5.3% vs. 9.6%; $p=0.551$). A key limitation to the study was that only 19 of the total 37 participating parents (21%) reported reading the pamphlet. They suggested adding a more "active" teaching or dissemination technique for parent education in future knowledge translation initiatives (Taddio, Smart, et al., 2014).

As Taddio et al. in 2014 showed, providing information about vaccination pain management, on its own, resulted in increased attempts by mothers to use pain management strategies during their infants' vaccination, however, these attempts were not always successful due to HCPs' resistance to the mothers' requests. Therefore, evaluating whether an additional strategy which supports mothers to openly discuss their preferences for pain management with HCPs is important in understanding

what strategies effectively increase the use of recommended pain management methods. For example, motivational interviewing (MI) is supported in the literature but is yet untried in any area targeting parents of infants or children about pain management.

Summary

In summary, little is known about the extent to which evidence-based effective pain management strategies for infants during vaccinations are included in online information available to parents. In addition, no study has evaluated the acceptability, feasibility and preliminary efficacy of parent-targeted KT interventions aimed at increasing the use of recommended pain management strategies during vaccination. In fact, it is not known if providing parents with information about effective online pain management during infant vaccination, with or without provision of additional MI strategies, will result in increased use of recommended effective pain management strategies for infants during subsequent vaccination.

As a result, two independent studies were conducted to address these knowledge gaps: i) a prospective pilot RCT to evaluate feasibility, acceptability and preliminary efficacy of a parent-targeted KT intervention for improving the use of recommended pain management strategies during infant vaccination, with and without MI-based affirmation statements and questions; ii) a cross-Canada online environmental scan to critically appraise publicly available parent-targeted resources about infant vaccination.

References

- Alshaikh, F., Ramzan, F., Rawaf, S., & Majeed, A. (2014). Social network sites as a mode to collect health data: a systematic review. *Journal of Medical Internet Research, 16* (7), e171.
- Anderson, J. W., Johnstone, B. M., & Remley, D. T. (1999). Breast-feeding and cognitive development: a meta-analysis. *The American Journal of Clinical Nutrition, 70*(4), 525–535.
- April, K. T., Rader, T., Hawker, G. A., Stacey, D., O'Connor, A. M., Welch, V., ... Bennett, C. (2016). Development and alpha-testing of a stepped decision aid for patients considering nonsurgical options for knee and hip osteoarthritis management. *The Journal of Rheumatology, 43*(10), 1891–1896.
- Axelin, A., Lehtonen, L., Pelander, T., & Salanterä, S. (2010). Mothers' different styles of involvement in preterm infant pain care. *Journal of Obstetric, Gynecologic & Neonatal Nursing, 39*(4), 415–424.
- Axia, G., & Bonichini, S. (2005). Are babies sensitive to the context of acute pain episodes? Infant distress and maternal soothing during immunization routines at 3 and 5 months of age. *Infant and Child Development, 14*(1), 51–62.
- Benoit, B., Martin-Misener, R., Latimer, M., & Campbell-Yeo, M. (2017). Breast-Feeding Analgesia in Infants. *The Journal of Perinatal & Neonatal Nursing, 31*(2), 145–159.
- BORN Ontario. (2016). Better Outcomes Registry and Network. Data Analysis for Annual Report 2014-2016. Retrieved June 10, 2019, from https://www.bornontario.ca/assets/documents/Annual_report_2014-2016_-_Data_Slides.pdf
- Brouwers, M., Stacey, D., & O'Connor, A. (2010). Knowledge creation: synthesis, tools and products. *Cmaj: Canadian Medical Association Journal, 182*(2), E68–E72.
- Brouwers, M., Kho, M. E., Browman, G. P., Burgers, J. S., Cluzeau, F., Feder, G., ... Zitzelsberger, L., for the AGREE Next Steps Consortium. (2010). AGREE II: Advancing guideline

- development, reporting and evaluation in healthcare. *Canadian Medical Association Journal*, 182(18), E839-42.
- Bueno, M., Yamada, J., Harrison, D., Khan, S., Ohlsson, A., Adams-Webber, T., ... Stevens, B. (2013). A systematic review and meta-analyses of nonsucrose sweet solutions for pain relief in neonates. *Pain Research and Management*, 18(3), 153–161.
- Canadian Institute of Health Research (CIHR). (2016). Knowledge Translation. Retrieved February 7, 2019, from <http://www.cihr-irsc.gc.ca/e/29418.html>
- Carey, K. B., Scott-Sheldon, L. A. J., Carey, M. P., & DeMartini, K. S. (2007). Individual-level interventions to reduce college student drinking: A meta-analytic review. *Addictive Behaviors*, 32(11), 2469–2494.
- Centers for Disease Control and Prevention. (2017). Vaccines & Immunizations. Retrieved 08.2018, from https://www.cdc.gov/vaccines/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fdefault.htm
- Centers for Disease Control and Prevention. (2018). Nationwide Breastfeeding Goals. Retrieved February 7, 2019, from <https://www.cdc.gov/breastfeeding/data/facts.html>
- Chambers, C. T., Taddio, A., Uman, L. S., McMurtry, C. M., & Team, Help. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review. *Clinical Therapeutics*, 31, S77–S103.
- Chan, S., Pielak, K., McIntyre, C., Deeter, B., & Taddio, A. (2013). Implementation of a new clinical practice guideline regarding pain management during childhood vaccine injections. *Paediatrics & Child Health*, 18(7), 367–372.
- Chen, S. L., Harrison, D., Huang, R. R., Zhang, Q., Xie, R. H., & Wen, S. W. (2016). Efficacy of

sweet solutions in relieving pain caused by vaccination in infants aged 1 to 12 months: a systematic review. *Chinese Journal of Contemporary Pediatrics*, 18(6), 534-540.

Coulter, A., & Ellins, J. (2007). Effectiveness of strategies for informing, educating, and involving patients. *BMJ (Clinical Research Ed.)*, 335(7609), 24–7.

Department of Health and Human Services, Government of U.S. (2019). Healthy People 2020 Objectives. Retrieved February 7, 2019, <https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives>

DiLorenzo, M. G., Riddell, R. P., Flora, D. B., & Craig, K. D. (2018). Infant Clinical Pain Assessment: Core Behavioral Cues. *The Journal of Pain*, 19(9), 1024–1032.

Dol, J., Richardson, B., Boates, T., & Campbell-Yeo, M. (2018). Learning to parent from Google? Evaluation of available online health evidence for parents of preterm infants requiring neonatal intensive care. *Health Informatics Journal*, 25(4), 1265–1277.

Dunn, C., Deroo, L., & Rivara, F. P. (2001). The use of brief interventions adapted from motivational interviewing across behavioral domains: a systematic review. *Addiction*, 96(12), 1725–1742.

Farkas, C., Solodiuk, L., Taddio, A., Franck, L., Berberich, F. R., LoChiatto, J., & Solodiuk, J. C. (2015). Publicly Available Online Educational Videos Regarding Pediatric Needle Pain. *The Clinical Journal of Pain*, 31(6), 591–598.

Fitzgerald, M., & Walker, S. M. (2009). Infant pain management: a developmental neurobiological approach. *Nature Reviews Neurology*, 5(1), 35.

Franck, L. S., Berberich, F. R., & Taddio, A. (2015). Parent participation in a childhood immunization pain reduction method. *Clinical Pediatrics*, 54(3), 228–235.

Gance-Cleveland, B. (2007). Motivational interviewing: improving patient education. *Journal of Pediatric Health Care*, 21(2), 81–88.

- Gayes, L. A., & Steele, R. G. (2014). A meta-analysis of motivational interviewing interventions for pediatric health behavior change. *Journal of consulting and clinical psychology*, 82(3), 521.
- Government of Canada, Public Health Agency of Canada. (2019). National Advisory Committee on Immunization (NACI) - Immunization and Vaccines - Public Health Agency of Canada. Retrieved 07.2019 from <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>
- Gupta, S., & McKibbin, A. (2013). Informatics interventions. In J., & Graham, I. D, *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 3.4e, pp. 189-197). New Jersey, USA: John Wiley & Sons.
- Harrison, D. (2014). Be Sweet to Babies. Retrieved August, 2018, from <https://www.youtube.com/watch?v=L43y0H6XEH4&list=PLlZczt8t4Ac8cW3pbuRKJAEs3SoC5y8MB>.
- Harrison, D., Beggs, S., & Stevens, B. (2012). Sucrose for procedural pain management in infants. *Pediatrics*, 130(5), 918–925.
- Harrison, D., Elia, S., Manias, E., & Royle, J. (2014). Sucrose and lollipops to reduce immunisation pain in toddlers and young children: Two pilot randomised controlled trials. *Neonatal, Paediatric & Child Health Nursing*, 17(1), 19.
- Harrison, D., Elia, S., Royle, J., & Manias, E. (2013). Pain management strategies used during early childhood immunisation in Victoria. *Journal of Paediatrics and Child Health*, 49(4), 313–318.
- Harrison, D., Larocque, C., Reszel, J., Harrold, J., Aubertin, C. (2017). Be Sweet to Babies during painful procedures. *Advances in Neonatal Care*, 17(5), 372–380.
- Harrison, D., Modanloo, S., Desrosiers, A., Poliquin, L., Bueno, M., Reszel, J., & Sampson, M. (2018). A systematic review of YouTube videos on pain management during newborn blood

tests. *Journal of Neonatal Nursing*. 24(6), 325-330.

Harrison, D., Reszel, J., Bueno, M., Sampson, M., Shah, V. S., Taddio, A., ... Turner, L. (2016).

Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database of Systematic Reviews 2016*, Issue 10. Art. No.: CD011248.

Harrison, D., Sampson, M., Reszel, J., Abdulla, K., Barrowman, N., Cumber, J., ... Pound, C. M.

(2014). Too many crying babies: a systematic review of pain management practices during immunizations on YouTube. *BMC Pediatrics*, 14(1), 134.

Harrison, D., Stevens, B., Bueno, M., Yamada, J., Adams-Webber, T., Beyene, J., & Ohlsson, A.

(2010). Efficacy of sweet solutions for analgesia in infants between 1 and 12 months of age: a systematic review. *Archives of Disease in Childhood*, 95(6), 406–413.

Harrison, D., Wilding, J., Bowman, A., Fuller, A., Nicholls, S. G., Pound, C. M., ... Sampson, M.

(2016). Using YouTube to disseminate effective vaccination pain treatment for babies. *PLoS One*, 11(10), e0164123.

Harrison, D., Yamada, J., Adams-Webber, T., Ohlsson, A., Beyene, J., & Stevens, B. (2015). Sweet

tasting solutions for reduction of needle-related procedural pain in children aged one to 16 years. *Cochrane Database Systematic Reviews*, 2015:5.CD008408.

Harrison, G., Graham, I., Fervers, B., & Hoek, J. (2013). Adapting knowledge to local context. In

Straus, S. E., Tetroe, J., & Graham, I. D, *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 3.2, pp. 110-120). New Jersey, USA: John Wiley & Sons.

International Association for the Study of Pain (IASP). Pain terminology, (2017). Retrieved 07/2019,

from <https://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1698#Pain>

International Council of Nurses, *Code of Ethics for Nurses*. (2017). Retrieved 07/2019, from

<https://www.cna->

[aiic.ca/~media/cna/page-content/pdf-en/code-of-ethics-2017-edition-secure-interactive](https://www.cna-aiic.ca/~media/cna/page-content/pdf-en/code-of-ethics-2017-edition-secure-interactive)

Ismail, S. J., Langley, J. M., Harris, T. M., Warshawsky, B. F., Desai, S., & FarhangMehr, M. (2010).

Canada's National Advisory Committee on Immunization (NACI): evidence-based decision-making on vaccines and immunization. *Vaccine*, 28, A58–A63.

Jarrett, C., Wilson, R., O'Leary, M., Eckersberger, E., & Larson, H. J. (2015). Strategies for

addressing vaccine hesitancy—A systematic review. *Vaccine*, 33(34), 4180–4190.

Johnson, M. (2017). Motivational interviewing for vaccine hesitant parents. (Doctoral dissertation).

Boston University, USA.

Kassab, M., Foster, J. P., Foureur, M., & Fowler, C. (2012). Sweet-tasting solutions for needle-

related procedural pain in infants one month to one year of age. *Cochrane Database of*

Systematic Reviews 2012, Issue 12. Art. No.: CD008411

Kassab, M., Sheehy, A., King, M., Fowler, C., & Foureur, M. (2012). A double-blind randomised

controlled trial of 25 % oral glucose for pain relief in 2-month old infants undergoing

immunisation. *International Journal of Nursing Studies*, 49(3), 249–256.

Kikuta, A., Gardezi, F., Dubey, V., & Taddio, A. (2011). Practices and perceptions regarding pain

and pain management during routine childhood immunizations: Findings from a focus-group

study with nurses working at Toronto Public Health, Ontario. *Canadian Journal of Infectious*

Diseases and Medical Microbiology, 22(2), 43-48.

Kikuta, A., Boon, H., & Shah, V. (2010). Survey of attitudes and practices of physicians and nurses

regarding analgesia during routine childhood immunizations. *Canadian Journal of Infectious*

Diseases and Medical Microbiology, 21(4), 197.

Larson, H. J., Cooper, L. Z., Eskola, J., Katz, S. L., & Ratzan, S. (2011). Addressing the vaccine

- confidence gap. *The Lancet*, 378(9790), 526–535.
- Leite, A. M., Linhares, M. B. M., Lander, J., Castral, T. C., dos Santos, C. B., & Silvan Scochi, C. G. (2009). Effects of Breastfeeding on Pain Relief in Full-term Newborns. *The Clinical Journal of Pain*, 25(9), 827–832.
- Lisi, D., Campbell, L., Riddell, R. P., Garfield, H., & Greenberg, S. (2013). Naturalistic parental pain management during immunizations during the first year of life: Observational norms from the OUCH cohort. *PAIN*, 154(8), 1245–1253.
- Lundahl, B. W., Kunz, C., Brownell, C., Tollefson, D., & Burke, B. L. (2010). A meta-analysis of motivational interviewing: Twenty-five years of empirical studies. *Research on Social Work Practice*, 20(2), 137–160.
- McMullan, M. (2006). Patients using the Internet to obtain health information: how this affects the patient–health professional relationship. *Patient Education and Counseling*, 63(1–2), 24–28.
- O’Brien, K., Bracht, M., Macdonell, K., McBride, T., Robson, K., O’Leary, L., ... Lee, S. K. (2013). A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit. *BMC Pregnancy and Childbirth*, 13 Suppl 1(Suppl 1), S12.
- O’Neill, M. C., Ahola Kohut, S., Pillai Riddell, R., & Oster, H. (2019). Age Related Differences in the Acute Pain Facial Expression During Infancy. *European Journal of Pain*. 2019; 00:1-12.
- Pakpour, A. H., Gellert, P., Dombrowski, S. U., & Fridlund, B. (2015). Motivational interviewing with parents for obesity: an RCT. *Pediatrics*, 135(3), e644–e652.
- Parvez, E., Stinson, J., Boon, H., Goldman, J., Shah, V., & Taddio, A. (2010). Mothers' beliefs about analgesia during childhood immunization. *Paediatrics Child Health*, 15(5), 289-293.
- Posthumus, A. G., Schölmerich, V. L. N., Waelput, A. J. M., Vos, A. A., De Jong-Potjer, L. C., Bakker, R., ... Denktaş, S. (2013). Bridging between professionals in perinatal care: Towards

- shared care in the Netherlands. *Maternal and Child Health Journal*, 17(10), 1981–1989.
- Power, N., & Franck, L. (2008). Parent participation in the care of hospitalized children: A systematic review. *Journal of Advanced Nursing*, 62(6), 622–641.
- Prochaska, J. O., & DiClemente, C. C. (1982). Transtheoretical therapy: Toward a more integrative model of change. *Psychotherapy: Theory, Research & Practice*, 19(3), 276.
- Public Health Agency of Canada (2015). Vaccine coverage in Canadian children: Results from the 2011 Childhood National Immunization Coverage Survey. Retrieved 7/2019, from http://publications.gc.ca/collections/collection_2018/aspc-phac/HP40-156-2018-eng.pdf
- Public Health Agency of Canada (2016.). Publicly funded immunization programs in Canada - routine schedule for infants and children including special programs and catch-up programs. Retrieved 7/2019 from <http://www.phac-aspc.gc.ca/im/ptimprog-progimpt/table-%0A1-eng.php>.
- Quach, S., Pereira, J. A., Russell, M. L., Wormsbecker, A. E., Ramsay, H., Crowe, L., ... Kwong, J. (2013). The good, bad, and ugly of online recruitment of parents for health-related focus groups: lessons learned. *Journal of Medical Internet Research*, 15(11), e250.
- Ramenghi, L. A., Webb, A. V., Shevlin, P. M., Green, M., Evans, D. J., & Levene, M. I. (2002). Intra-oral administration of sweet-tasting substances and infants' crying response to immunization: a randomized, placebo-controlled trial. *Biology of the Neonate*, 81(3), 163–9
- Registered Nurses' Association of Ontario (2013). *Assessment and Management of Pain* (3rd ed.). Toronto, ON: Registered Nurses' Association of Ontario.
- Riddell, R. P., Taddio, A., McMurtry, C. M., Chambers, C., Shah, V., & Noel, M. (2015). Psychological interventions for vaccine injections in young children 0 to 3 years: systematic review of randomized controlled trials and quasi-randomized controlled trials. *The Clinical Journal of Pain*, 31(Suppl 10), S64.

- Riddell, R. R. P., Racine, N. M., Gennis, H. G., Turcotte, K., Uman, L. S., Horton, R. E., ... Lisi, D. M. (2015). Non-pharmacological management of infant and young child procedural pain. *Cochrane Database of Systematic Reviews* 2015, Issue 12. Art. No.: CD006275.
- Rollnick, S., Miller, W. R., Butler, C. C., & Aloia, M. S. (2008). *Motivational interviewing in health care: helping patients change behavior*. (pp. 3-33), New York: Guilford Press
- Roskin, J. A., Diviney, J., & Nanduri, V. (2014). The time to diagnosis of all childhood cancers presenting to a paediatric oncology shared care unit. *Arch Dis Child*, 99, A111.
- Russell, K., & Harrison, D. (2015). Managing pain in early childhood immunisation. *Kai Tiaki: Nursing New Zealand*, 21(2), 22.
- Ryan, G. S. (2013). Online social networks for patient involvement and recruitment in clinical research. *Nurse Researcher*, 21(1), 35–39.
- Rycroft-Malone, J., & Bucknall, T. (2010). Using theory and frameworks to facilitate the implementation of evidence into practice. *Worldviews on Evidence-Based Nursing*, 7(2), 57–58.
- Saarinen, H. L. (2010). Breastfeeding During Infant Immunization. (Doctoral dissertation), North Dakota State University, USA.
- Sampson, M., Cumber, J., Li, C., Pound, C. M., Fuller, A., & Harrison, D. (2013). A systematic review of methods for studying consumer health YouTube videos, with implications for systematic reviews. *PeerJ*, 1, e147-e147.
- Schechter, N., Bernstein, B., & Zempsky, W. (2010). Educational outreach to reduce immunization pain in office settings. *Pediatrics*. 126(6), e1514-e1521.
- Schein, R., Wilson, K., & Keelan, J. E. (2011). Literature review on effectiveness of the use of social media: a report for Peel Public Health. Retrieved from <https://www.peelregion.ca/health/resources/pdf/socialmedia.pdf>

- Schumacher, J. A., & Madson, M. B. (2014). *Fundamentals of motivational interviewing: Tips and strategies for addressing common clinical challenges*. Oxford University Press. New York, USA.
- Schurman, J. V., Deacy, A. D., Johnson, R. J., Parker, J., Williams, K., Wallace, D., ... Mroczka, K. (2017). Using quality improvement methods to increase use of pain prevention strategies for childhood vaccination. *World Journal of Clinical Pediatrics*, 6(1), 81.
- Shah, A. P. (2008). Sucrose is effective as an analgesic during infant immunizations (Pediatrics 2008; 121). *Pediatric Emergency Care*, 24, 21–27.
- Shah, P. S., Herbozo, C., Aliwalas, L. L., & Shah, V. S. (2012). Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database of Systematic Reviews*, (12). Issue 12. Art. No.: CD004950.
- Shah, V., Taddio, A., McMurtry, C. M., Halperin, S. A., Noel, M., Riddell, R. P., & Chambers, C. T. (2015). Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: systematic review and meta-analysis. *The Clinical Journal of Pain*, 31(Suppl 10), S38.
- Skene, C., Franck, L., Curtis, P., & Gerrish, K. (2012). Parental Involvement in Neonatal Comfort Care. *JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing*, 41(6), 786–797.
- Sobell, L. C., & Sobell, M. B. (2008). Motivational interviewing strategies and techniques: Rationales and examples. Retrieved on April, 24, 2019, from https://ucedd.georgetown.edu/DDA/documents/mi_rationale_techniques
- Stacey, D., & Hill, S. (2013). Patient-direct and patient-mediated KT interventions. In *Knowledge Translation in Health Care: Moving from Evidence to Practice*, (2nd ed., Chapter 3.4f, pp.197–211). John Wiley & Sons, New Jersey, USA.

Statistics Canada. (2010). Internet use by individuals, by type of activity (Internet users at home).

Retrieved October 29, 2017, from <http://www.statcan.gc.ca/tables-tableaux/sum-som/101/cst01/comm29a-eng.htm>

Stevens, B., Yamada, J., Ohlsson, A., Haliburton, S., & Shorkey, A. (2016). Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database of Systematic Reviews* 2016, Issue 7. Art. No.: CD001069. DOI: 10.1002/14651858.CD001069.pub5.

Straus, S. E., Tetroe, J. M., & Graham, I. D. (2013). Knowledge translation is the use of knowledge in health care decision making. *Journal of Clinical Epidemiology*, 64(1), 6–10.

Sudsawad, P. (2007). *Knowledge translation: Introduction to models, strategies, and measures*. Austin, TX: Southwest Educational Development Laboratory, National Center for the Dissemination of Disability Research.

Taddio, A., Chambers, C. T., Halperin, S. A., Ipp, M., Frpc, C., Lockett, D., ... Glasgow, F. (2009). Inadequate Pain Management During Routine Childhood Immunizations: The Nerve of It. *Clinical Therapeutics*, 31(C), S152–S167.

Taddio, A., Hogan, M.-E., Gerges, S., Girgis, A., Moyer, P., Wang, L., ... Ipp, M. (2012). Addressing parental concerns about pain during childhood vaccination: is there enough time to include pain management in the ambulatory setting? *The Clinical Journal of Pain*, 28(3), 238–242.

Taddio, A., Ilersich, A. L., Ipp, M., Kikuta, A., Shah, V., & Team, Help. (2009). Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations: systematic review of randomized controlled trials and quasi-randomized controlled trials. *Clinical Therapeutics*, 31, S48–S76.

Taddio, A., Ipp, M., Thivakaran, S., Jamal, A., Parikh, C., Smart, S., ... Katz, J. (2012). Survey of the

- prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine*, 30(32), 4807–4812.
- Taddio, A., Ipp, M., Vyas, C., Parikh, C., Smart, S., Thivakaran, S., ... Shah, V. (2014). Teaching parents to manage pain during infant immunizations: laying the foundation for better pain management practices. *The Clinical Journal of Pain*, 30(11), 987–994.
- Taddio, A., MacDonald, N. E., Smart, S., Parikh, C., Allen, V., Halperin, B., & Shah, V. (2014). Impact of a parent-directed pamphlet about pain management during infant vaccinations on maternal knowledge and behavior. *Neonatal Network*, 33(2), 74-82.
- Taddio, A., McMurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., ... Mousmanis, P. (2015). Reducing pain during vaccine injections: clinical practice guideline. *Canadian Medical Association Journal*, 187(13), 975–982.
- Taddio, A., Manley, J., Potash, L., Ipp, M., Sgro, M., & Shah, V. (2007). Routine immunization practices: use of topical anesthetics and oral analgesics. *Pediatrics*, 120(3), e637-e643.
- Taddio, A., Parikh, C., Yoon, E. W., Sgro, M., Singh, H., Habtom, E., ... Shah, V. (2015). Impact of parent-directed education on parental use of pain treatments during routine infant vaccinations: a cluster randomized trial. *Pain*, 156(1), 185–191.
- Taddio, A., Shah, V., Leung, E., Wang, J., Parikh, C., Smart, S., ... Sgro, M. (2013). Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics*, 13(1), 23.
- Taddio, A., Smart, S., Sheedy, M., Yoon, E. W., Vyas, C., Parikh, C., ... Shah, V. (2014). Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations: A cluster randomized trial. *Pain*, 155(7), 1288–1292.

- Tansky, C., & Lindberg, C. E. (2010). Breastfeeding as a pain intervention when immunizing infants. *The Journal for Nurse Practitioners*, 6(4), 287–295.
- Tustin, J. L. (2016). The Internet and Childhood Immunizations in Canada. (Doctoral dissertation), University of Toronto, Canada.
- Tustin, J. L., Crowcroft, N. S., Gesink, D., Johnson, I., & Keelan, J. (2018). Internet exposure associated with Canadian parents' perception of risk on childhood immunization: cross-sectional study. *JMIR Public Health and Surveillance*, 4(1), e7.
- Tustin, J. L., Crowcroft, N. S., Gesink, D., Johnson, I., Keelan, J., & Lachapelle, B. (2017). Facebook recruitment of vaccine-hesitant Canadian parents: cross-sectional study. *JMIR Public Health and Surveillance*, 3(3), e47.
- Valeri, B. O., Holsti, L., & Linhares, M. B. M. (2015). Neonatal pain and developmental outcomes in children born preterm: a systematic review. *The Clinical Journal of Pain*, 31(4), 355–362.
- World Health Organization. (2015). Weekly epidemiological record Relevé épidémiologique hebdomadaire. Retrieved February 2, 2018, from <http://www.who.int/wer>
- World Health Organization. (2019). Immunization, Vaccines and Biologicals. Retrieved July 2019, from <https://www.who.int/immunization/en/>

Chapter 2 - Theoretical Framework and Methods

In this chapter, the theoretical framework and the methods used in the two studies completed for this dissertation are presented. In this dissertation, the KTA framework informed the two studies with respect to design, methods, and interpretation of the results. Study 1 is a prospective two-armed pilot randomized controlled trial. Study 2 is an environmental scan of publicly available infant vaccination resources that parents may access in their search for vaccination information.

Purpose

Aim. The overarching aim of this dissertation is to improve the use of recommended pain management strategies during infant vaccination by investigating the quality and efficacy of evidence-based online parent resources.

Objectives.

Study 1:

i) Evaluate the feasibility and acceptability of study interventions, procedures, tools and processes in promoting the use of pain management strategies during vaccinations of infants at two, four or six months of age.

ii) Evaluate the preliminary efficacy of parent-targeted interventions prior to infant vaccination in promoting the use of pain management strategies during vaccinations of infants at two, four or six months of age.

iii) Identify the baseline knowledge, intention to use, and recommendation to use pain management strategies during vaccination of infants at two, four or six months of age.

Study 2: Identify and critically appraise the quality of online publicly available parent-targeted resources concerning early childhood vaccination, for infant pain management strategies.

Theoretical Framework

This dissertation is informed by the Knowledge to Action (KTA) framework (Appendix A). The theoretical underpinning of this dissertation is based on the knowledge creation and action cycle of the KTA framework, where knowledge about publicly available parent-targeted resources is synthesized and multifaceted, tailored KT interventions (e.g., parent resources) are disseminated with the aim of increasing the use of pain management strategies during vaccination of infants.

The Canadian Institutes of Health Research (CIHR) defines the term Knowledge Translation (KT) as “a dynamic and iterative process that includes the synthesis, dissemination, exchange, and application of knowledge to improve health, provide more effective health services and products and strengthen the healthcare system.” (Canadian Institutes of Health Research (CIHR), 2016). KT theories, models, and frameworks are being used in health research for different purposes such as improvement of patient outcomes and quality of care, explaining influences of contextual factors, evaluating knowledge uptake, dissemination, or adaptation of KT initiatives, helping in evaluating a KT process, research design, and interpretation of the results (Mitchell, et al., 2010; Rycroft-Malone & Bucknall, 2010). Using a theoretical or conceptual framework in implementation science is important to guide the development and processes of studies, inform the goal of the research, determine the study tools, evaluate rationale and eventually, assist in the explanation of the findings (Rycroft-Malone & Bucknall, 2010).

The KTA framework was developed based on over 30 planned action theories and illustrates a dynamic cycle including knowledge synthesis, dissemination, exchange and application, and strategies to facilitate the process of change (Graham et al., 2006). This framework presents the implementation of research findings by using the “knowledge creation funnel” from which research findings enter the “knowledge-to-action cycle”. KTA fosters an interactive cycle between knowledge

producers and end-users (Graham et al., 2006). The KTA framework is divided into two phases: knowledge creation and action cycle (Straus, Tetroe, & Graham, 2013). The process starts from the middle of the framework; knowledge creation (Appendix A). The inverted funnel represents production and synthesis of knowledge, which is further broken down into three phases: (1) knowledge inquiry, (2) knowledge synthesis, and (3) creation of knowledge products and/or tools. As knowledge moves down the funnel, it becomes more refined, more summarized and therefore more useful for knowledge users. The knowledge products in this funnel are categorized as three generations. First-generation knowledge, which is knowledge obtained from primary research studies. Second-generation knowledge is synthesized knowledge of individual research studies, such as systematic reviews, scoping reviews or meta-analyses. Third-generation knowledge consists of knowledge tools or products such as clinical practice guidelines, decision aids, rules, or care pathways (Brouwers, Stacey, & O'Connor, 2013).

In the next phase (action cycle), based on the results of the knowledge creation phase, knowledge enters the action cycle which includes, eight steps, each of which can be influenced by the knowledge creation phase (Straus, Tetroe, & Graham, 2013). The cycle starts by identifying the problem, assessing facilitators and barriers, selecting, tailoring, and implementing an intervention, monitoring, evaluating, and sustaining knowledge use (Graham et al., 2006). These two phases of knowledge creation and action are fluid, meaning that knowledge from the action phase can impact the knowledge creation phase and vice versa (Graham, Tetroe, & Group, 2007).

To address the topic of pain care during infant vaccination, the KTA framework informed the two studies in this dissertation with respect to design, methods, and interpretation of the results. Firstly, the research problem was identified and the supporting evidence around the topic was reviewed. In addition, knowledge had already been created and synthesized in the form of systematic

reviews and meta-analyses about vaccination pain management (Harrison, Reszel, et al., 2016; Riddell et al., 2015; Shah et al., 2015). Based on the knowledge creation, knowledge tools and products had been produced in the form of clinical practice guidelines (Taddio, McMurtry, et al., 2015), and parent-targeted videos and tip sheets, produced with community health partners (Taddio, Parikh, et al., 2015; Harrison, 2014; Taddio et al., 2013). Study 1 was built on the action cycle of the KTA framework. The evidence was adapted to the local context, and consumer-targeted interventions were selected, tailored and implemented. Finally, the use of knowledge (evidence-based pain management strategies) was monitored and the outcomes were evaluated. In line with the KTA knowledge creation phase, Study 2 of this dissertation was conducted; a review of existing online-based KT resources about vaccination pain management. This study aimed to create a knowledge base about resources accessible to parents. Each of the steps taken is presented in Study 1 and 2 of this dissertation and the findings are interpreted with an integrative approach in the integrated discussion chapter.

Methods of Study 1: Feasibility, Acceptability and Preliminary Efficacy Evaluation of a Parent-targeted Intervention

Study 1 of this dissertation was built on the action cycle of the KTA framework.

Dissemination and delivery of KT resources to knowledge users was the next step according to the action cycle (Straus, Tetroe, & Graham, 2013). To do so, the KT resources were selected, adapted to the local context, tailored and implemented, and the use of evidence-based pain management strategies was evaluated.

Study design. Study 1 is a prospective two-armed pilot randomized controlled trial (RCT). Well-conducted RCTs guard against the high risk of bias, for determining the efficacy of an intervention in clinical research and for establishing cause and effect relationships between intervention and outcomes (Lancaster, Dodd, & Williamson, 2004; Thabane et al., 2010). RCTs can provide high-quality evidence when there is uncertainty of the efficacy of an intervention. The first recommended step in planning a well-conducted high-quality RCT is to pilot test the study procedures, interventions and study tools. An acceptability and feasibility study allows the researcher to do a preliminary assessment of the study procedures, recruitment strategies, implementation, and evaluation (Lancaster et al., 2004; Thabane et al., 2010). Pilot studies are conducted before a larger clinical trial, on a smaller scale with similar procedures and methods. Typically, in pilot studies, the researchers aim to identify issues related to study design, sample size, data collection and analysis procedures (Harrison, Elia, Manias, & Royle, 2014).

Objectives.

i) To evaluate the feasibility and acceptability of data collection tools, participant recruitment procedures and implementation processes of parent targeted interventions prior to infant vaccination at two, four, or six months (primary outcome);

ii) To evaluate the preliminary efficacy of parent targeted interventions prior to infant vaccination in promoting the use of pain management strategies during vaccination of infants at two, four, or six months (secondary outcome);

iii) To identify parents' knowledge, previous use, intention and recommendation to use the recommended pain management strategies during vaccinations of infants at two, four, or six months (other outcomes).

Research questions.

i) Are the participant recruitment procedures, intervention delivery procedures, and data collection tools acceptable and feasible to allow parents to participate and complete the study?

ii) Does the MI-informed affirmative statement and questions (AS&Q) help in promoting the use of recommended pain management strategies during vaccinations of infants compared to the control group?

iii) Are parents aware of, or have they used any of the recommended pain management strategies before the intervention and do they intend to use or recommend these strategies to other parents in the future episodes of painful procedures in their infants?

Participants. Parents living in Canada with an infant under six months of age were invited to participate through an online recruitment process. Parents were eligible if they had an infant scheduled to receive their two, four, or six-month routine vaccination as per the childhood immunization schedule of the province the parents were living in, and they were able to read, speak and understand English sufficiently to understand the resources used in the intervention and complete the surveys. Exclusion criteria included parents who could not understand, read or communicate in English or were not planning to have their infant vaccinated.

Recruitment process. Brief information on the study goals and the researchers' affiliation, followed by a hyperlink to a survey, were posted on online platforms including Facebook, Twitter, and parent forums (Appendix B, advertisement script). The use of Internet-based methods for participant recruitment is cost-effective and potentially feasible in terms of reaching large numbers of people from broad ethnicity, cultural and geographical context (Cook et al., 2015; Ryan, 2013). This method also has been successful in reaching marginalized people due to easier access to people with a physical limitation or the ones who live far distances. One of the important advantages of online recruitment over the face to face method is decreasing participant burden, as it is much easier for them to withdraw at any time point without feeling any social pressure (Tustin, 2016; Ryan, 2013).

When participants clicked on the survey link, they were directed to a REDCap (Research Electronic Data Capture) survey. REDCap is an online and secure application for building surveys and managing databases. The first page contained questions to screen the potential respondents for research eligibility. Following the self-completion of the questions, if the respondents were not eligible, a brief message containing a thank-you note and explanation about their in-eligibility to continue the study was sent to them through REDCap system. However, if they met the listed screening criteria, they were directed to the next page which was the study's consent form (Appendix C). Participants were then invited to read the forms and provide online informed consent to participate in this study. They were then directed to the next page which was the demographic survey (Appendix D). A hyperlink directed participants to a brief baseline knowledge survey asking questions about previous awareness and intention to use specified recommended pain management strategies in their infants' future vaccination episodes (Appendix E). In addition, they were invited to provide an email address to be contacted for the following steps of the study.

Interventions. There were two interventions compared in this study: 1) Be Sweet to Babies videos and tip sheet (Intervention 1); and 2) Be Sweet to Babies videos, tip sheet and motivational interviewing-informed Affirmative Statements and Questions (AS&Q) (Appendix F) (Intervention 2). The Be Sweet to Babies vaccination pain management videos and tip sheets were provided to all participants. A link to the Be Sweet to Babies vaccination pain management videos showing parents how to use breastfeeding, upright secure holding, and small volumes of sweet solutions during vaccination was sent to all participants. The tip sheet is a KT resource previously developed in partnership with the Children's Hospital of Eastern Ontario (CHEO) and Ottawa Public Health (Appendix G) and has been publicly available on the Ottawa Public Health Website since June 2013. The content presented about pain management for infants during vaccination is the same information as illustrated in the video. Participants in the Intervention 2 group were also given AS&Q. This intervention follows the general principles of the MI approach. This AS&Q intervention consists of three scaled questions and four open-ended questions and presents brief informative and affirmative questions and statements. This aims to help the parents reflect on their own thoughts and support them to advocate for the use of the recommended pain management strategies during their infant's vaccination. The data on parents' reflections regarding questions four to seven are not collected as part of the study. Parents are encouraged to write their responses for their own reflections. AS&Q was developed by the researcher and reviewed further by a panel of parent representatives (five parents of infants living in Canada with different ethnic backgrounds, level of education, and English language skills) and HCP representatives (five nurses with experience working with parents and infants) and the research team with experience in KT research. Data were collected only for questions one, two, and three of AS&Q. As stated above, the goal in the final four open-ended questions was not to collect any information but aimed to encourage the parents to reflect on their own thoughts,

intentions, planned actions and confidence. The MI verbal approach involves: asking permission, change talk, and exploring the importance of the problem and the participant level of confidence with an issue. Open-ended questions, reflective listening, normalization, and the non-judgmental COLUMBO approach (named after the behavior of Peter Falk in a television series called Columbo), are used to help clients address discrepancies between what they say and their behavior. In addition, the MI approach includes statements supporting self-efficacy, readiness to change, affirmation, and advice/feedback to help patients argue for the importance of changing by realizing unexpected contradictions (Sobell & Sobell, 2008). The verbal MI approach has been well established in synthesized studies (Gayes & Steele, 2014), which were discussed earlier in this thesis. In this current study, the MI approach was modified for online delivery of statements and questions. This tool was reviewed by parents, HCPs representatives and KT specialists of this dissertation and revised according to their feedback. However, this online approach to delivering MI informed interventions has not previously been reported. Therefore, pilot testing this new MI-based intervention (AS&Q) to prepare the parents to take the lead in advocating for and using recommended pain management strategies during their infant's vaccination was one of the key aims of this thesis.

The AS&Q elements in this study are:

i) *Exploring importance and confidence*. This element aims to support the participants to acknowledge the need for behavior change (of advocating for pain management strategies during infant vaccination) and explore to what extent they are confident that this change is possible. In the intervention, statements and questions 1 and 2 address this element (Appendix F).

ii) *Readiness to change ruler*. This element allows the clinician/researcher to realize the participant's readiness and motivation to change by using a continuum from "0 not ready at all" to "5 ready to change definitely". Question number three is related to this element in the intervention,

specifically asking the parents to reflect on the following question. “How ready you are to use your choice of these pain management strategies during your baby’s vaccination. Rate your readiness on the scale below, from one not ready at all to five very ready”

iii) *Statement supporting self-efficacy.* This element aims to support the self-confidence of the participants in their ability to change. This relates to the importance and confidence and readiness to change scales. Questions one, two and three of this intervention are developed based on this MI principal.

iii) *Open-ended questions.* In this study, this element aims to encourage the participants to reflect on their stories, thoughts, experiences, concerns. These questions and statements can help the parents to have a deeper understanding of their views and concerns. Questions and statements four and five relate to this element.

iv) *Decisional balancing.* This aims to help the participant to realize the benefit and risks of the options they have in practice. This technique has been used in Study 2 for developing the open-ended questions of AS&Q.

v) *Affirmation.* These are statements that help the participants to realize their efforts, strengths, and successes by acknowledging their attempt to change behavior. All five questions are related to this MI principal. These five elements make up the AS&Q intervention. As specified above, data was collected for questions one, two, and three of AS&Q. The goal in questions four and five was to encourage the parents to reflect on their own thoughts.

Outcome measurements. The primary outcome was the feasibility and acceptability of the interventions and all study processes. Feasibility was evaluated by participation, consent, response, completion and attrition rates. Acceptability was measured with a self-report 14-item survey in which parents were asked to rate their agreement (Strongly Disagree, Disagree, Not Sure, Agree, Strongly

Agree) with statements about the interventions, study tools, procedure, and process. Pilot studies evaluating feasibility aim to identify potential methodological problems in the implementation of an intervention for consideration in planning for a larger study (Thabane et al., 2010).

The secondary outcome was to establish the preliminary efficacy of the interventions in increasing the use of recommended pain management strategies. Following the online delivery of the interventions, and the infants' vaccinations, the impact of the interventions was evaluated. This was measured by the number of vaccination episodes where any of the recommended pain management strategies were used during two, four, or six months scheduled infant vaccination.

Additional study data collected and outcomes included: demographic characteristics of parents/infant dyads, parents' baseline knowledge about the recommended pain management strategies, previous use of the recommended pain management strategies, intention to use the pain management strategies in future painful procedures and number of parents recommending the use of pain management to other parents. Outcomes were measured by self-report surveys.

These study data and outcomes were measured using data from four surveys:

1. Baseline demographic survey: Included 16 questions about parents' level of education, occupation, sex, age, ethnicity, marital status, number of other children, and their infant's date of birth, and sex.
2. Baseline knowledge survey: Included seven questions about parents' existing knowledge regarding the recommended pain management strategies.
3. Knowledge utilization survey: Included seven questions about the use of recommended pain management strategies at their infants' two, four, or six months vaccination time (Appendix H).

4. Acceptability survey: Included 15 questions about the understandability, applicability, and acceptability of the study procedures, data collection tools, educational materials, and interventions (Appendix I).

If parents had not completed the questionnaire after two weeks, up to three reminder emails were sent to them. Studies have shown that multiple reminders increase the response rates to surveys without being burdensome (Howell, Quine, & Talley, 2003; Dillman & Bowker, 2001). Following the study completion, all the parents were informed of their group allocation and they were re-offered the Be Sweet to Babies vaccination educational videos and tip sheet as well as a summary of the study results, written in a user-friendly format if they had indicated they would like to receive it.

Development and modification of surveys. The first three surveys used in this study were the modified version from a pilot study by the Be Sweet to Babies research team (Harrison et al., 2017). The surveys were then re-assessed by the study research team for face and content validity for the purpose of this current study. In addition, they were reviewed by parents and HCPs representatives prior to the study to ensure clarity and face validity in this population. The questions were then revised for comprehensiveness and clarity.

Sample size. A convenience sample of 50 parent/infant dyads in each group of control and intervention was considered to be sufficient to achieve the study's goals of evaluating all study processes and establishing preliminary efficacy of the intervention. In addition, it was anticipated that this sample size could potentially provide sufficient data to inform a sample size estimation for a full-scale RCT. Considering the possible attrition through the online delivery processes, the target study sample was increased to 150 parents in total.

Randomization. Eligible parents of infants who responded to the study invitation were randomized to either Intervention 1 or Intervention 2 in a 1:1 ratio before the infants' two, four, or

six-month vaccination. Participants were stratified according to the infant's age of receiving the vaccine (two, four, or six months).

Allocation concealment mechanism. The random allocation sequence was generated and concealed using a computer software generated random number list via the REDCap system.

Blinding. Parents were not told of the details of the interventions in the two study groups in the beginning of the study. The study was a partially blind design as just parents were blinded to which parent-targeted intervention they received.

Statistical methods. All data were collected electronically by using the REDCap survey tool. SPSS version 23.0 (SPSS Inc, Chicago, Illinois) was used to perform all descriptive and inferential statistical analyses. Descriptive data were summarized using means and standard deviations if normally distributed and medians and interquartile ranges if non-normally distributed. Demographic characteristics were analyzed using the Student's t-test for continuous data or chi-squared test for categorical data. For measuring the number of use of any one of recommended pain management strategies (Used/Not-used, dichotomous outcome) the chi-squared test and Mann-Whitney test were used.

Ethical considerations. The goal of the study was clearly explained in the online advertisement posts. At the beginning of entering the online study process, potential participants were invited to read the ethical approval forms from the University of Ottawa Research Ethics Board (REB), and parents were invited to give informed consent online if they were interested in taking part in this study. Obtaining and recording informed consent means that the respondents agreed freely to take part in the study and had an understanding of the study's goal, benefits, and risks (Kraut et al., 2004).

All respondents were notified that their participation was voluntary, and they were welcome to withdraw from the study at any stage. Participants were also assured that all personal information was kept confidential. The online recruitment of participants for research had minimal ethical risks. This method reduces the social pressure on participants to answer and participate in a survey and it makes it easier for them to withdraw without any pressure. If the participants decided to withdraw from the research, all the educational resources were sent to them after they clicked the “leave this study” button. To prevent multiple entries to the study, and to allow posting of all materials, participants were asked to submit their email address to complete the study.

In the following chapters, the results of the two studies of this dissertation are presented. Both studies were submitted for publication and the results are therefore presented according to the specific journals’ format.

Methods of Study 2: Parent Resources for Infant Vaccinations: A Cross-Canada Environmental Scan

Based on the identified research problem and evidence presented in Chapter 1 of this thesis, and in line with the knowledge creation phase in the KTA framework, Study 2, an environmental scan of publicly available infant vaccination resources was conducted. According to the KTA framework, KT resources such as videos, factsheets, booklets and websites can facilitate the process of understanding and application of evidence for knowledge users, in this case, parents of infants (Brouwers, Stacey, & O'Connor, 2013). Therefore, in Study 2, existing online resources about vaccination pain management were identified and critically appraised to create a knowledge base of publicly available quality KT resources for parents.

Objectives. To identify and critically appraise the quality of online publicly available parent-targeted resources concerning early childhood vaccination, for infant pain management strategies.

Research questions. i) What are the available online parent-targeted resources for vaccination of infants?; ii) Within these resources, what is the nature and quality of content focusing on evidence-based pain management strategies?

Study design. An environmental scan was conducted to online publicly available parent-targeted resources concerning early childhood vaccination. The resources were critically appraised for quality and content, regarding information about evidence-based recommended infant pain management strategies. An environmental scan is a passive and unobtrusive strategy to analyze the phenomena externally. The aim is to organize and collect information without interfering or changing the information (Hatch & Pearson, 1998). Environmental scans that have been used by business researchers are now recognized as a valuable strategy to provide policymakers with knowledge about the current context for any potential future change (Graham, Evitts, & Thomas-MacLean, 2008).

Search strategy. The environmental scan was conducted using two main Internet sources, Google searches and Social Media networks (Facebook, YouTube, and Twitter). The searches were conducted by one person (SM) in February 2018, using the most popular searched keywords according to the Google Trend (Google Trend, 2018). Google Trend allows the researcher to optimize their search results by selecting the most popular keywords used by the public when looking for online information. Multiple keywords were entered into the search toolbar of Google Trend. The output graphs showed a worldwide trend which could be adjusted by time range and country. As a result, the following search terms were used independently: a) Vaccine AND “Parent OR Mom OR Father” and b) “Childhood immunization”. Given the dynamic content of the Internet information, the search results were scanned over 24 hours in order to reduce the chance of changes in findings based on previous searches. A new account was used to search Facebook, YouTube, Twitter, and Google, to eliminate the interference of previous search history in new search results. The results of each search term (two different search terms) in each database (four different platforms) were scanned. The screening of the online resources followed a discontinuation rule (Sampson et al., 2013) to distinguish the most relevant resources from the less relevant ones. This rule allows the researcher to study only the highly-relevant results of web searches and is essential for the studies with a large or dynamically changing data that cannot easily be captured as a whole in one day. However, there was no protocol or guideline for this rule and we followed the validated structure reported by similar previous studies: The process was discontinued when 20 sequential records achieved redundancy. Since this discontinuation process has not been validated (Sampson, et al., 2013), the next 50 records were also screened to make sure no related resources were missed. Using this method, further screening is unlikely to result in additional eligible resources (Sampson et al. 2013). Each of the search engines of different social media platforms (i.e., Facebook, Twitter, and YouTube) were

searched separately for eligible resources. Moreover, Google's advanced search was then used to identify any further resources that may have been missed in the direct searching of social media. While searching YouTube, if a video met the inclusion criteria, the first five videos shown on the suggested marginal column (right side of the screen) were screened further for eligibility. This study followed the discontinuation rule published by Sampson et al. (2013) for screening YouTube videos (Sampson, et al., 2013). This method allows researchers to have relevant-ranked results out of the dynamic and huge size of records (Sampson, et al., 2013).

Selection of eligible resources. The following criteria were applied to include resources: a) accessible to Canadians; b) containing information relating to infant vaccinations, and c) parent-targeted (aiming to disseminate information to parents) about vaccination for infants. Resources were excluded if there were duplicates, related to animal vaccination, not parent-targeted (i.e., targeting health care providers), news or a commercial piece, focused on vaccination of children, adolescents or adults, related to anti- or pro-vaccination debates, not accessible to the public, or not informational (i.e., personal website, forums). There was no limit applied regarding the publication date. Two expert informants in the field of vaccination pain management in infants reviewed the final list of parent-targeted resources for completeness and suggested possible additional eligible resources if any. These experts included a professor with specialized knowledge in vaccination pain management and a nurse practitioner who advocates for the use of pain management strategies in childhood vaccination.

Data collection. Data were extracted by one screener (SM) into spreadsheets on Excel 2016 (Microsoft, Redmond, WA). The characteristics of each resource were collected (i.e., name, record type, upload/update date, affiliation, the Internet domain (.ca, .org, .com, etc.), and country of origin). Resources were screened further by same screener (SM) for information about pain management

strategies during vaccination information, and the accuracy of information was assessed against current evidence from clinical practice guidelines and systematic reviews (Harrison et al., 2016; Taddio, et al., 2015; Kassab, et al., 2012). Each resource was reviewed to determine the presence of information relating to breastfeeding, sweet solutions, or secure holding and close contact by caregivers during vaccination.

Quality appraisal. The final list of included resources was appraised independently by two reviewers (SM and JC) for quality assessment, using the Control and Prevention (CDC) Clear Communication Index (<https://www.cdc.gov/ccindex/index.html>) (Appendix J). The CDC tool presents the criteria used to evaluate consumer health-related information. This includes evaluation of accuracy and appropriateness of resources (based on resource audience) and detection of misleading or poor-quality information (Kaicker, et al., 2010). The tool was designed to identify the communication features of public resources that increase the understanding and clarity of the information, regardless of the format or distribution channel. It has four sections consisting of four open-ended questions and 20 scored items. Evaluation of the resources is based on the following seven categories; main message and call to action, language, information design, and state of the science, behavioral recommendations, numbers, and risk. The four sections include:

- Part A: Main message and call to action, literacy level, information design, state of the science;
- Part B: Behavioral recommendations;
- Part C: Numbers (Presenting the numbers that are necessary to support the main message in common terms for public);
- Part D: Risk (Explaining benefits and actual risk of behaviors, treatments, and preventive measures to non-expert audiences to make informed decisions) (Baur & Prue, 2014).

Scoring. CDC Clear Communication Index Score Sheet

(<https://www.cdc.gov/healthcommunication/pdf/clearcommunicationindex/fillableformmay2013.pdf>)

was used for Website records. The result obtained is based on 20 scored items. The scores were added up according to the Yes =1, or No = 0 answers. Questions 1-11 form Part A (11 scores), and questions 12-20 form Parts B (three scores), C (three scores), and D (three scores). All scores do not necessarily apply to all resources. For calculation of the total score, the total point that each record earned (numerator) was divided by the total possible points that the material could have earned (denominator) and multiplied by 100 (Note: the online tool does the required calculations). If the total score was 90 or above, it was considered to have addressed most of the required items that make the resource easy to understand and use. If the total score for the online resource was 89 or below, it meant the resource needed revision and improvement. The CDC index was chosen over similar quality appraisal tools introduced in the literature (Wiley et al., 2017; Charnock & Shepperd, 2004; Eysenbach, 2002), since it has been identified as a comprehensive tool for appraisal of health information in different formats (print and web, Facebook, written scripts, Tweets, infographics). However, the CDC index has not been used or validated for video format resources. In fact, there was no standardized tool or guideline for evaluating the quality of online information in video format (Drozd et al., 2018). However, CDC published a social media guideline and best practice on the process of preparing videos for CDC YouTube channels (Appendix K). This includes a list of recommendations for high-quality consumer-friendly video resources (Centers for Disease Control and Prevention, 2012). Therefore, in addition to the CDC Clear Communication tool, the guideline was also used to appraise the quality of video format resources in this study. The guideline evaluates video records in further domains including videos' content, authorities, length, date, reference, title,

description, keywords, category, and playlist. The total scoring added up to 20 points, the same as the websites score.

Two independent evaluators (SM and JC) participated in a training session (calibration exercise) for the CDC index scoring of resources. Their scores were gathered and compared to resolve any differences. Where there was disagreement, the resource was revisited and discussed. If disagreements remained, a third reviewer (DH) was consulted to reach a consensus.

Data analysis. Summary statistics and descriptive analysis were used to synthesize data regarding the characteristics of online resources. If data were normally distributed, mean and standard deviations, and minimum and maximum values were used. If data were not normally distributed or presented in a categorical format, median and interquartile range (IQR) or numbers and proportions were used.

The process of the search strategy, selection of eligible resources, data collection, and data analysis are presented in Chapter 4 for Study 2 of this dissertation.

References

- Baur, C., & Prue, C. (2014). The CDC Clear Communication Index is a new evidence-based tool to prepare and review health information. *Health Promotion Practice, 15*(5), 629–637.
- Brouwers, M., Stacey, D., & O'Connor, A., (2013). Knowledge translation tools. In Straus, S. E., Tetroe, J., & Graham, I. D, *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 2.2, pp. 50-62). New Jersey, USA: John Wiley & Sons.
- Canadian Institute of Health Research (CIHR). (2016). Knowledge Translation. Retrieved February 7, 2019, from <http://www.cihr-irsc.gc.ca/e/29418.html>
- Centers for Disease Control and Prevention. (2012). Social Media Guidelines and Best Practices: CDC YouTube Channel, 1–11, Retrieved August 2018, from <https://www.cdc.gov/SocialMedia/Tools/guidelines/pdf/onlinevideo.pdf>
- Centers for Disease Control and Prevention. (2014). CDC Clear Communication Index A Tool for Developing and Assessing CDC Public Communication Products User Guide CDC Clear Communication Index, 1–33., Retrieved, August 2018, from <https://www.cdc.gov/ccindex/tool/index.html>
- Charnock, D., & Shepperd, S. (2004). Learning to DISCERN online: applying an appraisal tool to health websites in a workshop setting. *Health Education Research, 19*(4), 440–446.
- Comparison of methods for recruiting and engaging parents in online interventions: study
- Cook, F., Seymour, M., Giallo, R., Cann, W., Nicholson, J. M., Green, J., & Hiscock, H. (2015). Comparison of methods for recruiting and engaging parents in online interventions: study protocol for the Cry Baby infant sleep and settling program. *BMC pediatrics, 15*(1), 174.
- Drozd, B., Couvillon, E., & Suarez, A. (2018). Medical YouTube videos and methods of evaluation: literature review. *JMIR medical education, 4*(1), e3.

- Eysenbach, G., Powell, J., Kuss, O., & Sa, E.-R. (2002). Empirical studies assessing the quality of health information for consumers on the World Wide Web: a systematic review. *JAMA*, 287(20), 2691–2700.
- Gayes, L. A., & Steele, R. G. (2014). A meta-analysis of motivational interviewing interventions for pediatric health behavior change. *Journal of Consulting and Clinical Psychology*, 82(3), 521.
- Google Trends. <https://trends.google.com/trends/?geo=CA>. (Accessed August, 2018).
- Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map? *Journal of Continuing Education in the Health Professions*, 26(1), 13–24.
- Graham, I. D., Tetroe, J., & Group, KT Theories Research Group. (2007). Some theoretical underpinnings of knowledge translation. *Academic Emergency Medicine*, 14(11), 936–941.
- Graham, P., Evitts, T., & Thomas-MacLean, R. (2008). Environmental scans: How useful are they for primary care research? *Canadian Family Physician*, 54(7), 1022–1023.
- Harrison, D. (2014). Be Sweet to Babies. Retrieved from <https://www.youtube.com/watch?v=L43y0H6XEH4&list=PLIZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB> (Accessed August, 2018).
- Harrison, D., Elia, S., Manias, E., & Royle, J. (2014). Sucrose and lollypops to reduce immunisation pain in toddlers and young children: Two pilot randomised controlled trials. *Neonatal, Paediatric & Child Health Nursing*, 17(1), 19.
- Harrison, D., Larocque, C., Reszel, J., Harrold, J., Aubertin, C. (2017). Be Sweet to Babies during painful procedures. *Advances in Neonatal Care*, 17(5), 372–380.
- Harrison, D., Reszel, J., Bueno, M., Sampson, M., Shah, V. S., Taddio, A., ... Turner, L. (2016). Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database of*

Systematic Reviews 2016, Issue 10. Art. No.: CD011248.

Hatch, T. F., & Pearson, T. G. (1998). Using environmental scans in educational needs assessment.

Journal of Continuing Education in the Health Professions, 18(3), 179–184.

Kaicker, J., Debono, V. B., Dang, W., Buckley, N., & Thabane, L. (2010). Assessment of the quality and variability of health information on chronic pain websites using the DISCERN instrument.

BMC Medicine, 8(1), 59.

Kassab, M., Foster, J. P., Foureur, M., & Fowler, C. (2012). Sweet-tasting solutions for needle-related procedural pain in infants one month to one year of age. *Cochrane Database of*

Systematic Reviews 2012, Issue 12. Art. No.: CD008411

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies:

recommendations for good practice. *Journal of Evaluation in Clinical Practice*, 10(2), 307–312.

Riddell, R. P., Taddio, A., McMurtry, C. M., Chambers, C., Shah, V., & Noel, M. (2015).

Psychological interventions for vaccine injections in young children 0 to 3 years: systematic review of randomized controlled trials and quasi-randomized controlled trials. *The Clinical Journal of Pain*, 31(Suppl 10), S64.

Ryan, G. S. (2013). Online social networks for patient involvement and recruitment in clinical research. *Nurse Researcher*, 21(1), 35–39.

Rycroft-Malone, J., & Bucknall, T. (2010). Using theory and frameworks to facilitate the

implementation of evidence into practice. *Worldviews on Evidence-Based Nursing*, 7(2), 57–58.

Sampson, M., Cumber, J., Li, C., Pound, C. M., Fuller, A., & Harrison, D. (2013). A systematic review of methods for studying consumer health YouTube videos, with implications for

systematic reviews. *PeerJ*, 1, e147-e147.

Shah, V., Taddio, A., McMurtry, C. M., Halperin, S. A., Noel, M., Riddell, R. P., & Chambers, C. T.

- (2015). Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: systematic review and meta-analysis. *The Clinical Journal of Pain*, 31(Suppl 10), S38.
- Sobell, L. C., & Sobell, M. B. (2008). Motivational interviewing strategies and techniques: Rationales and examples. Retrieved on April, 24, 2019, from https://ucedd.georgetown.edu/DDA/documents/mi_rationale_techniques
- Straus, S. E., Tetroe, J., & Graham, I. D. (2013). Introduction knowledge translation: what it is and what it isn't. In *Knowledge translation in health care: Moving from Evidence to Practice*, (2nd ed, Chapter 1.1., pp. 1–13). John Wiley & Sons, New Jersey, USA.
- Sudsawad, P. (2007). *Knowledge translation: Introduction to models, strategies, and measures*. Austin, TX: Southwest Educational Development Laboratory, National Center for the Dissemination of Disability Research.
- Taddio, A., McMurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., ... Mousmanis, P. (2015). Reducing pain during vaccine injections: clinical practice guideline. *Canadian Medical Association Journal*, 187(13), 975–982.
- Taddio, A., Parikh, C., Yoon, E. W., Sgro, M., Singh, H., Habtom, E., ... Shah, V. (2015). Impact of parent-directed education on parental use of pain treatments during routine infant vaccinations: a cluster randomized trial. *Pain*, 156(1), 185–191
- Taddio, A., Shah, V., Leung, E., Wang, J., Parikh, C., Smart, S., ... Sgro, M. (2013). Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics*, 13(1), 23.
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., ... Goldsmith, C. H. (2010). A

tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology*, 10(1), 1.

Tustin, J. L. (2016). *The Internet and Childhood Immunizations in Canada*. (Doctoral dissertation),

University of Toronto, Canada.

Wiley, K. E., Steffens, M., Berry, N., & Leask, J. (2017). An audit of the quality of online

immunisation information available to Australian parents. *BMC Public Health*, 17(1), 76.

Chapter 3 -The Feasibility, Acceptability, and Preliminary Efficacy of Parent-targeted Interventions in Vaccination Pain Management of Infants: A Pilot Randomized Control Trial (RCT)

Shokoufeh Modanloo*, PhD (c)^{1,2}, Sandra Dunn, RN, PhD^{1,2,3}, Dawn Stacey, RN, PhD^{1,4},

Denise Harrison, RN, PhD^{1,2}

1 School of Nursing, University of Ottawa,

2 Children's Hospital of Eastern Ontario (CHEO) Research Institute,

3 Better Outcomes Registry & Network (BORN),

4 Ottawa Hospital Research Institute, Ontario.

*Corresponding author, School of Nursing, Faculty of Health Sciences, University of Ottawa, Ottawa, Ontario. 451 Smyth road, Roger Guindon Hall

Conflicts of Interest and Source of Funding:

There is no conflict of interest to declare. Shokoufeh Modanloo has received an International Admission Scholarship and International Doctoral Scholarship from the University of Ottawa, Ottawa, Ontario. For the remaining authors none were declared.

This manuscript has been submitted to the Clinical Journal of Pain, thus it is formatted as per the journal requirements.

Abstract

Objectives. To evaluate the feasibility, acceptability and preliminary efficacy of parent-targeted interventions for improving the use of pain management strategies during vaccination of infants.

Methods. A two-armed pilot randomized control trial (RCT) was conducted. Two study groups: Intervention 1) Be Sweet to Babies videos and a tip sheet or Intervention 2; Intervention 1 plus a motivational interviewing informed Affirmative Statements and Questions (AS&Q). Data were collected by online surveys and included questions about knowledge and use of recommended strategies, and feasibility and acceptability of the study processes and interventions. Feasibility was evaluated by participation, consent, response, completion and attrition rates. Descriptive and inferential statistical analyses were used.

Results. A total of 201 parents responded to the online study advertisement post, of which 151 were subsequently randomized into the study groups (Intervention 1, n= 76, Intervention Two, n=75). Success of the recruitment process (151 people in a week), high rates of completed consent forms (170/201, 85%), completed surveys in total (89/151, 59%), over 95% use of pain management strategies following the interventions, over 94% satisfaction with interventions, study processes and 88% intention to recommend the strategies to other parents determined the feasibility and acceptability of the study. Most parents knew at baseline that breastfeeding (121, 76%), sweet solutions (104, 65%) and upright secure holding (93, 58%) reduced pain during vaccination; however, just over half of participants (83, 52%) had previously used these strategies. Following the intervention and subsequent vaccination, almost all parents used at least one pain management strategy (49/49 (100%) and 38/40 (95%) respectively for Intervention 1 and 2).

Discussion. The study interventions and processes were feasible and acceptable to those parents who completed the study. Recommended pain management strategies during vaccination were observed equally in both intervention groups.

Introduction

Early childhood vaccinations are vital for public health for the prevention of life-threatening infectious diseases worldwide (1). However, vaccinations are painful and result in distress and anxiety for infants and, in many cases, their parents (2). Untreated vaccination pain may lead to subsequent non-compliance with vaccination schedules, development of needle fears, and avoidance of future health care (3). It is reported that 63% of children have a fear of needles, and 10% of noncompliance with the vaccination schedule is reported to be due to needle-related pain (4).

Clinical practice guidelines (2) and high-quality synthesized evidence have shown that sucrose (5–7), breastfeeding (8), and upright secure holding (2) effectively reduce pain during vaccination in infants (9). A position statement published by the World Health Organization (WHO) recommends the administration of sweet-tasting oral vaccines before injections and breastfeeding infants during vaccination (10). Despite the evidence and national and international recommendations, published reports show that effective pain management strategies are inconsistently used for infants during vaccination (2, 11–13)

Inconsistent use of recommended pain management strategies may be partly due to the lack of parents' knowledge or confidence in using these strategies during painful procedures (14). Parents have reported dissatisfaction and lack of knowledge as the main barrier for advocating for pain management during painful procedures for their infants as well as a desire to learn more about effective pain care during needle-related procedures (15). To improve parents' knowledge, a series of videos were developed by the 'Be Sweet to Babies' team and Media House at the Children's Hospital of Eastern Ontario (CHEO) (16). Brief videos, co-produced by parents of infants and clinicians, demonstrate the use of breastfeeding, small volumes of sweet solutions and holding infants upright during vaccination. These videos are examples of knowledge translation (KT) tools, targeted at

parents with the aim of empowering parents to use and advocate for these strategies. The videos are posted on YouTube and hosted on the CHEO public Internet and are freely available through social media platforms (<http://yt.vu/p/PLIZczt8t4Ac8cW3pbuRKJAES3SoC5y8MB>).

However, education alone may not be sufficient to increase the use of recommended pain management strategies during infant vaccination. Additional strategies may empower parents to advocate for their infant's pain management. A strategy called Motivational Interviewing (MI), which is a patient (in this case, parents) centered method introduced by Rollnick & Miller in 1995 (17) can improve health outcomes by facilitating the process of change in health behaviors (18,19). The contribution of the MI approach to behavior change has been well established in synthesized studies (20,21). A meta-analysis of 119 MI studies reported that MI resulted in statistically significant behavior changes in a wide range of health problems from substance abuse, health-related behaviors (diet, exercise, and safe sex), gambling, and engagement in treatment variables (21). In addition, a systematic review of 37 studies with a pediatric focus found that MI was effective in changing both parents' (11 studies) and children's (23 studies) behaviors in different health conditions such as pediatric obesity, asthma, HIV/AIDS, type one diabetes, dental health, accident prevention, calcium intake (20). A motivational technique delivered online, based on principals of the MI approach may further support parents to advocate for use of effective and recommended pain management strategies during vaccination.

The Internet has increased public access to online health information, and social media specifically, is known to be an important influencing factor in parents' health behavior (23). Online platforms such as social media networks and parent forums are cost-effective pathways to reach out to parents, who live in different geographic locations (24,25). Thus, online delivery of information may be effective in preparing parents to use pain management strategies during the vaccination of

their infants. Therefore, the overall aim of this study was to investigate the feasibility, acceptability and, preliminary efficacy of parent-targeted interventions for pain management during vaccination of infants.

Materials and Methods

This study is informed by the KTA framework, which is an interactive dynamic cycle based on over 30 planned action theories (26). This study was informed by the action cycle of the KTA framework, where parent-targeted KT resources were implemented to increase the use of pain management strategies during vaccination of infants. Knowledge enters the action cycle which includes eight steps of identifying the problem, assessing facilitators and barriers, selecting, tailoring, and implementing an intervention, monitoring, evaluating, and sustaining knowledge use (26). Accordingly, in this study, the KT parent-targeted resources were selected, adapted to the local context, tailored and implemented, and the use of evidence-based pain management strategies was monitored and the outcome was evaluated.

Trial design. This study was a prospective two-armed pilot randomized controlled trial (RCT), aimed to evaluate the feasibility, acceptability and preliminary efficacy of parent-targeted interventions for vaccination pain management of infants. The objectives of this study were: i) to evaluate the feasibility and acceptability of data collection tools, participant recruitment procedures and implementation processes of parent-targeted interventions prior to infant vaccination at two, four, or six months; ii) to evaluate the preliminary efficacy of parent-targeted interventions prior to infant vaccination in promoting the use of pain management strategies during vaccination of infants at two, four, or six months, and iii) to identify parents' previous knowledge and use, plus intention and recommendation to use the recommended pain management strategies during their infants' two, four, or six months vaccination. This pilot RCT is registered with ClinicalTrials.gov with the ID number of

NCT03968432. The CONSORT 2010 checklist was used for reporting the RCT (<http://www.consort-statement.org/>).

Participants. Parents living in Canada with an infant under 6 months of age were invited to participate through an online recruitment process. Parents were eligible if they had an infant scheduled to receive their 2, 4, or 6-month routine vaccination as per the childhood immunization schedule of the province the parents were living in, and they were able to read, speak and understand English sufficiently to understand the videos and complete the surveys. Exclusion criteria included parents who could not understand, read or communicate in English or were not planning to have their infant vaccinated.

Recruitment process. Brief information on the study goals and the researchers' affiliation followed by a hyperlink to a survey were posted on online platforms including Facebook, Twitter, and parent forums. When participants clicked on the survey link, they were directed to a REDCap (Research Electronic Data Capture) survey. The first page included questions to screen the respondents for eligibility. If they were eligible, they were automatically invited online to provide consent to participate in the study, complete the demographic survey and answer seven questions about previous awareness and intention to use recommended pain management strategies during their infants' future vaccination. Finally, they were asked to provide an email address to be contacted for access to the study interventions.

Interventions. There were two interventions compared in this study: 1) Be Sweet to Babies Videos and tip sheet (Intervention 1); and 2) Be Sweet to Babies Videos, tip sheet, and motivational interviewing informed Affirmative Statements and Questions (AS&Q) (Intervention 2). The Be Sweet to Babies vaccination pain management videos and a tip sheet were provided to all participants as both resources are publicly available and demonstrate the efficacy of the evidence-based pain

management strategies for infants' vaccination. The tip sheet was developed in partnership with CHEO and Ottawa Public Health as a knowledge translation resource and is publicly available at (<http://www.parentinginottawa.ca/en/immunizations.aspx>). The content about pain management for infants during vaccination in the tip sheet is consistent with the information presented in the videos.

Participants in the Intervention 2 group were also provided with the AS&Q (Figure 1.). This intervention follows the general principles of the MI approach. The AS&Q included seven questions and statements based on the MI approach which was developed by the researcher and reviewed further by a panel of parent representatives (five parents of infants living in Canada with different ethnic backgrounds, level of education, and English language skills) and HCP representatives (five nurses with experience working with parents and infants) and the research team with experience in KT research. This AS&Q intervention consisted of three scaled questions and four open-ended questions, aimed to present brief informative and affirmative questions and statements to help the parents reflect on their own thoughts and support them to advocate for the use of the recommended pain management strategies during their infant's vaccination. Data were collected only in questions one, two, and three of AS&Q. The goal of the four final open-ended questions was not to collect any information but to encourage the parents to reflect on their own thoughts.

Outcome measurements

The primary outcome was the feasibility and acceptability of the interventions and all study processes. Feasibility was evaluated by participation, consent, response, completion and attrition rates. Acceptability was measured with a self-report 14-item survey in which parents were asked to rate their agreement (Strongly Disagree, Disagree, Not Sure, Agree, Strongly Agree) with statements about the interventions, study tools, procedures, and processes.

The secondary outcome was to establish the preliminary efficacy of the interventions in increasing the use of recommended pain management strategies. Following the online delivery of the interventions, and the infants' vaccinations, the impact of the interventions was evaluated. This was measured by the number/proportion of vaccination episodes where any of the recommended pain management strategies were used during 2, 4, or 6 months scheduled infant vaccination.

Additional study outcomes included: parents' baseline knowledge about the recommended pain management strategies, previous use of the pain management strategies, intention to use the pain management strategies in future painful procedures and recommendations to use the pain management strategies to other parents. Outcomes were measured by self-report surveys.

Data were collected using four brief study surveys:

Baseline demographic survey. Included 16 questions about parents' level of education, occupation, sex, age, ethnicity, marital status, number of other children, and their infant's date of birth, and sex.

Baseline knowledge survey. Included 7 questions about parents' existing knowledge regarding the recommended pain management strategies. All scored as dichotomous Yes or No.

Knowledge utilization survey. Included 7 questions about the use of recommended pain management strategies at their infants' 2, 4, or 6 months vaccination. All scored as dichotomous Yes or No.

Acceptability survey. Included 15 questions about understandability, applicability, and acceptability of the study procedure, tools, educational materials, and interventions.

Development and modification of surveys. The first three surveys were a slightly modified version from a pilot study by the Be Sweet to Baby research team (27). The surveys were then re-assessed by the study research team for face and content validity for the purpose of this current study.

In addition, they were reviewed by parents and HCPs representatives prior to the study to ensure clarity and face validity in this population. The questions were then revised for comprehensiveness and clarity. All the study's surveys were reviewed, confirmed and modified by a group of parents and HCPs representatives. If parents had not completed the surveys in two weeks after sending the links via email, a weekly email reminder was sent for a maximum of three weeks.

Three to four reminders have been shown to increase the response rates to surveys without being burdensome (28,29).

Sample size. A sample of 50 parent/infant dyads in each of the two intervention groups was considered sufficient to achieve the study's goal of evaluating the feasibility and acceptability of the parent-targeted and parent-mediated resources (30). In addition, it was anticipated that this sample could provide sufficient data to allow for the calculation of a sample size for a full-scale RCT. Considering the possible attrition through the online delivery processes, the target study sample was increased to 150 parents in total.

Randomization. Eligible parents of infants who responded to the study invitation were randomized to either Intervention 1 or 2 in a 1:1 ratio before the infants' 2, 4, or 6-months vaccination. Participants were stratified according to the infant's age of receiving the vaccine (two, four, or six months). The random sequence was generated using a computer software generated random number list via the REDCap system. The allocation sequence was concealed using a computer-generated randomization sequence system via the REDCap system.

Blinding. The study was a partially blinded design as the parents were blinded to which parent-targeted intervention they were receiving. They were not told about the differences in the interventions administered to the two study groups in the beginning.

Statistical methods. All data were collected electronically using the REDCap survey tool. SPSS version 23.0 (SPSS Inc, Chicago, Illinois) was used to perform all descriptive and inferential statistical analyses. Descriptive data were summarized using means and standard deviations for continuous data if normally distributed and medians and interquartile ranges if non-normally distributed. Demographic characteristics were analyzed using the Student's t-test for continuous data or chi-squared test for categorical data. For measuring the number/proportion of use of anyone recommended pain management strategies (Used/Not-used, dichotomous outcome), the chi-squared test and Mann-Whitney test were used.

Ethical considerations. The study was approved by the affiliated University Research Ethics Board (REB). At the beginning of entering the online study process, participants were asked to read the ethical approval forms, and give informed consent online. If the participants decided to withdraw from the research, all the educational resources were sent to them after they clicked the "leave this study" button. To prevent multiple entries to the study, and to allow posting of all materials, participants were asked to submit their email address to complete the study. In appreciation of the time participating, all participants were offered an e-gift card to Tim Horton's coffee stores in Canada (valued: \$10.00), at the completion of the data collection.

Results

Study participants. The study's advertisement scripts were distributed via Facebook, Twitter, Parent forums, between July 24th, 2018 and August 1st, 2018. A total of 201 people clicked on the eligibility criteria surveys within one week. A total of 170 of the 201 (85%) respondents consented to participate in the study and 162 (95%) completed the demographics survey. Demographic data for the 162 parents are therefore presented below. A total of 154 (90%) parents subsequently provided their email address, however three parents (2%) were missed in the processes before randomization. 151 parents were subsequently randomized to the treatment groups.

Demographic characteristics. Most participants enrolled prior to their infant's 4-month vaccination appointment (88/162, 54%) and most participants reported they saw the study's advertisement post on Facebook (98/162, 60%). Most participants were: mothers (158/162, 97%); married or in a common-law relationship (160/162, 98%), had a university-level education (128/162, 79%), were working full-time outside the home (117/162, 72 %) and were living in Ontario (105/162, 65 %). The mean age of participants was 30.2 years old (SD 3.6), and from diverse ethnicities, although most were Caucasian (93/162, 58%). Most were first-time mothers (116/162, 72%), had a vaginal delivery (118/162, 72%), and were currently breastfeeding (149/162, 92%).

“INSERT TABLE 1 HERE”. *Table 1. Characteristics of respondents to baseline demographic survey*

Baseline knowledge and previous use. The baseline knowledge survey of infant vaccination pain management was completed by 159 of the original 170 participants who consented to take part in the study (93%). Two-thirds of the respondents (100/159, 63%) had not seen the “Be Sweet to Babies” videos before. However, over two-thirds knew that breastfeeding (121/159, 76%) and sweet solutions (104/159, 65%) reduced vaccination pain in infants and over half (93/159, 58%) knew that upright secure holding helped to reduce distress during vaccination. Just over half the participants (83/159, 52%) had used at least one of these pain management strategies (Table 2).

“INSERT TABLE 2 HERE”. *Table 2. Knowledge and use of pain management strategies in respondents to baseline knowledge survey*

A total of 151 parents were randomized into the study groups (Intervention 1, n= 76, Intervention 2, n=75) before their infant's upcoming vaccination. Of these 151 parents, 89 (58%) continued in the study and completed all data collection evaluating feasibility and acceptability, and preliminary efficacy outcomes (Figure 2).

Feasibility and acceptability. Study feasibility was shown by the success of the recruitment process (151 people in a week), rates of completed consent forms (170/201, 85%), provision of email addresses (154/201, 77%) and number of participants randomized (151/201, 75%). However, 62 (41%) participants failed to complete the final surveys. This left only 89 of the 151 who were randomized (59%), completing all the study surveys. For those 89 parents who completed the full study, study acceptability was high, as shown by the level of satisfaction with the study tools, procedures, and interventions. Results showed that there were high satisfaction rates with the length of videos [Intervention 1 (48/49, 98%), Intervention 2 (40/40, 100%)], the time requirements for the study completion [Intervention 1 (48/49, 98%), Intervention 2 (38/40, 95%)], and overall satisfaction with participation in this study [Intervention 1 (47/49, 96%), Intervention 2 (40/40, 100%)] (Table 3). Most parents reported that the written information (Including AS&Q and tip sheet) [Intervention 1 (46/49, 94%), Intervention 2 (39/40, 97%)] and videos [Intervention 1 (47/49, 96%), Intervention 2 (40/40, 100%)] were helpful to them, and easy to apply in real life [Intervention 1 (46/49, 94%), Intervention 2 (38/40, 97%)]. They reported that the tip sheet was easy to read and understand [Intervention 1 (46/49, 94%), Two (37/40, 93%)], and the videos were easy to understand [Intervention 1 (48/59, 98%), Intervention 2 (40/40, 100%)]. In addition, most parents were interested in participating in a future study [Intervention 1 (46/49, 94%), Intervention 2 (38/40, 96%)]. Almost all would recommend breastfeeding, sucrose and/or upright holding to other parents [Intervention 1 (47/49, 96%); Intervention 2 (39/40, 98%)] and intended to use any of these strategies in their baby's future vaccination [Intervention 1 (49/49, 100 %); Intervention 2 (40/40, 100 %)] (Mostly breastfeeding [Intervention 1 (37/49, 75%); Intervention 2 (34/40, 85%)]. However, there were no statistically significant differences between the groups on any outcomes ($p > 0.05$). (Table 3).

“INSERT TABLE 3 HERE” *Table 3. Acceptability of study tools, procedure, and interventions by study participants*

Preliminary efficacy of interventions. Intervention 1 (Videos and a tip sheet) was received by 155 participants before randomization. Of the 75 participants randomized into the Intervention 2 group, only 43/75 (57%) answered the AS&Q survey. Of these, most participants rated the importance of using breastfeeding, sweet solutions or holding during their baby’s vaccination as “very important” (32/43, 74%); most felt “very confident” (30/43, 69%) to inform health care providers of their preferred pain management strategies, and most were “very ready” (35/43, 81%) to use their chosen pain management strategy in the upcoming vaccination of their infants (Figure 3).

“INSERT FIGURE 3 HERE”. *Figure 3. Affirmative Statements and Questions (AS&Q)*

The knowledge utilization survey was completed by 89 participants randomized to Intervention 1 (49, 47%) and intervention 2 (40, 53%). The results showed that most participants in both groups remembered the videos and tip sheet from the first survey [Intervention 1 (41/49, 84%); intervention 2 (35/40, 87%)]. Of the participants who responded to the survey, almost all described using at least one pain management strategy [Intervention 1 (49/49, 100%); Intervention 2 (38/40, 95%)] (mostly breastfeeding [intervention 1 (39/49, 80%); intervention 2 (33/40, 82%)] during their infant’s vaccination. Twenty-seven (55%) and 23 (57%) of parents in intervention 1 and 2 respectively, used more than one strategy. After participation in the study, almost all respondents in both groups [Intervention 1 (47/49, 96%); Intervention 2 (39/40, 97%)] felt confident to help reduce their baby’s pain during vaccination. There was no statistically significant difference between the two groups in terms of confidence, intent, and plans to recommend the pain management strategies to other parents (Table 4).

“INSERT TABLE 4 HERE”. *Table 4. Knowledge utilization information after the subsequent vaccination in study participants*

Discussion

A pilot randomized control trial was conducted to evaluate the feasibility, acceptability, and preliminary efficacy of parent-targeted interventions (Be Sweet to Babies videos, accompanying tip sheet, AS&Q), the study’s recruitment process, tools, and procedures developed with the aim of improving the use of effective pain management strategies during infant vaccination informed by KTA framework.

Regarding the primary outcome of the study, the online recruitment strategy, study processes, and interventions used in this study were shown to be reasonably feasible according to the success of the recruitment process (151 people in a week), high rates of completed consent forms (170/201, 85%), provision of email addresses (154/201, 77%), number of participants randomized (151/201, 75%), and the total number of participants who completed all the study surveys (89/151, 59%). These numbers are promising compared to the response rates reported in the similar online studies, as a systematic review of 19 public health studies reported the average response rate of 40.5% (42). This rate was for one-time and only-survey studies, they added that this number goes down up to 20% less for RCT design studies. In addition, another systematic review of 10 online studies reported the response rate of 2% to 27%, with an average of 12% (23). Noteworthy, our study had a lost-to-follow-up rate of 41% (62/151). Reasons for drop out were not captured. However, considering the online and multi-faceted nature of the study, the feasibility of the study procedure is promising in terms of using similar recruitment processes for larger studies in the future. However, given the small size, no significant difference between groups in using the recommended pain management strategies, the use of AS&Q intervention for a larger RCT remains questionable and the results of this

pilot study cannot provide valid estimates to guide power calculations for larger RCTs. The study interventions and procedures were acceptable to parents who completed this study. All parents were satisfied with participation in the study and with their infant's vaccination experience. Parental satisfaction with the vaccination experience of their infant has the potential to increase parents' trust, compliance with vaccination schedule, and eventually may result in improved health outcomes for the child and community (32).

Regarding the secondary outcome of this study, our results indicate preliminary efficacy of the parent-targeted educational materials (Be Sweet to Babies videos and tip sheet) based on the increased uptake of used pain management strategies from baseline. Following the KTA action cycle steps, the use of pain management strategies was evaluated after the interventions. Almost all participants in both groups used at least one of the strategies in the subsequent vaccination (over 95%). Similar effectiveness of parent-targeted interventions for improving vaccination pain management for infants and children was shown by the multidisciplinary team named Help Eliminate Pain in Kids (HELPinKIDS) (33,34). They created a clinical practice guideline and parent resources including an informative video for parents explaining various psychological and pharmacological strategies to use during infant vaccination (<https://www.youtube.com/watch?v=5Oqa1Fag5eQ>) (33,34). In contrast, Taddio et al. reported that the use of written educational materials only, such as tip sheets and booklets in parental education was unsuccessful in increasing parents' uptake of knowledge in subsequent pain care of infants during vaccination. They reported only one-fifth of the parents in their study read the printed KT intervention (35). They further suggested adding audio-visual strategies to boost the uptake of knowledge and disseminate these resources on publicly accessible platforms for parents to encourage the use of pain management strategies during vaccination (35). In our study, the utilization rate of effective pain management strategies after the

interventions was shown to be above what has been reported in similar studies about implementation of parent-targeted education about vaccination pain management (35–37). For example, Taddio et al (2014) showed a significant increase in the use of one or more pain management strategies (breastfeeding, sweet solutions, and topical anesthetics) in a group of parents who received pain education (2 days of group instruction, 6 hours/day; total, 12 hours) at the prenatal period compared to the standard care group (34% vs 17%). In another similar study, Taddio et al (2015) also reported that parents receiving an educational package (pain management video and pamphlet) used significantly more pain management strategies during vaccination (breastfeeding, sweet solutions, holding, and topical anesthetics compared to the control group immediately following the education (80% vs 26%), and 2 months after (68% vs 32%). However, there was a loss to follow-up for 30% of the parents in a telephone survey 2 months following the subsequent vaccination (14).

In our study, results showed no significant differences between Intervention 1 and 2 in the use of pain management strategies. However, the aim of the pilot RCT, as per all pilot studies, was not to establish the efficacy of the intervention nor was it powered to detect a change (38). Yet, the Intervention 2 group felt 30% more confident compared to baseline, to use these strategies and all intend to use at least one of the recommended pain management strategies in the future. The similar use of the MI principals was used in a study by April et al. (2016) in developing a decision aid tool. Although the MI-based items were not evaluated in their study, they concluded that the decision aid tool helped participants to clarify their values and make an informed decision in their journey with nonsurgical options for knee and hip osteoarthritis management. Further research is needed to develop, modify and evaluate the MI-informed components of interventions for future studies.

Coincidentally, the recruitment of this study happened to be at the time of the Measles outbreak in Canada (Fall 2018). This may have drawn the attention of parents to the study's

advertisement posts on different online platforms. However, such media coverage also brings to light the anti-vaccine as opposed to the pro-vaccine arguments. In our study, on one hand, pro-vaccine parents who responded to our posts may have been interested to learn more about improving vaccination experience. Positive feedback was given to the authors through supportive comments under the advertisement posts and other parents were encouraged to join the study. However, parents opposed to the vaccination itself provided negative feedback to the study's advertisement posts in efforts to change other parents' minds about vaccination or participation in the study. This led to removing the advertisement post from one of the popular online parent forums. In addition, hosts of other online platforms with large numbers of members declined to post the advertisement scripts of the study due to the history of conflicts between anti- and pro-vaccination parents. This unforeseen response driven by anti-vaccination individuals was an unintended process of this study. This needs to be considered in future public campaigns aiming to improve pain management during infant vaccination.

Strengths and Limitations

The strength of this study includes the novel approach to online recruitment and study processes, which included all the processes of online delivery, blinding the participants, allocation concealment, and randomization sequence generation. In addition, the brevity of the videos, written materials and survey time requirement (less than 10 min per survey), were all positively viewed by the participating parents. No previous studies had been conducted on interventions based on MI principals as delivered online in a brief format. This reflects an innovative strategy of the study procedure and process. However, the AS&Q, based on MI techniques, had not therefore been previously tested. However, the AS&Q question/statements were reviewed by HCPs and parent representatives prior to the study for acceptability and understandability of the content, style, and

clarity.

Despite the strengths, this study had some limitations, one of the most common limitations of online studies is the risk of self-selection bias (29), since there was no way of knowing if participants were actually eligible as reported. This may influence the generalizability of results and lead to sampling bias, as the online recruitment process is unlikely to reach the less educationally and socioeconomically privileged groups who may not have access to the internet. Most parents in this study were female Caucasians, with high levels of education who were residents in the province of Ontario. These participants may have already been motivated enough to learn more and take action in using the recommended pain reduction strategies during their infants' vaccination. Another limitation is that parents who decided to participate in this study were in all likelihood, already motivated enough to learn more and take action in helping to reduce their infants' vaccination pain. Moreover, study outcomes were completed by self-report surveys and the researchers could not know the extent of the fidelity of the interventions; i.e., if the videos were watched all the way through or the tip sheet was read. However, it has been shown that mothers' response to self-report surveys is reliable (36) and if the educational material is brief enough parents usually study them to the end (43).

In this study, the rate of breastfeeding reported by mothers at baseline in this study (63% exclusively, 37% combination) was higher than what is reported in general in Ontario (62% exclusively breastfeeding at discharge, and only 33% continue for six months) (41). In addition, they reported they were more likely to use breastfeeding rather than other strategies in the future vaccination of their infants and were more likely to recommend breastfeeding to other parents as a safe pain management strategy. This is neither a limitation nor strength of this study, however this may have resulted in a more positive response to the study procedures as well as the high rates of breastfeeding during vaccination. There is also a chance that parents had already been informed about

breastfeeding, sucrose and holding for comforting their infants during the perinatal period or during newborn screening, which may have positively impacted the rate of using these strategies later in infancy during vaccination. Lack of face-to-face individualized delivery of information to parents may be considered as a limitation in this study, however the popularity of online platforms and ease of reaching out to parents at their convenient time and location, coupled with permission to withdraw at any stage of the study are important advantages of online recruitment and delivery of educational materials compared to in-person delivery of information. Another limitation of the online data collection procedure is the potential risk of duplicate submissions which happens when internet users submit multiple responses to take advantage of the incentives. Although it is difficult to prevent this bias, some strategies were used to reduce this risk such as submission of email addresses was required to continue in the study process, and an accessible and realistic incentive was offered.

Conclusion

This pilot RCT showed feasibility and acceptability of study processes in participants who completed the study for comparing online delivered parent-targeted and mediated interventions aimed to improve the use of pain management strategies for infants during vaccination. Both interventions (Be Sweet to Babies videos and tip sheet with and without the AS&Q) resulted in very high parent-reported use of effective pain management strategies during vaccination. This study contributes to the knowledge of using online platforms in conducting all stages of the research process. In addition, this study contributes to implementation science by determining ways to changing health behavior in parents and empowering them to advocate for their infant's pain care during vaccination.

References

1. Centers for Disease Control and Prevention. No Title [Internet]. 2017. Available from: <https://www.cdc.gov/>
2. Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, et al. Reducing pain during vaccine injections: clinical practice guideline. *Can Med Assoc J.* 2015; 187(13):975–82.
3. Chambers CT, Taddio A, Uman LS, McMurtry CM, Team Help. Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review. *Clin Ther.* 2009; 31:S77–103.
4. Taddio A, Ipp M, Thivakaran S, Jamal A, Parikh C, Smart S, et al. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine.* 2012; 30(32):4807–12.
5. Harrison D, Yamada J, Adams-Webber T, Ohlsson A, Beyene J, Stevens B. Sweet tasting solutions for reduction of needle-related procedural pain in children aged one to 16 years. *Cochrane Database of Systematic Reviews* 2015, Issue 5. Art. No.: CD008408.
6. Kassab M, Foster JP, Foureur M, Fowler C. Sweet-tasting solutions for needle-related procedural pain in infants one month to one year of age. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD008411
7. Chen SL, Denise H, Huang RR, Zhang Q, Xie RH, Wen SW. Efficacy of sweet solutions in relieving pain caused by vaccination in infants aged 1 to 12 months: a systematic review. *Chinese Journal of Contemporary Pediatrics*, 18(6), pp.534-540.
8. Harrison D, Reszel J, Bueno M, Sampson M, Shah VS, Taddio A, et al. Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database of Systematic Reviews* 2016, Issue 10. Art. No.: CD011248.

9. Shah V, Taddio A, McMurtry CM, Halperin SA, Noel M, Riddell RP, et al. Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: systematic review and meta-analysis. *Clin J Pain*. 2015;31(Suppl 10):S38.
10. World Health Organization. Weekly epidemiological record Relevé épidémiologique hebdomadaire [Internet]. 90 (39). 2015 [cited 2018 Feb 2]. p. 505–16. Available from: <http://www.who.int/wer>
11. Riddell RRP, Racine NM, Gennis HG, Turcotte K, Uman LS, Horton RE, et al. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database of Systematic Reviews* 2015, Issue 12. Art. No.: CD006275.
12. Harrison D, Wilding J, Bowman A, Fuller A, Nicholls SG, Pound CM, et al. Using YouTube to disseminate effective vaccination pain treatment for babies. *PLoS One*. 2016;11(10):e0164123.
13. Russell K, Harrison D. Managing pain in early childhood immunisation. *Kai Tiaki Nurs New Zeal*. 2015; 21(2):22.
14. Taddio A, Ipp M, Vyas C, Parikh C, Smart S, Thivakaran S, et al. Teaching parents to manage pain during infant immunizations: laying the foundation for better pain management practices. *Clin J Pain*. 2014;30(11):987–94.
15. Franck LS, Berberich FR, Taddio A. Parent participation in a childhood immunization pain reduction method. *Clinical pediatrics*, 54(3), 228-235.
16. Harrison D. Be Sweet to Babies [Internet]. Retrieved from <https://www.youtube.com/watch?v=L43y0H6XEH4&list=PLlZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB>
17. Rollnick, S., Miller, W. R., Butler, C. C., & Aloia, M. S. (2008). *Motivational interviewing in*

- health care: helping patients change behavior. (pp. 3-33), New York: Guilford Press
18. Pakpour AH, Gellert P, Dombrowski SU, Fridlund B. Motivational interviewing with parents for obesity: an RCT. *Pediatrics*. 2015;135(3):e644–52.
 19. Gance-Cleveland B. Motivational interviewing: improving patient education. *J Pediatr Heal Care*. 2007;21(2):81–8.
 20. Gayes LA, Steele RG. A meta-analysis of motivational interviewing interventions for pediatric health behavior change. *American Psychological Association*; 82(3), 521.
 21. Lundahl BW, Kunz C, Brownell C, Tollefson D, Burke BL. A meta-analysis of motivational interviewing: Twenty-five years of empirical studies. *Res Soc Work Pract*. 2010; 20(2):137–60.
 22. Tustin JL. *The Internet and Childhood Immunizations in Canada*. 2016. Doctoral dissertation, University of Toronto, Canada.
 23. Alshaikh F, Ramzan F, Rawaf S, Majeed A. Social network sites as a mode to collect health data: a systematic review. *J Med Internet Res*. 2014; 16(7):e171.
 24. Tustin JL, Crowcroft NS, Gesink D, Johnson I, Keelan J, Lachapelle B. Facebook recruitment of vaccine-hesitant Canadian parents: cross-sectional study. *JMIR public Heal Surveill*. 2017; 3(3):e47.
 25. Tustin JL, Crowcroft NS, Gesink D, Johnson I, Keelan J. Internet exposure associated with Canadian parents' perception of risk on childhood immunization: cross-sectional study. *JMIR public Heal Surveill*. 2018; 4(1):e7.
 26. Straus, S. E., Tetroe, J., & Graham, I. D. (2013). Introduction knowledge translation: what it is and what it isn't. In *Knowledge translation in health care: Moving from Evidence to Practice*, (2nd ed, Chapter 1.1., pp. 1–13). John Wiley & Sons, New Jersey, USA.

27. Harrison D, Larocque C, Reszel J, Harrold J, Aubertin C, Dowling D, et al. Be Sweet to Babies during painful procedures. *Adv Neonatal Care*. 2017; 17(5):372–80.
28. Howell SC, Quine S, Talley NJ. Ethics review and use of reminder letters in postal surveys: are current practices compromising an evidence-based approach? *Med J Aust*. 2003; 178(1):43.
29. Dillman DA, Bowker DK. The web questionnaire challenge to survey methodologists. *Online Soc Sci*. 2001; 53–71.
30. Harrison D, Elia S, Manias E, Royle J. Sucrose and lollipops to reduce immunisation pain in toddlers and young children: Two pilot randomised controlled trials. *Neonatal, Paediatr Child Heal Nurs*. 2014; 17(1):19.
31. Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101.
32. Taddio A, Ilersich AL, Ipp M, Kikuta A, Shah V, Team Help. Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations: systematic review of randomized controlled trials and quasi-randomized controlled trials. *Clin Ther*. 2009; 31:S48–76.
33. Chan S, Pielak K, McIntyre C, Deeter B, Taddio A. Implementation of a new clinical practice guideline regarding pain management during childhood vaccine injections. *Paediatr Child Health*. 2013; 18(7):367–72.
34. Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, et al. Reducing pain during vaccine injections: clinical practice guideline. *CMAJ*. 2015 Sep; 187(13):975–82.
35. Taddio, A., MacDonald, N. E., Smart, S., Parikh, C., Allen, V., Halperin, B., & Shah, V. (2014). Impact of a parent-directed pamphlet about pain management during infant

- vaccinations on maternal knowledge and behavior. *Neonatal Network*, 33(2), 74-82.
36. Taddio A, Smart S, Sheedy M, Yoon EW, Vyas C, Parikh C, et al. Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations : A cluster randomized trial. *Pain*. 2014; 155(7):1288–92.
 37. Taddio A, Parikh C, Yoon EW, Sgro M, Singh H, Habtom E, et al. Impact of parent-directed education on parental use of pain treatments during routine infant vaccinations: a cluster randomized trial. *Pain*. 2015; 156(1):185–91.
 38. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol*. 2010; 10(1):1.
 39. Leite AM, Linhares MBM, Lander J, Castral TC, dos Santos CB, Silvan Scochi CG. Effects of Breastfeeding on Pain Relief in Full-term Newborns. *Clin J Pain*. 2009 Nov; 25(9):827–32.
 40. Shah PS, Herbozo C, Aliwalas LL, Shah VS. Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database Syst Rev*. 2012 ;(12). Art. No.: CD004950
 41. BORN Ontario. Better Outcomes Registry and Network. Data Analysis for Annual Report 2014-2016 [Internet]. December 2016. 2016 [cited 2019 Jun 10]. Available from:
<https://www.bornontario.ca/assets/documents/Annual report 2014-2016 - Data Slides.pdf>
 42. Blumenberg, C., & Barros, A. J. (2018). Response rate differences between web and alternative data collection methods for public health research: a systematic review of the literature. *International journal of public health*, 63(6), 765-773.
 43. Wormald, B. (2012). Video Length, Pew Ressearch Center. Retrieved from
<https://www.journalism.org/2012/07/16/video-length/>

Figure 1. Affirmative Statements and Questions (AS&Q) Tool

Please read each statement and complete the survey below about your confidence and readiness to use any of the recommended pain management strategies (breastfeeding, sweet solutions, and upright secure holding) for your baby during vaccination.

Thank you!

-
- 1) Thinking about the information you have been given in the "Be Sweet to Babies" videos and the pamphlet, how important to you is it to use breastfeeding, sweet solutions or upright secure holding as pain management strategies during your baby's 2, 4 or 6-month vaccination?

Rate the importance on the scale below, from 1= Not important at all, to 5= Very important.

1 (Not important at all) 2 3 4 5 (Very important)

-
- 2) Recognizing your confidence will help you to discuss pain management for your baby during vaccination. How confident are you to inform your doctors or nurses that you want to use your preferred pain management strategy?

Rate your confidence on the scale below, from 1= Not Confident, to 5 = Very Confident.

1 2 3 4 5

-
- 3) How ready are you to use your choice of these pain management strategies during your baby's vaccination?

Rate your readiness on the scale below, from 1= Not Ready at all to 5 = Very Ready

1 2 3 4 5

For the next questions, think about possible answers. If you wish, you can take notes for yourself. Please be aware that you do not need to write or submit your answers for these questions.

Imagine a scenario in which you are taking your baby to a health clinic to get vaccinated, and you are willing to use one of the recommended pain management strategies.

- 4) What could help support you to use these pain management strategies during your baby's vaccination?

- 5) What do you think the benefits of using these pain management strategies may be?

- 6) What might hold you back or get in your way to use your preferred/most applicable pain management strategy?

- 7) How could you overcome any potential obstacles to using your preferred pain management strategies?

Figure 2. CONSORT Flow Diagram

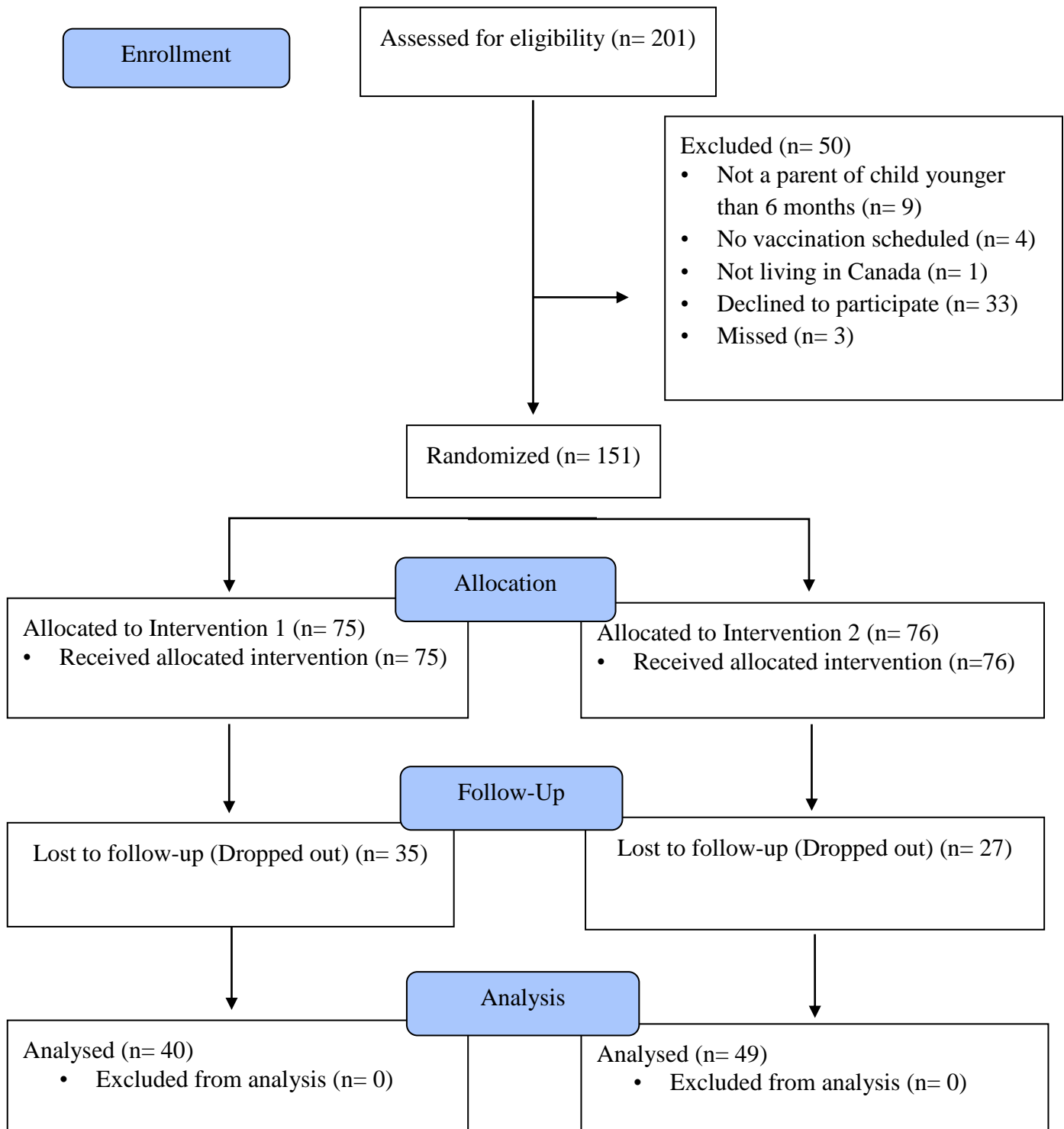


Table 1. Characteristics of Respondents to Baseline Demographic Survey

Parents' information	Age (Y)	Min 19	Max 42	Mean 30.2	SD 3.6					
	Relationship to child	Mother (158, 97%)	Father (3, 2%)	Aunt (1, 1%)						
	Employment status	Outside the home - Full time (117, 73%)	Full-time homemaker (21, 13%)	Outside the home - Part time (5, 3%)	Casual (5, 3%)	Unemployed (5, 3%)	I prefer not to answer (4, 2%)	Student (3, 2%)	Self-employed (2, 1%)	
	Province of residence	ON (105, 64%)	BC (23, 14%)	AB (16, 10%)	QC (11, 7%)	SK (3, 2%)	Irrelevant (2, 1%)	NS (1, 1%)	NB (1, 1%)	
	Education level	University (128, 79%)	College (32, 19%)	High School (1, 1%)	I prefer not to answer (1, 1%)					
	Marital status	Married (153, 94%)	Common law (7, 4%)	Separated (1, 1%)	Single (1, 1%)					
	Ethnicity	Caucasian (93, 57%)	Indigenous (45, 28%)	Asian (10, 6%)	Hispanic (5, 3%)	Middle Eastern (5, 3%)	I prefer not to answer (2, 1%)	African (1, 1%)	Other (1, 1%)	
	Other children	0 (116, 72%)	1 (25, 15%)	2 (17, 11%)	3 (4, 2%)					
	Recruitment platforms	Facebook (98, 51%)	Twitter (48, 25%)	Messengers* (20, 10%)	Emails (15, 8%)	Other (2, 1%)				
Infant's information	Sex of baby	Female (82, 51%)	Male (80, 49%)							

	Upcoming vaccination episode	4 months (88, 54%)	2 months (47, 29%)	6 months (27, 17%)		
	Type of delivery	Vaginal (118, 73%)	C/S (43, 26%)	I prefer not to answer (1, 1%)		
	Breastfeeding	Exclusively breastfeeding (93, 63%)	Combination (55, 37%)	Not currently but I did in the past (9, 6%)	I never breastfed (2, 1%)	I prefer not to answer (2, 1%)

WhatsApp, Facebook Messengers, WeChat, Telegram. ** Random numbers or their infant's age numbers.

Table 2. Knowledge and Use of Pain Management Strategies in Respondents to Baseline Knowledge Survey

	Intervention 1 (n= 76)			Intervention 2 (AS&Q) (n= 75)				
	YES		NO	Not Sure	YES	NO	Not Sure	
The previous view of any of the "Be Sweet to Babies" videos	28, 37 %	YouTube 19, 67%	45, 59%	3, 4%	25, 33 %	YouTube 16, 64%	48, 64 %	2, 3%
		Conference 1, 4%				Conference 2, 8%		
		Webinar 7, 25%				Webinar 6, 24%		
		University 1, 4%				University 1, 4%		
Knew about use of BF ¹	60, 79 %		10, 13%	6, 8%	56, 75%		14, 19%	5, 6%
Knew about use of upright secure holding	46, 60%		24, 32%	6, 8%	45, 60 %		26, 35%	4, 5%
Knew about use of SS ²	50, 66%		19, 25%	7, 9%	52, 70%		18, 24%	5, 6%
Previous use of any of these pain management strategies	40, 53%		35, 46%	1, 1%	40, 53%		33, 44%	2, 3%
Intention to use in upcoming vaccination	61, 80%	BF 46,75%	15, 20%	0, 0%	61, 81%	Bf 38, 62%	12, 16%	2, 3%
		SS 31, 51%				SS 35, 57%		
		Holding 26, 43%				Holding 23, 38%		
Recommendation to other parents	67, 88%	BF 54, 81%	7, 9%	2, 3%	67, 89%	BF 107, 76%	8, 11%	0, 0%
		SS 31, 46%				SS 72, 51%		
		Holding 25, 37%				Holding 53, 38%		

¹Breastfeeding

²Sweet Solutions

Figure 3. Affirmative Statements and Questions (AS&Q)

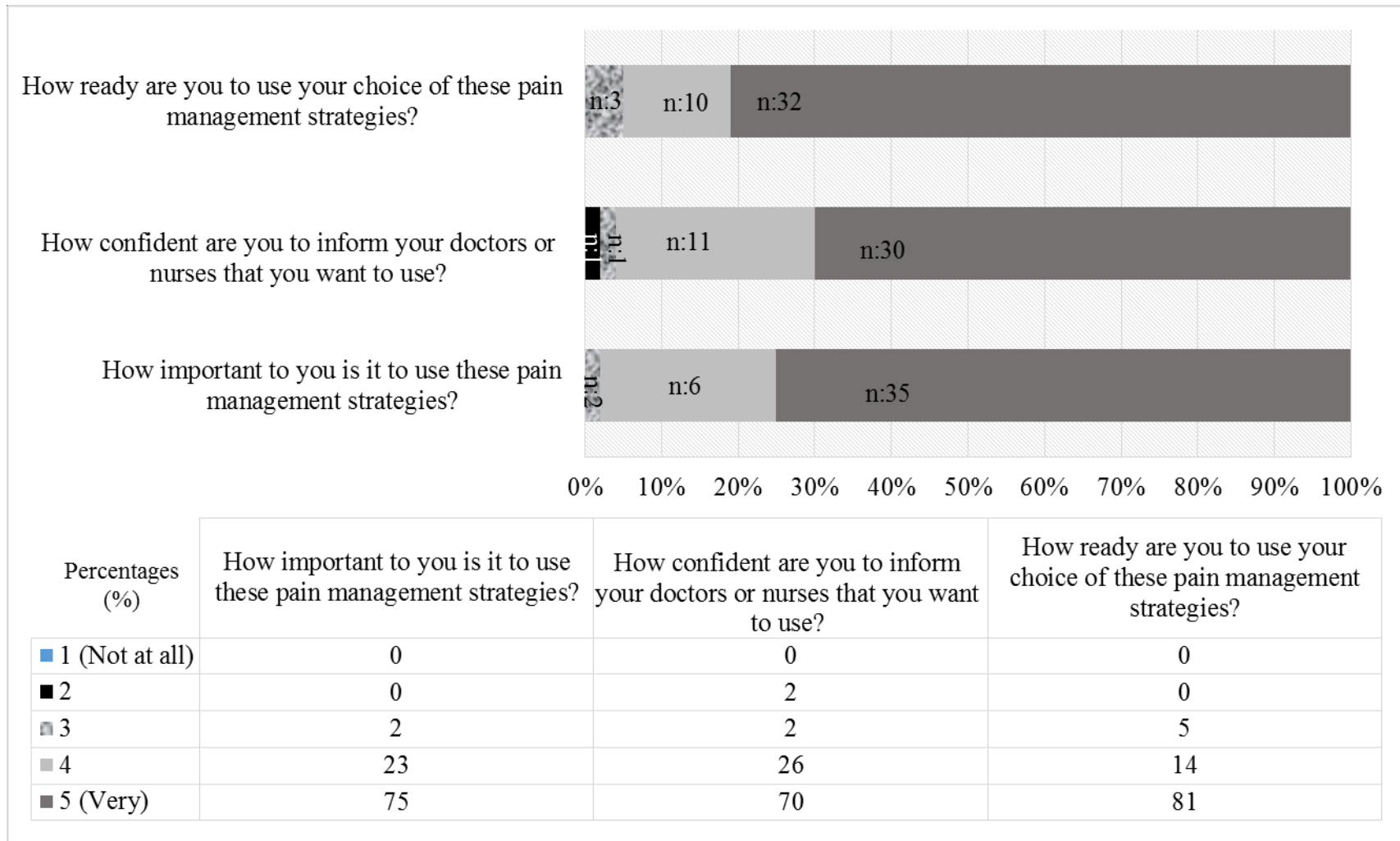


Table 3. Acceptability of Study Tools, Procedure, and Interventions

		Intervention 1 (n: 49)					Intervention 2 (n: 40)					
		<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Not Sure</i>	<i>Agree</i>	<i>Strongly Agree</i>	<i>Strongly Disagree</i>	<i>Disagree</i>	<i>Not Sure</i>	<i>Agree</i>	<i>Strongly Agree</i>	P value (χ^2)
Easy to read, understand and complete	1*	0, 0%	0, 0%	3, 7%	28, 64%	13, 29%	0, 0%	0, 0%	1, 2%	27, 69%	11, 28%	0.39
	2*	0, 0%	0, 0%	1, 2%	21, 47%	23, 51%	0, 0%	0, 0%	4, 10%	12, 30%	24, 60%	0.059
	3*	Not given this intervention					0, 0%	0, 0%	1, 3%	20, 51%	18, 46%	---
	4*	0, 0%	0, 0%	3, 7%	17, 37%	26, 56%	0, 0%	0, 0%	1, 2%	18, 45%	21, 53%	0.29
Satisfied with the requirements		0, 0%	0, 0%	1, 2%	20, 41%	28, 57%	0, 0%	0, 0%	2, 5%	12, 30%	26, 65%	0.49
Tip sheet easy to understand		0, 0%	0, 0%	3, 6%	16, 33%	30, 61%	0, 0%	0, 0%	3, 7%	9, 23%	28, 70%	0.56
Video easy to understand		1, 2%	0, 0%	0, 0%	13, 27%	35, 71%	1, 2%	0, 0%	0, 0%	13, 27%	35, 71%	0.63
Satisfied with length of the videos		0, 0%	0, 0%	1, 2%	17, 35%	31, 63%	0, 0%	0, 0%	0, 0%	10, 25%	30, 75%	0.37
Helpful written information		0, 0%	1, 2%	2, 4%	14, 28%	32, 66%	0, 0%	0, 0%	1, 3%	9, 22%	30, 75 %	0.66
Helpful videos		0, 0%	1, 2%	1, 2%	20, 41%	27, 55%	0, 0%	0, 0%	0, 0%	10, 25%	30, 75%	0.20
Easy to apply in real life		0, 0%	0, 0%	3, 6%	15, 31%	31, 63%	0, 0%	0, 0%	2, 5%	9, 22%	29, 73%	0.69
Satisfied participated		0, 0%	0, 0%	2, 4%	20, 41%	27, 55%	0, 0%	0, 0%	0, 0%	12, 30%	28, 70%	0.20
Interested in a future study		1, 2%	0, 0%	2, 4%	20, 41%	26, 53%	0, 0%	1, 2%	1, 2%	13, 33%	25, 63%	0.56

*1. Demographic Information Survey, 2. Knowledge Awareness Survey, 3. AS&Q, 4. Knowledge Utilization Survey

Table 4. Knowledge Utilization Information after Subsequent Vaccination

	Intervention 1 (n = 49)			Intervention 2 (n = 40)			
	YES	NO	Not Sure	YES	NO	Not Sure	
Remembered the videos and tip sheet	(41, 82%)	(1, 2%) I just watched (8, 16%)	(0, 0%)	(35, 87%)	(0, 0%) I just watched (5, 13%)	(0, 0%)	
Used any of the pain management strategies during the last vaccination	(49, 98%)	BF* (39, 80%) SS* (24, 49%) Holding* (30, 61%)	(0, 0%)	(1, 2%)	(38, 95%)	BF* (33, 87%) SS* (20, 53%) Holding (25, 66%)	(2, 5%) (0, 0%)
Felt more confident how to reduce pain during vaccination	(47, 94%)	(1, 2%)	(2, 4%)	(39, 97%)	(0, 0%)	(1, 3%)	
Recommend these pain management strategies to other parents	(47, 94%)	BF* (41, 87%) SS* (27, 57%) Holding* (19, 40%)	(1, 2%)	(2, 4%)	(39, 98%)	BF* (34, 87%) SS (24, 62%) Holding* (11, 28%)	(1, 2%) (0, 0%)
Intend to use one of the three pain management strategies in future vaccination episodes	(49, 98%)	BF* (37, 76%) SS* (27, 55%) Holding* (19, 39%)	(0, 0%)	(1, 2%)	(40, 100%)	BF* (34, 85%) SS* (22, 55%) Holding* (10, 25%)	(0, 0%) (0, 0%)

*NB. More than one strategy was used, recommended, or intended to be used.

Chapter 4 -Parent Resources for Early Childhood Vaccination: An Online Environmental Scan

Shokoufeh Modanloo*^{1,2}, Dawn Stacey^{1,3}, Sandra Dunn^{1,2,4}, Juliana Choueiry^{1,2} Denise Harrison^{1,2}

¹ School of Nursing, University of Ottawa, Ottawa, Ontario, Canada.

² Children's Hospital of Eastern Ontario (CHEO) Research Institute, Ottawa, Ontario, Canada.

³ Ottawa Hospital Research Institute, Ontario, Ottawa, Ontario, Canada.

⁴ Better Outcomes Registry & Network (BORN), Ottawa, Ontario, Canada.

*Corresponding author

This paper was submitted to the Journal of Vaccine, thus, it is formatted according to the journal guideline.

The paper was subsequently accepted and published. Citation: Modanloo, S., Stacey, D., Dunn, S., Choueiry, J., & Harrison, D. (2019). Parent resources for early childhood vaccination: An online environmental scan. *Vaccine*, 37(51), 7493-7500.

<https://doi.org/10.1016/j.vaccine.2019.09.075>

Abstract

Background. Early childhood vaccination is one of the most important public health interventions. However, the injections are painful. Thus, clinical practice guidelines recommend using pain management strategies (breastfeeding, secure upright holding, and sucrose) for infants. Public access to online health information has increased due to the advent of the Internet. Parents are likely to find thousands of websites, discussion forums, and online video platforms of variable quality. This study aims to identify and critically appraise the quality of online parent-targeted resources concerning early childhood vaccination and determine the inclusion of recommended infant pain management strategies.

Methods. An environmental scan of two main Internet sources was conducted: i) Google, ii) Social Media networks including Facebook, YouTube, and Twitter. Resources including information relating to infant vaccination and available to Canadians were included. The characteristics of resources were collected and summarized. The resources quality was evaluated independently by two research personnel using the CDC Clear Communication Index. A CDC index score of 90% and above indicates the resource is an acceptable public communication material. Means and standard deviations were used for normally distributed data; median and interquartile range (IQR) or numbers and proportions were used for data not normally distributed or presented in categorical format.

Results. There were 55 online resources in website format and 10 resources in video format. Overall, the mean score for the quality of resources was $60\% \pm 0.19$. Most resources were scored as moderate to low quality (33% to 87%). Only 5% of material scored as acceptable quality with 95% needing further revisions and improvements. In terms of content, 30 (46%) resources presented information about pain management strategies during vaccination, including breastfeeding (24, 37%), holding (27, 42%), and sweet solutions (22, 34%). The remaining 35

(54%) resources made no clear statement regarding any pain management strategies during vaccination.

Conclusion. Most publicly accessible online parent-targeted vaccination resources were of poor quality and did not contain information related to the use of recommended pain management strategies during vaccination.

Keywords: Vaccination, Immunization, Internet, Parents, Child

Introduction

Early childhood vaccination is the most important public health intervention to protect against life-threatening infectious diseases worldwide [1]. In the first year of life, the childhood vaccination schedule includes up to 20 vaccine injections [2]. These vaccinations, although necessary for public health, are associated with pain and distress at the time of administration. In addition, a fear of needles has been reported in up to 63% of children [3], potentially leading to the child being uncooperative during future painful procedures, developing a fear of medical events and subsequently avoiding health care and immunization [4,5].

Clinical practice guidelines [4] and high-quality synthesized evidence show that breastfeeding [6], sucrose [7–9] and upright secure holding [4] effectively reduce pain during vaccination in infants [10]. The World Health Organization (WHO) has a position statement recommending the administration of sweet-tasting oral vaccinations before injections and the use of breastfeeding during infant vaccinations [11]. Despite the evidence, these pain reduction strategies are not consistently used [4,12–14], highlighting an important gap in translating this knowledge into practice [4].

The inconsistent use of these evidence-based recommended pain management strategies during infants' vaccination might be due in part to lack of parental knowledge or confidence in providing comfort or in advocating for use of pain management in health care settings [15]. In fact, parents have expressed their dissatisfaction with their knowledge of pain care and have identified a knowledge gap in their education as the main barrier to comforting their infants during painful procedures. They also reported a desire to learn more about effective pain management during vaccinations [16]. Thus, it is crucial to educate parents as this can potentially increase the use of effective pain management strategies during vaccination [4]. In other words,

including parent-targeted informational resources on accessible educational platforms may empower them to comfort their infants during vaccination [17].

The advent of the Internet has increased public access to online health information. Statistics Canada reported that 70% of Canadians used the Internet to search for medical or health related-information [18]. In addition, social media platforms (i.e., Facebook and Twitter) provide an influential platform for sharing health information and consumer-to-consumer knowledge exchange, particularly among young parents [19]. YouTube is also a popular website for video-sharing among parents and has been used in health education dissemination since 2005 [19]. Online information can empower individuals in health care decision making, self-care, and may improve health behaviour by increasing public understanding of medical conditions. In addition, online information can enable communication with health care providers [19, 20]. While there are many benefits to access online information, there are also challenges. Parents of infants and children seeking information regarding vaccinations and related pain management strategies are likely to find thousands of websites, discussion forums, and video platforms of variable quality. Thus, identifying accurate or appropriate information can be difficult and overwhelming for parents [21]. As a result, parents might not feel confident in trusting these online information sources [20, 22].

Little is known of the extent to which evidence-based pain management strategies for infants during vaccinations are included in parent-targeted online information. The degree of accessibility and user-friendliness of this information is also unknown. Therefore, this study aims to identify and critically appraise the quality of online parent-targeted resources concerning early childhood vaccination and determine the inclusion of recommended infant pain management strategies. The objectives of this study are to critically appraise: a) the quality of the available

online parent-targeted resources focusing on infant vaccination, and b) the content relating to evidence-based pain management strategies of the available online parent-targeted resources

Methods

Study design. We conducted an environmental scan of publicly available resources accessible to parents searching for vaccination information. An environmental scan is a passive and unobtrusive strategy to analyze the phenomena externally. It aims to organize and collect information without interfering or changing the evidence [23].

Search strategy. The environmental scan was conducted using two main Internet sources, Google searches and Social Media networks (Facebook, YouTube, and Twitter). The searches were conducted by one person (SM) in February 2018, using the most popular searched keywords according to the Google Trend [24]. Google Trend allows the researcher to optimize their search results by selecting the most popular keywords used by the public when looking for online information. Multiple keywords were entered the search toolbar of Google Trend, the output graphs showed a worldwide trend which could be adjusted by time range and country. As a result, the following search terms were used independently: a) Vaccine AND “Parent OR Mom OR Father” and b) “Childhood immunization”. Given the dynamic content of the Internet information, the search results were scanned over 24 hours in order to reduce the chance of changes in findings based on previous searches. A new account was used to search Facebook, YouTube, Twitter, and Google, to eliminate the interference of previous search history in new search results.

Results of each search term (2 different search terms) in each database (4 different platforms) were scanned. The process was discontinued when 20 sequential records achieved redundancy. Since this discontinuation process has not been validated [19], the next 50 records were also screened to make sure no related resources were missed. The search strategy is shown

in the PRISMA flowchart (Figure.1). Each of the search engines of different social media platforms (i.e., Facebook, Twitter, and YouTube) were searched separately for eligible resources. Moreover, Google's advanced search was then used to identify any further resources that may have been missed in the direct searching of social media. While searching YouTube, if a video met the inclusion criteria, the first five videos shown on the suggested marginal column (right side of the screen) were screened further for eligibility. This study followed the discontinuation rule published by Sampson et al (2013) for screening YouTube videos [19]. This method allows researchers to have relevant-ranked results out of the dynamic and huge size of records [19].

Figure 1. PRISMA flow diagram

Selection of eligible resources. The following criteria were applied to include resources, a) accessible to Canadians, b) containing information relating to infant vaccinations, c) parent-targeted (aiming to disseminate information to parents) about vaccination for infants. Resources were excluded if there were duplicates, related to animal vaccination, not parent-targeted (i.e., targeting health care providers), news or commercial piece, focused on vaccination of children, adolescents or adults, related to anti- or pro-vaccination debates, not accessible to the public, or not informational (i.e., personal website, forums). There was no limit applied regarding the publication date. Two expert informants in the field of vaccination pain management in infants reviewed the final list of parent-targeted resources for completeness and suggested possible additional eligible resources if any. These experts included a professor with specialized knowledge in vaccination pain management and a nurse practitioner who advocates for the use of pain management strategies in childhood vaccination.

Data collection. Data were extracted by one screener (SM) into spreadsheets on Excel 2016 (Microsoft, Redmond, WA). The characteristics of each resource were collected (i.e.,

name, record type, upload/update date, affiliation, the Internet domain (.ca, .org, .com, etc.), and country of origin). Resources were screened further by the same screener (SM) for information about pain management strategies during vaccination information, and the accuracy of information was assessed against current evidence from clinical practice guidelines and systematic reviews [4,6,8]. Each resource was reviewed to determine the presence of information relating to breastfeeding, sweet solutions, or secure holding and close contact by caregivers during vaccination.

Quality appraisal. The final list of included resources was appraised independently by two reviewers (SM and JC) for quality assessment, using the Control and Prevention (CDC) Clear Communication Index (<https://www.cdc.gov/ccindex/index.html>). The CDC tool presents the criteria used to evaluate consumer health-related information. This includes evaluation of accuracy and appropriateness of resources (based on resource audience) and detection of misleading or poor-quality information [25]. The tool was designed to identify the communication features of public resources that increase the understanding and clarity of the information, regardless of the format or distribution channel. It has four sections consisting of four open-ended questions and 20 scored items. Evaluation of the resources is based on the following seven categories; main message and call to action, language, information design, and state of the science, behavioral recommendations, numbers, and risk. The four sections include these: Part A: Main message and call to action, literacy level, information design, state of the science, Part B: Behavioral recommendations, Part C: Numbers (Presenting the numbers that are necessary to support the main message in common terms for public) and, Part D: Risk (Explaining benefits and actual risk of behaviors, treatments, and preventive measures to non-expert audiences to make informed decisions) [26].

Scoring. CDC Clear Communication Index Score Sheet

(<https://www.cdc.gov/healthcommunication/pdf/clearcommunicationindex/fillableformmay2013.pdf>) was used for Website records. The result obtained is based on 20 scored items. The scores were added up according to the Yes =1, or No = 0 answers. Questions 1-11 in Part A, 11 scores, and questions 12-20 in Parts B (3 scores), C (3 scores), and D (3 scores) that may not apply to all resources. For calculation, the total score according to the instruction, the total point that each record earned (numerator) was divided by and multiplied by 100 (Note: Online tool does the required math). If the total score was 90 or above, it was addressed most of the required items that make the record easier to understand and use. If the total score was 89 or below, it means the record needed revision and improvement. CDC index was chosen over similar quality appraisal tools introduced in literature [32, 35,36] since it has been identified as a comprehensive tool for appraisal of health information in different formats (print and web, Facebook, written scripts, Tweets, infographics). However, CDC index has not been used or validated for video format resources. In fact, there was no standardized tool or guideline for evaluating the quality of online information in video format [27]. However, CDC published a social media guideline and best practice on the process of preparing videos for CDC YouTube channels. This includes a list of recommendations for high-quality consumer-friendly video resources [28]. Therefore, in addition to the CDC Clear Communication tool, the guideline was also used to appraise the quality of video format resources in this study. The guideline evaluates video records in some further domains including videos' content, authorities, length, date, reference, title, description, keywords, category, and playlist. The total scoring added up similar to websites score (20 points).

Two independent evaluators (SM and JC) participated in a training session (calibration exercise) for the CDC index scoring of resources. Their scores were gathered and compared to resolve the differences. Where there was disagreement, the resource was revisited and discussed. If disagreements remained, a third reviewer (DH) was consulted to reach a consensus.

Data analysis. Summary statistics and descriptive analysis were used to synthesize data regarding the characteristics of online resources. If data were normally distributed, mean and standard deviations, minimum, and maximum were used, if data were not normally distributed or presented in a categorical format, median and interquartile range (IQR) or numbers and proportions were used.

Results

Search strategies. The search yielded 2944 links, of which 2304 records were excluded after screening. From the remaining 640 records, 585 records were excluded for reasons relating to animal vaccination, not parent-targeted, anti-/ pro-vaccine debates, not childhood immunization, and duplicates (Figure 1). Fifty-five records were identified for inclusion. In addition, 4 records were added to the final list based on the expert informants' suggestions and 6 records were added while browsing the original records. Consequently, 65 records were included and appraised for quality, 55 in website format and 10 in video format.

A full list of included resources in both website and video format with their characteristics is provided in Table 1. Most records were categorized as educational resources posted by health care organizations (36, 55%) or professional associations (22, 34%). The remaining records were posted by an academic institute (2, 3%), were web pages hosted by individuals (2, 3%), online encyclopedias (2, 3%), or had no identified affiliation (1, 2%). Although no location restriction was applied to the search strategy, most resources (52, 80%) were produced in North America (25 in Canada, 27 in the USA) and the remaining resources

were produced in Australia, UK, New Zealand, South Africa, Switzerland, and Norway (9, 14 %) or unknown (4, 6 %). Thirty-seven resources (57%) had been updated or uploaded in the last 7 years (earliest May 2012 to the latest January 2019) and no date was provided for 28 resources (43%). Assessing the Internet domain of the 55 websites, most records had a country code (24, 44 %) (i.e., .ca, .au.), or had generic domains used for general purposes such as commercial or non-profit organizations (i.e., .com, .org) (23, 42%). Eight records (14%) had a sponsored domain, used by businesses or industries (i.e., .edu, .gov).

Table 1. Characteristics of included resources

Regarding the 10 video resources, the earliest video was uploaded in May 2012 and the most recent was uploaded in March 2017. The median number of the videos' statistics are as follows, number of views 13,123 (IQR 66,661.25, Min 203, Max 132,654), number of "likes" 30 (IQR 2.75, Min 0, Max 80), number of "dislikes" 2 (IQR 2.75, Min 0, Max 25), and number of comments 0 (IQR 11.75, Min 0, Max 25), length 114 seconds (IQR 134.5, Min 81, Max 788). The following theme was emerged after reviewing the content of 10 included videos: benefits of childhood vaccination, understanding the routine childhood vaccination schedule and reminders tools, risks of not getting a child vaccinated, pain management strategies to reduce the needle pain. More information about videos' uploaded date, affiliation, and country of origin, CDC Clear Communication score and inclusion of pain management information are shown in Table 1.

Quality appraisal. The overall mean CDC Clear Communication Index score of the website resources was $60\% \pm 0.19$ (Min 14% and Max 93%) with a range of 33% to 87%. Results of the website resources in the four domains were, Part A (main message and call to action, language, information design, state of the science), mean scores of $66\% \pm 0.24$, Part B

(behavioral recommendations), $70\% \pm 0.28$, Part C (numbers), $69\% \pm 0.14$, And part D (risks), $60\% \pm 0.28$. Out of all eligible websites and videos, only three resources (5%) met the CDC guideline score of at least 90%, considered as acceptable quality to be published online. The large majority of resources (62, 95%) scored below 89% [2]. The list of scores for each resource is provided in Table 1.

Pain management strategies. Of the 65 resources, 30 (46%) included information about pain management strategies during vaccination, including breastfeeding (24, 37%), skin to skin care (4, 6%), holding (27, 41%), sweet solutions (22, 34%), distraction (i.e., watching videos, blowing bubbles, singing, toys) (27, 41%), non-nutritive sucking (6, 9%), nutritive sucking i.e., bottle feeding (2, 3%), stroking (6, 9%), swaddling (2, 3%), topical anesthetic (EMLA or Ametop) (16, 25%), talking (23, 35%) (Figure 2).

Of the 35 (54%) resources that did not include information about pain management strategies, 14 resources referred to other websites providing pain management information via embedded links. However, these links were not clearly identified in the original resource and were not assessed. As a side note, even when resources did include information about pain management, it was not easy to navigate them on the websites according to the time required for an author to locate them (~ 5-10 min). However, evaluating the navigation trail of resources was not the aim of this study and requires further analysis.

Figure 2. Vaccination pain management strategies addressed in resources

Discussion

This environmental scan demonstrated that the Internet and social media platforms are sources of information about infant vaccination for parents. However, only 5% met the CDC rating for quality and less than half included information about recommended pain management strategies to use during vaccination. When resources did include pain management information,

it was not easily identifiable on the websites as it was frequently buried under other health information or vaccine safety information. Evaluating the ease of access to these resources was not the focus of this study. While the quality and accuracy of online information need significant attention, being easy to locate and navigate to relevant information is important as well.

In comparison with similar studies, Dol et al. (2018) evaluated the quality of online resources available to parents of preterm infants requiring neonatal intensive care. They included 197 websites and reported that the most common topics covered were the experience of being a parent of a preterm infant, health concerns, skin-to-skin care, and breastfeeding and feeding problems. However, the issue of neonatal pain was discussed in only 10 (5%), whereas in our study it was discussed in 30 (46%) resources. In addition, recent systematic reviews of YouTube videos determining the use of recommended pain management strategies during the needle-related painful procedure in infants and children [21,30,31] reported sub-optimal use of recommended pain management strategies. Thus, our findings continue to highlight the sub-optimal inclusion of infant pain management information in publicly available online parent-targeted resources.

In terms of the health information quality, the results of this study showed that only 5% included resources considered as acceptable quality resources based on the CDC Clear Communication Index. In fact, most resources scored as poor to moderate quality. Consistent with these results, assessment of 75 publicly accessible vaccination resources for Australian parents with a researcher-made 43-item quality appraisal tool in six domains (disclosure of ownership, transparency of sponsorship, mission of site, quality of information, accountability to users, and quantity of information) resulted in a mean quality score of 55% [32].

In addition, other studies examining online information available to parents with a child affected by a different health problem such as preterm newborns [22], clubfoot [33], and epilepsy [34] demonstrated similar results to this study with poor-to moderate quality. In contrast to our study, websites included in those studies were evaluated by the DISCERN tool (a standard tool for quality appraisal of written health information on treatment choices) [35]. Furthermore, a systematic review of 79 studies, evaluating 5941 publicly accessible websites and 1329 web pages about consumer health information, demonstrated that 70% of the online information was of poor quality [36].

Screening for the eligible resources in this current environmental scan identified a large number of anti-vaccination websites. In fact, as shown in Figure 1, 748 resources were excluded for this reason. Most of the websites promoting anti-vaccination information were found on social media sites, nor were they owned by reputable healthcare or academic organizations or foundations. In addition, in a systematic review of 87 YouTube videos about vaccination, more than two-thirds of videos (65.5%) promoted anti-vaccination messages [37]. Although the assessment of the anti-vaccination movement was not the aim of this study, it was evident that huge amounts of time and resources were spent on anti- or pro-vaccination campaigns.

There is a need to improve online parent-targeted resources pertaining to pain management during vaccinations. Several informative resources aiming to improve pain management during early childhood vaccinations were produced by reputable sources in video and website formats. For example, the Canadian Institutes of Health Research (CIHR)-funded HELPinKIDS team posted a 13:08-minute video on YouTube explaining different pharmacological and psychological strategies useful for parents to use during their babies' vaccination (<https://www.youtube.com/watch?v=5Oqa1Fag5eQ>) [38, 39]. Another example is

the Be Sweet to Babies video series developed professionally at the Children's Hospital of Eastern Ontario (CHEO) showing parents and nurses how to use breastfeeding and small amounts of sweet solutions as pain management strategies during vaccination [40,41] in three separate brief videos showing: a) breastfeeding during 2-month vaccination

(<https://www.youtube.com/watch?v=FrKmAth4ZGc&list=PLIZczt8t4Ac8cW3pbuRKJAES3SoC5y8MB&index=9>), b) breastfeeding during 6-month vaccination

(<https://www.youtube.com/watch?v=55tejVjzzwE&list=PLIZczt8t4Ac8cW3pbuRKJAES3SoC5y8MB&index=12>) and c) sucrose in infants less than 12 months of age during vaccination

(<https://www.youtube.com/watch?v=7NDJ463j2iI&list=PLIZczt8t4Ac8cW3pbuRKJAES3SoC5y8MB&index=16>).

Although the focus of this study was not the evaluation of online information-seeking behaviour among parents, the amount of poor-quality and misleading information is concerning". It is important for health care providers and health agencies to be aware of the online parent-targeted content relating to childhood vaccinations in order to ensure that accurate and high-quality information is available. In fact, poor quality or inaccurate information can have negative effects on health behaviours and uptake of recommended public health interventions [37].

Strengths and Limitations

To our knowledge, this is the first study to critically appraised available online parent-targeted information regarding pain management during infant vaccinations. Having two reviewers independently appraise the quality of resources adds to the study's strengths. However, this study had some limitations. Given the dynamic status of online information and to reduce interference with previous search results, attempts were made to reduce the change in the search results by screening all output in the span of one day. However, publicly accessible online information needs frequent monitoring to keep up with the myriad of resources posted. In this

study, the popular search engines Google, Twitter, Facebook, and YouTube were screened for publicly accessible parent-targeted childhood vaccination resources. However, there are other search engines that exist such as Bing, Yahoo, or Ask.com that parents might be using to access health information. In addition, although the most common search terms suggested by Google Trend were used in this study, it is possible that parents may use different search terms and therefore, may obtain different search results. Moreover, if parents look further there is a chance that they might find relevant information in the records that were excluded in this study.

Conclusion

This environmental scan of online parent-targeted resources relating to infant vaccination included 65 resources, most of which lacked accurate and easy to find information about effective pain management strategies. This highlights the need to develop accurate, trustworthy high-quality parent-targeted resources and disseminate through knowledge translation interventions aimed at improving the use of recommended pain management strategies during infant vaccination. Further research is required to evaluate the efficacy of such interventions to change parental behaviours and its impact on their engagement to use recommended pain management strategies during infant vaccinations is required.

Declarations of interest:

None.

Acknowledgments:

The authors would like to thank Dr. Christine Chambers, Sharon Laplante, and Nicole MacKenzie who helped us as the informant panel in reviewing the list of resources. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Funding:

The first author was supported by the International Admission Scholarship and International Doctoral Scholarship at School of Nursing, Faculty of Health Sciences, University of Ottawa, Ottawa, Ontario.

References

- [1] Strikas RA, Child A, Group AIW, Practices AC on I. Advisory committee on immunization practices recommended immunization schedules for persons aged 0 through 18 years—United States, 2015. *MMWR Morb Mortal Wkly Rep* 2015;64:93.
- [2] Centers for Disease Control and Prevention. 2017. <https://www.cdc.gov/>. (Date of access: 08.2018)
- [3] Taddio A, Ipp M, Thivakaran S, Jamal A, Parikh C, Smart S, et al. Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine* 2012;30:4807–12.
- [4] Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, et al. Reducing pain during vaccine injections: clinical practice guideline. *Can Med Assoc J* 2015;187:975–82.
- [5] Chambers CT, Taddio A, Uman LS, McMurtry CM, Team Help. Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review. *Clin Ther* 2009;31:S77–103.
- [6] Harrison D, Reszel J, Bueno M, Sampson M, Shah VS, Taddio A, et al. Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database of Systematic Reviews* 2016, Issue 10. Art. No.: CD011248.
- [7] Harrison D, Yamada J, Adams-Webber T, Ohlsson A, Beyene J, Stevens B. Sweet tasting solutions for reduction of needle-related procedural pain in children aged one to 16 years. *Cochrane Database of Systematic Reviews* 2015, Issue 5. Art. No.: CD008408.
- [8] Kassab M, Foster JP, Foureur M, Fowler C. Sweet-tasting solutions for needle-related procedural pain in infants one month to one year of age. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD008411

- [9] Chen SL, Harrison D, Huang RR, Zhang Q, Xie RH, Wen SW. Efficacy of sweet solutions in relieving pain caused by vaccination in infants aged 1 to 12 months: a systematic review 2016. Vol.18 No.6, Jun. 2016 534-540.
- [10] Shah V, Taddio A, McMurtry CM, Halperin SA, Noel M, Riddell RP, et al. Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: systematic review and meta-analysis. *Clin J Pain* 2015;31:S38.
- [11] World Health Organization. Weekly epidemiological record Relevé épidémiologique hebdomadaire. 90(39) 2015:505–16. <http://www.who.int/wer> (Accessed February 2nd, 2018).
- [12] Harrison D, Elia S, Royle J, Manias E. Pain management strategies used during early childhood immunisation in Victoria. *J Paediatr Child Health* 2013;49:313–8.
- [13] Russell K, Harrison D. Managing pain in early childhood immunisation. *Kai Tiaki Nurs New Zeal* 2015;21:22.
- [14] Riddell RRP, Racine NM, Gennis HG, Turcotte K, Uman LS, Horton RE, et al. Non-pharmacological management of infant and young child procedural pain. *Cochrane Database of Systematic Reviews* 2011, Issue 10. Art. No.: CD006275.
- [15] Taddio A, Ipp M, Vyas C, Parikh C, Smart S, Thivakaran S, et al. Teaching parents to manage pain during infant immunizations: laying the foundation for better pain management practices. *Clin J Pain* 2014;30:987–94.
- [16] Franck LS, Berberich FR, Taddio A. Parent participation in a childhood immunization pain reduction method. *Clin Pediatr* 2015;54:228–35.
- [17] Taddio A, Shah V, Leung E, Wang J, Parikh C, Smart S, et al. Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain:

- usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatr* 2013;13:23.
- [18] Statistics Canada. Internet use by individuals, by type of activity (Internet users at home). Stat Canada 2010. <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/comm29a-eng.htm> (Accessed October 29, 2017).
- [19] Sampson M, Cumber J, Li C, Pound CM, Fuller A, Harrison D. A systematic review of methods for studying consumer health YouTube videos, with implications for systematic reviews. *PeerJ* 2013;1:e147.
- [20] McMullan M. Patients using the Internet to obtain health information: how this affects the patient–health professional relationship. *Patient Educ Couns* 2006;63:24–8.
- [21] Farkas C, Solodiuk L, Taddio A, Franck L, Berberich FR, LoChiatto J, et al. Publicly Available Online Educational Videos Regarding Pediatric Needle Pain. *Clin J Pain* 2015;31:591–8.
- [22] Dol J, Richardson B, Boates T, Campbell-Yeo M. Learning to parent from Google? Evaluation of available online health evidence for parents of preterm infants requiring neonatal intensive care. *Health Informatics J* 2018;146045821775256. doi:10.1177/1460458217752564.
- [23] Hatch TF, Pearson TG. Using environmental scans in educational needs assessment. *J Contin Educ Health Prof* 1998;18:179–84.
- [24] Google Trends. <https://trends.google.com/trends/?geo=CA>. (Accessed August, 2018).
- [25] Kaicker J, Debono VB, Dang W, Buckley N, Thabane L. Assessment of the quality and variability of health information on chronic pain websites using the DISCERN instrument. *BMC Med* 2010;8:59.

- [26] Baur C, Prue C. The CDC Clear Communication Index is a new evidence-based tool to prepare and review health information. *Health Promot Pract* 2014;15:629–37.
- [27] Drozd B, Couvillon E, Suarez A. Medical YouTube Videos and Methods of Evaluation: Literature Review. *JMIR Med Educ* 2018;4.
- [28] Centers for Disease Control and Prevention. Social Media Guidelines and Best Practices: CDC YouTube Channel 2012:1–11.
<https://www.cdc.gov/SocialMedia/Tools/guidelines/pdf/onlinevideo.pdf>.
- [29] Centers for Disease Control and Prevention. CDC Clear Communication Index A Tool for Developing and Assessing CDC Public Communication Products User Guide CDC Clear Communication Index 2014:1–33.
<http://www.cogitatiopress.com/ojs/index.php/mediaandcommunication/article/view/515>.
- [30] Harrison D, Sampson M, Reszel J, Abdulla K, Barrowman N, Cumber J, et al. Too many crying babies: a systematic review of pain management practices during immunizations on YouTube. *BMC Pediatr* 2014;14:134.
- [31] Harrison D, Modanloo S, Desrosiers A, Poliquin L, Bueno M, Reszel J, et al. A systematic review of YouTube videos on pain management during newborn blood tests. *J Neonatal Nurs* 2018; 24:325-30.
- [32] Wiley KE, Steffens M, Berry N, Leask J. An audit of the quality of online immunisation information available to Australian parents. *BMC Public Health* 2017;17:76.
- [33] Kumar VS, Subramani S, Veerapan S, Khan SA. Evaluation of online health information on clubfoot using the DISCERN tool. *J Pediatr Orthop B* 2014;23:135–8.
- [34] Cerminara C, Santarone ME, Casarelli L, Curatolo P, El Malhany N. Use of the DISCERN tool for evaluating web searches in childhood epilepsy. *Epilepsy Behav*

- 2014;41:119–21.
- [35] Charnock D, Shepperd S. Learning to DISCERN online: applying an appraisal tool to health websites in a workshop setting. *Health Educ Res* 2004;19:440–6.
- [36] Eysenbach G, Powell J, Kuss O, Sa E-R. Empirical studies assessing the quality of health information for consumers on the world wide web: a systematic review. *Jama* 2002;287:2691–700.
- [37] Basch CH, Zybert P, Reeves R, Basch CE. What do popular YouTube™ videos say about vaccines? *Child Care Health Dev* 2017;43:499–503.
- [38] Chan S, Pielak K, McIntyre C, Deeter B, Taddio A. Implementation of a new clinical practice guideline regarding pain management during childhood vaccine injections. *Paediatr Child Health* 2013;18:367–72.
- [39] Taddio A, Smart S, Sheedy M, Yoon EW, Vyas C, Parikh C, et al. Impact of prenatal education on maternal utilization of analgesic interventions at future infant vaccinations : A cluster randomized trial. *Pain* 2014;155:1288–92. doi:10.1016/j.pain.2014.03.024.
- [40] Harrison D. *Be Sweet to Babies* 2014.
<https://www.youtube.com/playlist?list=PLIZczt8t4Ac8cW3pbuRKJAES3SoC5y8MB>
- [41] Harrison D, Wilding J, Bowman A, Fuller A, Nicholls SG, Pound CM, et al. Using YouTube to disseminate effective vaccination pain treatment for babies. *PLoS One* 2016;11:e0164123.

Figure 1. PRISMA flow diagram

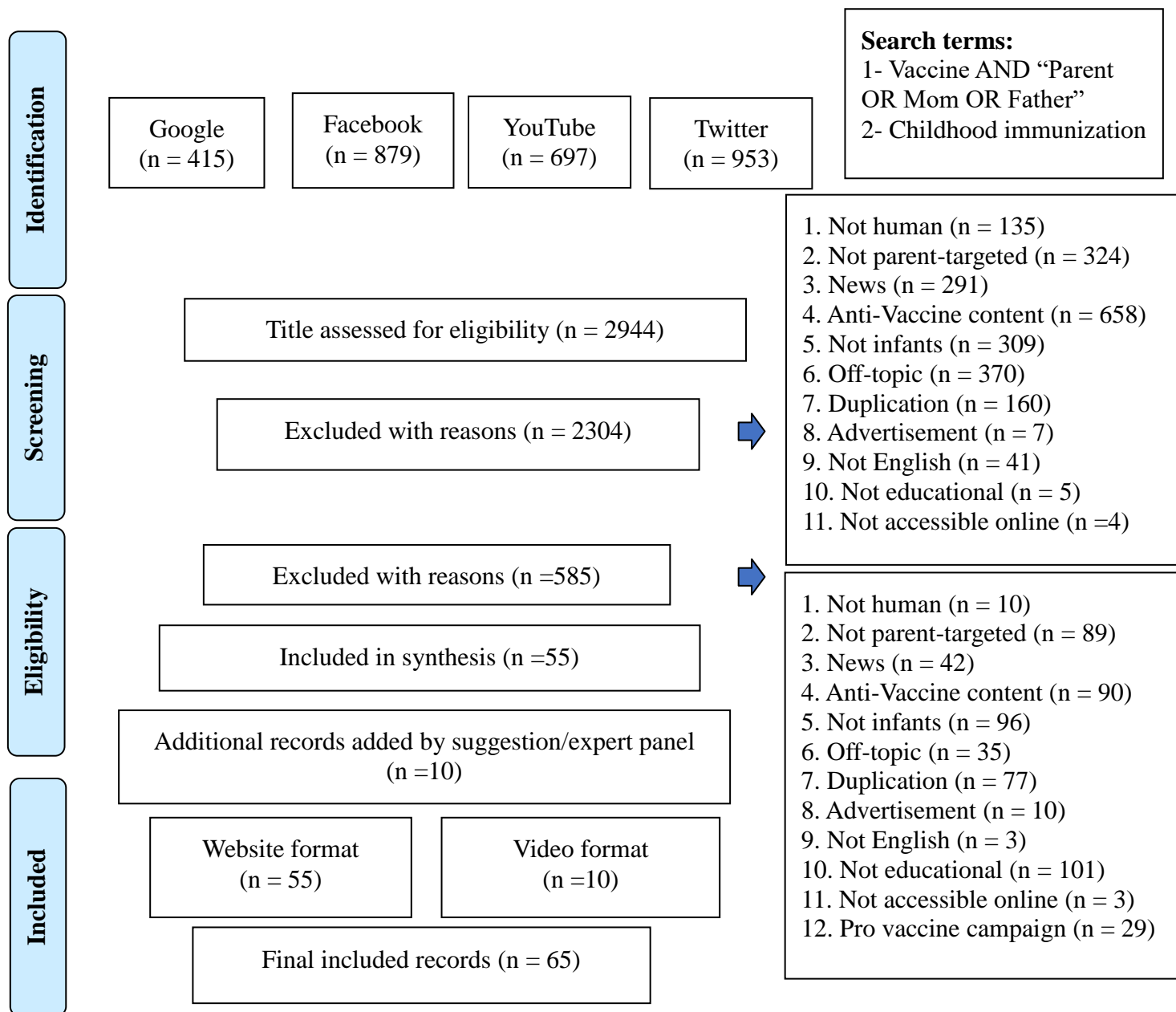


Figure 2. Vaccination Pain Management Strategies Addressed in Resources

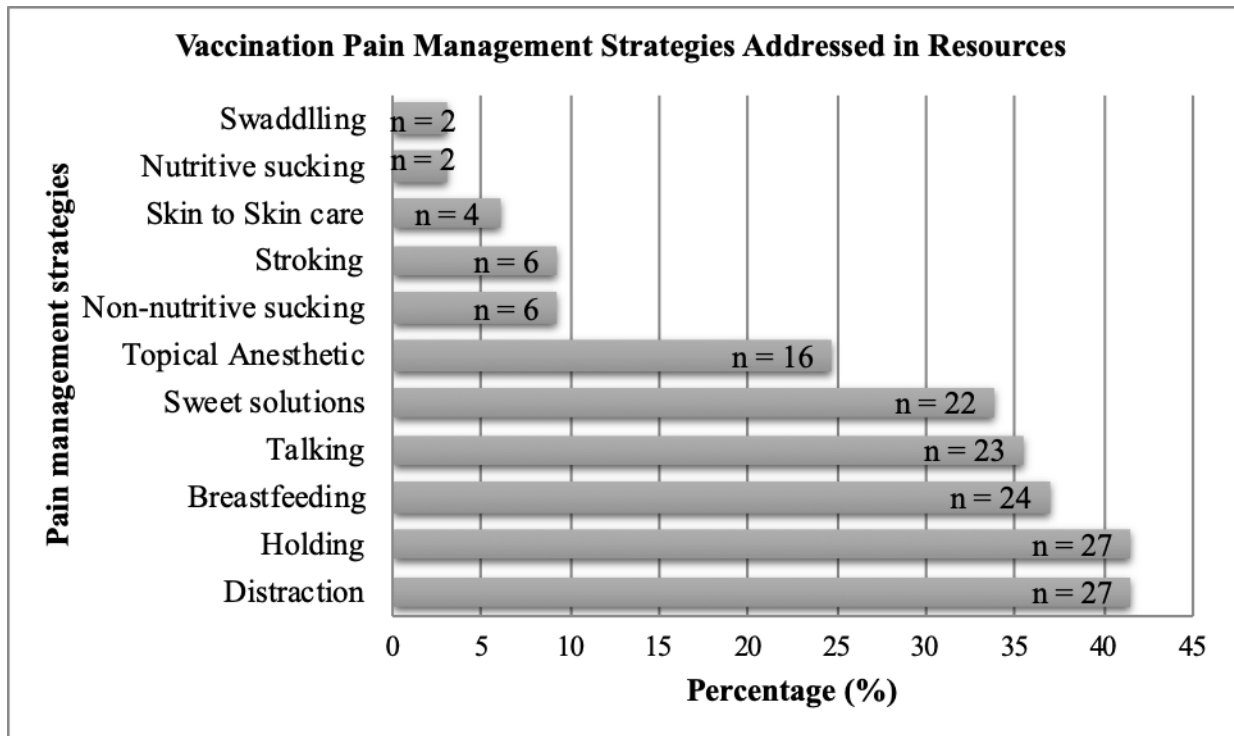


Table 1. Characteristics of Resources

Resource name and URL	Record type	CDC Score (%)	Affiliation	Country of origin	Updated/uploaded Date	Pain Management addressed
Children's Minnesota	Website	93	HCO*	USA	N.R**	Y
Colorado Children's Immunization Coalition (CCIC)	Website	90	Associations	USA	N.R	N
NSW government health	Website	90	HCO	Australia	N.R	N
CAN IMMUNIZE	Website	87	HCO	Canada	12.2018	Y
Vaccinate Oklahoma	Website	86	Associations	USA	N.R	Y
Government of Canada	Website	85	HCO	Canada	11.2018	Y
The vaccine mom	Website	85	blogs	N.R	N.R	N
Minnesota Childhood Immunization Coalition	Website	85	Associations	USA	N.R	N
Reduce the pain of vaccination in babies	VIDEO	85	HCO	Canada	3.2015	Y
The Vaccine Schedule Parents	VIDEO	80	Associations	USA	10.2013	N
Children's Hospital of Philadelphia	Website	80	Academic institute	USA	5.2017	N
Childhood immunisations – what to expect	VIDEO	80	HCO	Australia	5.2014	N
I VACCINATE	Website	78	Associations	USA	N.R	Y
Breastfeed to minimize vaccination pain - 2 months	VIDEO	76	HCO	Canada	10.2016	Y
Breastfeed to minimize vaccination pain – 6 months	VIDEO	76	HCO	Canada	2.2017	Y
Give sweet solutions to minimize vaccination pain	VIDEO	76	HCO	Canada	3.2017	Y
The Hospital for Sick Children	Website	75	HCO	Canada	7.2018	N
It's Ok to ask	Website	75	HCO	USA	N.R	N
Healthed, helping newzealander stay healthy	Website	75	HCO	New Zealand	2.2018	N
Protecting Your Child: Understanding Childhood Immunisation	VIDEO	75	HCO	Australia	12.2014	N
Government of Ontario	Website	73	HCO	Canada	8.2018	Y
The California Immunization Coalition	Website	73	Associations	USA	N.R	Y
HELPinKids&Adults	Website	71	HCO	Canada	N.R	Y

Australian Government, department of health	Website	70	HCO	Australia	8.2018	N
Immunizenevada	Website	70	Associations	USA	N.R	Y
Voices for vaccines	Website	68	Associations	USA	12.2016	N
the Colorado Children's Immunization Coalition	Website	68	Associations	USA	N.R	N
Immuizealberta	Website	65	HCO	Canada	N.R	Y
The Centre for Pediatric Pain Research	Website	63	HCO	Canada	N.R	Y
PATH's Vaccine Resource Library (VRL)	Website	63	Encyclopaedias	N.R	2.2018	Y
Vaccines.gov	Website	63	HCO	USA	7.2018	Y
Immunization Action Coalition	Website	60	Associations	USA	1.2019	N
Parenting in Ottawa	Website	57	Associations	Canada	1.2019	Y
American Academy of pediatrics	Website	57	Associations	USA	3.2014	Y
Vaccinate your family	Website	56	Associations	USA	12.2018	N
Immunize Canada	Website	55	Associations	Canada	5.2018	Y
Immunizebc	Website	55	HCO	Canada	5.2018	Y
Centers for disease control and prevention	Website	55	HCO	USA	4.2016	Y
Government of Newfoundland and Labrador	Website	55	HCO	Canada	12.2018	N
Vaccines For Children	VIDEO	53	HCO	USA	5.2012	N
Arizona Partnership for Immunization	Website	52	Associations	USA	N.R	Y
Childhood Immunizations	VIDEO	50	HCO	Canada	2.2016	N
Norwegian Institute of Public Health	Website	50	HCO	Norway	11.2018	N
Porcupine Health Unit	Website	50	HCO	Canada	N.R	N
NHS Choices	Website	50	HCO	UK	7.2016	N
parents of kids with infectious diseases	Website	50	Associations	Canada	N.R	N
Haldimand-Norfolk Health Unit	Website	47	Associations	Canada	N.R	N
Vaccines for Africa	Website	46	Academic institute	South Africa	3.2017	Y
Kansas Immunization Program	Website	45	HCO	USA	N.R	N
Saskatchewan Health Authority	Website	45	HCO	Canada	N.R	N
BC Pediatric Society	Website	43	Associations	Canada	N.R	N

Maine Immunization Program	Website	42	Associations	USA	N.R	N
Caring for kids	Website	40	Associations	Canada	5.2018	Y
Vaccine information you need	Website	40	HCO	USA	5.2018	Y
DTP vaccination	VIDEO	40	N.A	N.R	7.2014	N
Childhood immunizations in the United States	Website	37	Encyclopedias	USA	12.2018	N
World Immunization Week	Website	37	HCO	Geneva	9.2015	Y
Emedicine health	Website	37	Associations	USA	N.R	N
California vaccine for children	Website	36	HCO	USA	N.R	N
interior health	Website	35	HCO	Canada	N.R	N
Vaccine Awareness and Research (CVAR)	Website	33	HCO	USA	N.R	N
Canadian Paediatric Society	Website	31	Associations	Canada	5.2018	Y
MedlinePlus	Website	25	HCO	USA	10.2017	Y
The scientific parent	Website	25	blogs	N.R	N.R	N
Government of Nunavut	Website	14	HCO	Canada	N.A	Y

*Health Care Organization

**Not Recorded

Chapter 5 - Integrated Discussion

In this chapter, the key findings of the two studies in this dissertation are summarized. Findings are then discussed, compared and contrasted with related studies in the field, as underpinned by the KTA framework. A separate section of unplanned outcomes; namely, the impact of anti- or pro-vaccination movements will be discussed. Finally, implications for nursing practice, education, policy, and research in vaccination pain management of infants will be presented.

Through this dissertation, the key aim was to improve the use of recommended pain management strategies during infant vaccination. In line with this aim, two discrete, but inter-related studies were conducted. They are discrete because they are two independent studies and the results of one study were not required for the other study to be conducted. However, they are inter-related as they both contribute to improving the knowledge and practice of pain management for infants during vaccination in unique yet related ways. Both studies are informed by the KTA framework and focus on knowledge creation, dissemination and implementation phases of the KTA cycle. In this integrated discussion chapter, the key results of the two studies are presented within a discussion of the common and divergent findings in other studies in the literature.

Key Findings of Study 1

A pilot RCT of parent-targeted KT interventions delivered prior to vaccination of infants was conducted, in which online platforms were used to deliver and evaluate the interventions for parents as well as evaluate all the study processes. Study 1 was an evaluation of the feasibility, acceptability, and preliminary efficacy of parent-targeted interventions for improving the use of recommended pain management strategies during infant vaccination. Findings showed the online recruitment strategy and delivery of information (parent-targeted and mediated KT interventions) to parents about vaccination pain management, used in this study, is acceptable however the feasibility could be improved, especially regarding the MI-based intervention. Based on the KTA cycle step of tailoring

evidence to the local context, both interventions were designed to help translate the evidence into practice through use of parent-friendly resources. In addition, the AS&Q was designed to guide parents in the process of decision making by supporting them to express their personal values. The results of Study 1 however, showed no significant difference in the use of pain management strategies between the two groups. Therefore, there was insufficient evidence to support the efficacy of the MI-informed AS&Q intervention in addition to the Be Sweet to Babies videos and tip sheet, in improving the use of recommended effective pain management strategies during infant vaccination. However, pilot studies are not designed to establish the efficacy of interventions (Thabane et al., 2010). Yet, parents in this intervention 2 group felt more confident to use any of the three recommended pain management strategies than at baseline (30%) and all intended to use the pain management strategies in the future. This does highlight the potential benefit of the MI-informed AS&Q intervention.

In addition, results of Study 1 showed that the parent-targeted and mediated interventions (Be Sweet to Babies videos and a tip sheet) may increase the use of effective pain management strategies during infants' vaccination. In fact, the Be Sweet to Babies videos and accompanying tip sheet resulted in increased use of effective pain management strategies during vaccination to 44% more than what they reported in the baseline survey. This substantial increase in the use of any pain management strategy from baseline can be considered a clinically important difference (Grimshaw et al., 2006). It is also above the reported utilization rates of effective pain management strategies in similar studies of implementation of parent-targeted education relating to vaccination pain management (Taddio, Parikh, et al., 2015; Taddio, MacDonald, et al., 2014; Taddio, Smart, et al., 2014).

Key Findings of Study 2

An environmental scan of online publicly accessible resources (Google, YouTube, and social media networks such as Facebook, and Twitter) was conducted to investigate the quality of online parent resources. In line with the KTA cycle, in Study 2, existing online-based resources about vaccination pain management were identified, summarized and reviewed to create a knowledge base about what was publicly available. A total of 65 resources were included in the environmental scan. In addition to evaluating the quality of online parent-targeted resources, the contents of the same resources were further assessed for information related to pain management strategies during infant vaccination. Findings showed most publicly accessible online parent-targeted vaccination resources were of poor to moderate quality, and most resources did not contain easy-to-navigate information related to effective pain management strategies. In fact, according to the CDC Clear Communication Index, only three of the 65 (5%) resources included in the environmental scan were scored as acceptable with the other 62 (95%) needing further revisions.

In the following section of this chapter, the key results of the two studies are discussed to inform the overarching aim of this dissertation, to improve the use of recommended pain management strategies during infant vaccination.

The Internet is a key source of information for parents, and social media is a significant influencing factor in parents' health behavior (Alshaikh et al., 2014). As new research evidence emerges, using online platforms is increasingly playing an important role in the KTA cycle in facilitating knowledge dissemination and delivery of interventions in a timely and effective fashion (Gupta & McKibbin, 2013). Our findings highlighted that parents of infants and children are increasingly seeking online information as a source of knowledge about needle pain management. This is evident by a large number of views of many of the online resources identified in Study 2 and the extremely rapid recruitment of participants via online means, and high satisfaction rate of participating in Study 1. In addition, findings of similar studies about the evaluation of online pain management resources showed similar results of large numbers of views (Harrison, Sampson, et al., 2014; Farkas et al., 2015; Harrison, Wilding, et al., 2016; Campbell-Yeo et al., 2017).

However, our findings in Study 2, critical appraisal of the online resources about early childhood vaccination, showed that Canadian parents when searching online for vaccination educational resources are likely to find information with sub-optimal quality. The accessibility of poor to moderate-quality public resources is concerning (Basch, Zybert, Reeves, & Basch, 2017). Similar to our results, an appraisal of 75 vaccination information resources that were publicly accessible to Australian parents showed that many resources were scored as low to moderate quality, with a mean score of 55% (Wiley, Steffens, Berry, & Leask, 2017). In addition, other studies evaluated the quality of online resources available to parents of children with different health problems such as Talipes Equinovarus (clubfoot) (Kumar, Subramani, Veerapan, & Khan, 2014), epilepsy (Cerminara, Santarone, Casarelli, et al., 2014), and issues related to preterm newborns (Dol et al., 2018). Even though a different appraisal tool was used in these studies (DISCERN, a standard tool for quality appraisal of written health information on treatment choices (Charnock & Shepperd,

2004)), the findings were consistent with our results demonstrating low to moderate quality of online information.

In terms of using the online platforms for participant recruitment and disseminating study information, this dissertation showed that popular online platforms such as Facebook, Twitter, and parents' forums are feasible and acceptable pathways for reaching out to parents for knowledge dissemination, study recruitment and implementation purposes of research. In Study 2, high numbers of views of included resources highlighted the importance of popular online platforms for the delivery of consumer-targeted KT resources. In addition, in Study 1, all interventions were delivered to parents via online platforms. A pilot RCT method was used to evaluate the feasibility and acceptability of the interventions and methods of information delivery. This is a suitable method as there was no prior information on acceptability or feasibility of the online recruitment processes, data collection processes and delivery of information. The pilot design allows the researcher to assess the feasibility, acceptability, and fidelity of the study process, procedure, and interventions (Harrison, Elia, et al., 2014; Thabane et al., 2010). To evaluate the feasibility of the study's online processes, the following outcomes were measured: i) the number of parents within a specified time period who responded to the invitation to participate in the research; ii) the number of completed consent forms, iii) the number of email addresses provided; iv) the number of completed surveys. The target sample was 150 parents. In this study, 151 parents of infants were recruited in the space of one week. From the original 151 parents, 89 parents completed the study process to the end, this was a response rate of 59%. Although this 59% data collection completion rate from the original 151 is not optimal, this response rate is higher than what has been reported before in studies using social media for recruitment of participants. For example, response rates reported in a systematic review of ten studies exploring the use of social media sites such as Facebook for data collection for health research,

varied from only 2% to 27%, with an average of 12% (Alshaikh et al., 2014). Moreover, a scoping review of 30 studies using social media to recruit participants into medical research reported a median recruitment rate of 32% (Topolovec-Vranic & Natarajan, 2016). These authors stated that Facebook was the most used social media platform with 28 of the 30 studies using Facebook for study promotion and recruitment (Topolovec-Vranic & Natarajan, 2016). In line with these findings, Alshaikh et al. (2014) in their systematic review of ten studies suggested using social network sites for reaching younger populations and those who are challenging to reach, such as vulnerable and isolated populations. They reported that in eight out of 10 of the included studies, Facebook was used as a tool for data collection and participant recruitment and Myspace, and parental forums were used for the remaining two studies (Alshaikh et al., 2014). Both reviews showed that social network sites such as Facebook have the potential to be used in health research as a research tool to reach large numbers of participants and facilitate the process of data collection (Alshaikh et al., 2014; Topolovec-Vranic & Natarajan, 2016). More recently, Tustin et al. (2017) explored the effectiveness of social media networks to reach parents to participate in a web-based vaccine hesitancy survey. A large sample of Canadian parents (1097 parents) was recruited from Facebook within a short timeframe (one-month campaign), with one researcher running the campaign and data collection. As reported by Tustin et al. (2017), the response rate in their study was 23% (1097 of 4792 initially clicked on the advertisement link) and the survey completion rate was 65% (1097 of 1696 people who started the survey). They concluded that Facebook is a successful medium to recruit vaccine-hesitant parents in Canada (Tustin et al., 2017). These findings are promising in terms of the feasibility of online recruitment to reach out to parents for participation in research. For this current study, the short duration of one week, in which 201 parents responded to the recruitment invitation, may be due to factors such as widespread advertisement through social media, parent groups, and

mailing lists. Furthermore, the topic of infant vaccination may have received more attention during the recruitment phase of the study because of a measles outbreak and publicity about the need for vaccination as well as subsequent publicity from the anti-vaccination movements. These factors may have impacted the number of people searching for vaccination information online. In addition, for compensation of participants' time, a small incentive was offered to parents in our study (\$10.00 coffee card) that may have positively influenced the recruitment rate. Quach et al. (2013) evaluated the effect of incentives on online recruitment rates of Ontario parents, in a study about school immunization. They reported that adding a small incentive (\$5.00 gift card) significantly increased the recruitment rate through social media from 16.5% (222/1346) (no incentive) in a five-month recruitment period, to 83.5% (1124/1346) when an incentive was offered (Quach et al., 2013). Regarding the acceptability of online platforms to recruit parents and deliver health information, almost all participants in Study 1 were satisfied with the study requirements for enrolling, completing the surveys and completing the intervention-related materials. In addition, almost all participants reported that they would recommend the pain management strategies to other parents and nearly all intended to use these strategies during their infants' future painful procedures. Parents were satisfied with participating in this study and they were interested in participating in future similar studies. This highlights the acceptability of the study methods and interventions. In terms of subsequent results, the fact that more than 95% of participants used at least one of the recommended pain management strategies after the interventions highlights the potential feasibility of using an online approach to change health behaviors in parents.

Regarding the evidence-based pain management strategies, findings of this dissertation showed that recommended pain management information during vaccination was present in less than half of the 65 publicly available online parent-targeted resources in Study 2. In line with this result, a

quality appraisal of 197 websites available to parents of preterm infants requiring neonatal intensive care in NICU (Dol et al., 2018), and systematic reviews of YouTube videos (Farkas et al., 2015; Harrison et al., 2018; Harrison, Sampson, et al., 2014) reported infrequent inclusion of information about effective pain management strategies during needle-related painful procedures in infants and children. To address this sub-optimal access to resources, and use of pain management strategies during infant vaccination, and in line with the KTA framework, in Study 1, a series of online KT resources (Be Sweet to Babies vaccination videos and a tip sheet) was used as part of the parent-targeted and mediated KT interventions aimed at supporting parents to use effective pain management for infants undergoing vaccination. KT resources such as videos, factsheets, booklets and websites can facilitate the process of understanding and application of evidence for knowledge users, in this case, parents of infants (Kitson, & Straus, 2013). The Be Sweet to Babies vaccination videos were also identified and included as a publicly available resource in Study 2. The decision to use the Be Sweet to Babies videos in Study 1 were made before initiating Study 2, based on the evidence of acceptability and feasibility videos in the previous studies by Be Sweet to Babies team (Venegas, et al., 2019; Harrison, Larocque, et al., 2017; Harrison, Wilding, et al., 2016). The Be Sweet to Babies videos have been produced in multiple languages for global use, and the Portuguese language versions of the Be Sweet to Babies video series, showing the use of breastfeeding, skin-to-skin contact, and sweet solutions during newborn screening was used in a different study. A cross-sectional survey was developed and participants (both parents and HCPs) caring for newborn infants in Brazil were recruited by the "virtual snowball" sampling method, to evaluate the use of the Facebook platform to disseminate the video (Vieira, Harrison, Bueno, & Guimarães, 2018). Findings showed that after three months the Be Sweet to Babies Facebook page reached 28,364 views, in 45 municipalities across Brazil, 1531 people visited the page and 709 people completed the study

questionnaires (46.3% response rate based on visits to the Facebook page). There were 1126 "likes", and multiple positive comments. In addition, almost all respondents (99.7%) answered that they would use one of the pain management strategies in future painful procedures. The authors concluded that Facebook is a low cost, feasible and promising tool for data collection, knowledge dissemination and evaluation of KT interventions in a short period of time (Vieira, Harrison, Bueno, & Guimarães, 2018).

Several other informative video and online resources have also been produced, with the aim of disseminating accurate evidence-based information about pain management during early childhood vaccinations (Chan et al., 2013; Harrison, 2014; Taddio, et al., 2015). For example, the cross-Canada multidisciplinary team, HELPinKIDS produced an informative KT resource for parents in video format (<https://www.youtube.com/watch?v=5Oqa1Fag5eQ>), which explains different psychological and pharmacological strategies to reduce infant pain during vaccination (Taddio, et al., 2015). This is a 13-minute video, much longer than the brief videos used in this current study. The effectiveness of the HELPinKIDS video and educational materials in increasing the use of pain management strategies by parents were evaluated in two different RCTs (Taddio, Parikh, et al., 2015; Taddio, Smart, et al., 2014). For example, Taddio et al. (2015) showed that providing parents with a shortened eight-minute-long version of the HELPinKIDS video and a written pamphlet, increased the use of holding (51% vs. 19%), breastfeeding (25% vs. 8%), and sweet solutions (15% vs. 0%) compared to the control group of parents who received no pain management information during the initial and the follow-up (after two months) vaccination appointments. Furthermore, the education group experienced a higher adherence to using the strategies in the follow-up appointments. In another similar trial by Taddio et al. (2014), an additional 30-minute interactive presentation about infant vaccination pain management was included in an educational package (video and pamphlet)

for the intervention group. The information was delivered in a prenatal class. Results showed that using a one-time parent-targeted intervention increased the use of one or more of three pain management strategies (topical anesthetics, sweet solutions, and breastfeeding). The use of any one of the strategies was 17% higher in the intervention group compared to the control group, who only received the standard prenatal written educational information. The utilization of one or more effective strategies occurred in 34% of the intervention group and 17% of the control group. However, participants in the education group reported higher rates of attempted yet unsuccessful utilization (19%) of at least one pain management strategy (mostly breastfeeding) compared to the control group (5%) ($P = 0.001$). This was stated to be due to the HCPs not supporting the mothers to breastfeed. This shows the importance of having supportive clinicians, who know the evidence and are supportive of using the evidence, in addition to parental education, to using recommended pain management strategies. Similar to other studies (Taddio, Parikh, et al., 2015; Taddio, Smart, et al., 2014), in this dissertation, breastfeeding was shown to be the most commonly used strategy during vaccination of infants. This could be due to reasons such as a high proportion of mothers were breastfeeding, and there may have been no access to sweet solutions at the vaccination clinics, sweet solutions were not requested, or prepared or purchased beforehand.

Another example of a successful online network to reach out to parents and share information about children's pain management is a Canada-wide KT network called Solutions for Kids in Pain (SKIP), based at Dalhousie University and co-led by Children's Healthcare Canada. The SKIP founders describe it as a science-media collaboration project (Chambers, 2019). SKIP, expanded from the "It Doesn't Have to Hurt" initiative, was launched in 2012 and co-led by a University researcher and lead of the online parent forum, YummyMummyClub.ca. As a result of extensive online dissemination, SKIP is now working with more than 70 partners (including researchers,

policy-makers, and HCPs), and 48 different health organizations across Canada to improve children's pain management by mobilizing evidence-based solutions (Chambers, 2019).

In study 1 of this dissertation, there was insufficient evidence to support the efficacy of the MI-informed AS&Q intervention, in addition to the Be Sweet to Babies videos and tip sheet delivered online to parents, in improving the use of recommended effective pain management strategies during infant vaccination. The following points may explain potential reasons why the AS&Q intervention was not successful in increasing the use of effective vaccination pain management strategies in our study: i) the one-time and online nature of intervention delivery to participants, ii) the long delay from the delivery of information to the time of practice (up to three months), iii) lack of statistical power in the pilot study design and iv) lack of guarantee that parents read and understood the materials. Further exploration of such online administered MI-based behavioral change interventions is needed to further understand the potential benefits of this approach when delivered in a written form via online platforms. Thus, there is a need for further research to develop, modify and re-evaluate the MI-based interventions more extensively in the area of infant pain management.

Overall, both studies of this dissertation showed that the Internet is an important influencer on parents' knowledge and subsequently on their health behavior in their infant vaccination practices. In addition, the importance of dissemination of KT resources on popular publicly accessible online platforms to parents was highlighted. However, the current lack of publicly accessible high-quality information on online platforms relating to vaccination pain management highlights the need for improvement in the content and quality of information. In addition, online popular social media platforms need to be considered as important and effective communication venues for the public from health authorities and policy makers. In a parallel approach, academic and clinical settings have

a responsibility to ensure HCPs are up-to-date with evidence-based strategies in vaccination pain management. This synchronized approach may lead to both HCPs and parents to be better informed to improve the pain care of infants during vaccination. The pilot study findings of this dissertation have informed the need for, and processes for conducting a full-scale trial in the future.

Unplanned Outcome: The Impact of Anti- or Pro-Vaccination Movement

This dissertation did not aim to evaluate the impact of the vaccine safety movements on health behaviors among parents. However, both studies completed for this dissertation were influenced by these movements. While screening for the eligible resources to include in Study 2, many resources were recognized as information concerned with vaccine safety (pro- or anti-vaccination). These resources did not meet the inclusion criteria of Study 2 and were excluded. However, it was evident that Facebook was a key online platform used by anti-vaccination movements to disseminate their information. The information provided by the anti-vaccination groups was not seen on resources provided by any reputable healthcare or academic organizations or professional groups in Study 2.

The recruitment of participants for Study 1 may also have been influenced by the pro- anti-vaccination movements. Recruitment procedures of Study 1 occurred at the time of a Measles outbreak in Canada (fall, 2018) which might have led some parents to view our advertisement posts while they were searching for vaccine safety information. This might have helped the rapid distribution of study advertisement posts and as a result, increased the number of people who were recruited in the study. More specifically, some parents wrote supportive comments under the advertisement posts, encouraged other parents to join the study and showed interest in learning more about improving the vaccination experience of their infants. However, some parents provided discouraging feedback in response to the advertisement post. This included anti-vaccination

comments placed under the advertisement posts, which resulted in one of the advertisement posts being removed from a popular parent forum by the moderators to avoid further tension among the members. Some online platforms with large numbers of members (e.g. Facebook groups, or parents' forums) declined to post the advertisement of Study 1 due to a history of conflicts between the anti- and pro-vaccination groups.

Although the evaluation of the anti-, pro-vaccination movement was not the aim of this dissertation, it was evident in the online resources that considerable effort was put into these campaigns. Similar to our findings, two systematic reviews of YouTube vaccination videos revealed that over 66% of videos (Basch et al., 2017) and 40% of comments (Harrison, Sampson, et al., 2014) had an anti-vaccination content. Moreover, in similar studies by (Tustin, 2017; Tustin 2018), evaluation of the content of comments relating to online vaccination resources showed “non-positive” comments, which were related to misinterpretation about the risk of vaccination, the right to choose without judgment, mistrust in pharmaceutical industry/government/HCPs and past negative experience with vaccination. On the other hand, positive comments about vaccination were about explaining the risks of not vaccinating for children and the public, and judgments on the knowledge level of anti-vaccinators. Finally, it is noteworthy to mention that using online platforms for health research can be influenced by online trends focusing on subjects that were not in the scope of the study.

Summary

To our knowledge, this dissertation is the first study that has critically appraised available online parent-targeted information regarding pain management during infant vaccinations. In addition, this is the first study to our knowledge to evaluate the use of an MI-based technique in health behavior change of parents for vaccination pain management. The online nature of the study added to the novelty of the study since it reduces the risk of contamination bias between participants.

The consistency in the delivery of educational materials (videos and pamphlets) to all participants in both the intervention and control groups helped support the ethics and standards of care in the dissemination of evidence-based knowledge of pain management to all participants regardless of the allocated study group.

This dissertation provided evidence of the importance of online social media platforms in disseminating information relating to childhood vaccination pain management practices and knowledge. Overall, although most parents were breastfeeding, suboptimal use of pain management strategies, lack of confidence and self-advocacy behavior in parents for the use of these strategies, and the lack of high-quality vaccination pain management resources were the main barriers discovered in this dissertation. Thus, there is a need to address the insufficiency of quality online information and barriers to vaccination pain management. Moving forward with the incorporation of online platforms and social media networks, effective KT resources such as the Be Sweet to Babies, HELPinKIDS and the SKIP videos need to be widely shared with parents, HCPs, and organizational leaders. This research provides evidence about the importance of online platforms in the dissemination of knowledge and delivery of KT educational resources to parents. This study has contributed to the knowledge and practice of health behavior change in vaccination pain care. Furthermore, it has highlighted that the use of social media networks is a promising knowledge dissemination strategy and has the potential to be used as an effective tool for data collection and recruitment of research participants.

Considering the online and multi-faceted nature of the study, the feasibility of the study procedure is promising in terms of using similar recruitment processes for larger studies in the future. However, given the small size, no significant difference between groups in using the recommended pain management strategies, the use of AS&Q intervention for a larger RCT remains questionable

and the results of this pilot study cannot provide valid estimates to guide power calculations for larger RCTs.

Implications of Findings

This dissertation makes a substantial contribution to the body of evidence in relation to infant vaccination pain management, knowledge translation, and research methods. This section provides insight into the implications of these findings in nursing, nursing research, policy, and education.

Implications for practice. Findings of this dissertation highlight the importance of parent-targeted and mediated educational resources and the use of online popular platforms for the delivery of information about vaccination pain management in the diverse clinical settings where vaccinations take place. The findings may provide guidance in facilitating the administration of effective pain management strategies during the vaccination of infants in clinical settings by promoting the use and availability of high quality parent-targeted KT resources such as the tip sheet and videos, and guidance to access credible online resources for parents. Popular online platforms can be used for raising awareness for both HCPs and parents, by disseminating high quality KT resources (Alshaikh et al., 2014).

In addition, equipping HCPs with the necessary knowledge, resources, and guidance to support parents may support parents further to use these strategies during their infant's vaccination (Taddio, Ipp, et al., 2014, Taddio, Shah, et al., 2013). Settings may accommodate the use of any of the effective pain management by ensuring mothers have sufficient time and privacy, especially if breastfeeding, or have access to sucrose vaccination clinics. In addition, the importance of the parents' role, and their engagement in the pain care of their infants could be highlighted during parental education sessions such as prenatal sessions or at the time of newborn screening. In fact, educating parents beforehand may increase the adoption of pain management strategies as well as parents' comfort level and confidence in advocating for breastfeeding during upcoming vaccinations

or, if breastfeeding is not possible, sweet solutions and upright secure holding (Taddio, Smart, et al., 2014).

Implications for future research. The successful online recruitment process and effective delivery of information to parents in a cost- and time-efficient approach supports the use of online recruitment strategies and delivery of the interventions to parents about vaccination pain management for future studies. However, as a result of no significant difference between the study groups after delivery of the interventions, the use of AS&Q intervention for a larger RCT remains questionable. Additional evaluation is required to improve the use of such MI-components delivered online, in future research.

In this dissertation it was shown that there is no validated standardized tool to critically appraise the quality of resources in video format, thus, the development of a comprehensive, multi-faceted and validated tool that is compatible with different resources in different formats (e.g., websites, blogs, social media pages, videos, infographics, and handouts) is warranted.

Findings of this dissertation showed an increase in knowledge and use of effective pain management strategies almost two months after the intervention, however, it is not known whether parents retain the knowledge demonstrated in the KT materials, for future painful procedures of their infants. Research with a longer follow-up period may help evaluate the retention of knowledge and change in the health behavior of parents about infant vaccination pain management (Taddio, et al., 2015 & 2014; Chan, et al, 2013). A longitudinal study to measure the sustainability of knowledge retention 12 months vaccination is therefore suggested.

The pilot RCT was completed mostly by educated Caucasian mothers living in Canada. Therefore, comparing the results in other groups and targeting a more diverse population including lower socioeconomic groups and more culturally diverse groups is warranted.

Implications for policy. Health care leaders and policy makers play an important role in prioritizing and championing the use of recommended evidence-based practice strategies (Sarkies, Bowles, Skinner, et al., 2017). In order to facilitate the use of pain management strategies, public health leaders may consider the principals of effective pain care for infants in the process of policy-making by ensuring the inclusion of information in the clinical practice guidelines, and HCPs' adherence to the guidelines. Public health organizational leaders may help accommodate the use of the recommended pain management strategies by providing free sweet solutions and comfortable environments for mothers to breastfeed their infants. Health care managers can help to ensure that the HCPs are trained and aware of these strategies to support the parents' decision for their infant pain care.

In addition, online posting of reliable KT resources such as professionally produced videos and written information by public health authorities on popular online platforms may help increase the credibility and trustworthiness of KT resources about pain management during vaccination. The development of a well-managed online platform consisting of a collection of professionally produced KT resources accessible to both parents and HCPs would mitigate the problems of poor-quality online information (Wiley et al., 2017; Charnock & Shepperd, 2004; Eysenbach, 2002). Finally, scientists and policy makers should not underestimate the impact of social media influencers such as popular parenting bloggers or celebrities on promoting health behavioral changes among parents. Reaching out to public figures may help to promote the latest innovations and knowledge in vaccination pain management. A successful example of this strategy was "It Doesn't Have to Hurt" in partnership with a well-known online personality from "YummyMummyClub.ca". (Chambers, 2019).

Implications for education. The KT interventions evaluated in Study 1 may build

knowledge, readiness for change, and confidence in parents towards health behavior changes in vaccination pain management practices. To fully implement recommended evidence-based pain care during vaccination of infants, educational interventions also need to target HCPs in diverse settings where infant vaccinations take place (Russel and Harrison, 2015; Harrison, et al., 2013; Taddio, Shah, et al., 2013). In addition, the KT interventions need to target nursing, midwifery, medical, and health science students in undergraduate and graduate courses, and professors teaching such courses in colleges and universities. In this way, partnerships between parents and HCPs may improve and parents may be less likely to face resistance from HCPs when requesting the use of pain management strategies during their infant's vaccination. This information may be included in continuing education courses at workplaces for clinicians to update their knowledge on how to integrate the recommended pain management strategies into their routine practice.

Since new innovative advances on the topic of pain care in infants continues to emerge, it is essential for health science students to receive up-to-date education related to current pain management. For example, considering pain management as a license competency would ensure that graduating HCPs are well-prepared to provide evidence-based pain care. In addition, there is also a need to incorporate more information into family and child nursing curricula about implementation sciences, family engagement and shared decision-making.

Conclusion

Findings of this dissertation highlight the importance of online parent-targeted resources and KT interventions for improving the use of recommended pain management strategies during infant vaccination. This study showed the feasibility and acceptability of online platforms as an efficient method of recruitment of research participants. Furthermore, these platforms were shown to be an easy approach for disseminating health information and the delivery of KT interventions to parents of

infants. Popular online social media platforms have the potential to widely disseminate knowledge to consumers. Optimizing accessibility to evidence-based educational resources can improve healthcare practices; in this case, pain management practices for infants during vaccination.

The easy to implement and low-cost educational resources (videos and a tip sheet in this study) may improve the knowledge, and the use of breastfeeding, sweet solutions, and upright secure holding during vaccination of infants. Education of parents along with HCPs is important to integrate these effective pain management strategies as a normalized part of vaccination practices in diverse settings where infant vaccinations take place. Improving pain management for infants during painful vaccinations is important for infants and their parents and can improve the overall experiences of vaccination. Therefore, multifaceted online KT interventions and quality educational resources have the potential to support the knowledge needs and improve the health outcomes of infants and their parents.

References

- Alshaikh, F., Ramzan, F., Rawaf, S., & Majeed, A. (2014). Social network sites as a mode to collect health data: a systematic review. *Journal of Medical Internet Research, 16*(7), e171.
- April, K. T., Rader, T., Hawker, G. A., Stacey, D., O'Connor, A. M., Welch, V., ... Bennett, C. (2016). Development and alpha-testing of a stepped decision aid for patients considering nonsurgical options for knee and hip osteoarthritis management. *The Journal of Rheumatology, 43*(10), 1891–1896.
- Basch, C. H., Zybert, P., Reeves, R., & Basch, C. E. (2017). What do popular YouTube™ videos say about vaccines? *Child: Care, Health and Development, 43*(4), 499–503.
- Baur, C., & Prue, C. (2014). The CDC Clear Communication Index is a new evidence-based tool to prepare and review health information. *Health Promotion Practice, 15*(5), 629–637.
- Benoit, B., Martin-Misener, R., Latimer, M., & Campbell-Yeo, M. (2017). Breast-Feeding Analgesia in Infants. *The Journal of Perinatal & Neonatal Nursing, 31*(2), 145–159.
- BORN Ontario. (2016). Better Outcomes Registry and Network. Data Analysis for Annual Report 2014-2016. Retrieved June 10, 2019, from https://www.bornontario.ca/assets/documents/Annual_report_2014-2016_-_Data_Slides.pdf
- Brouwers, M., Stacey, D., & O'Connor, A. (2010). Knowledge creation: synthesis, tools and products. *Cmaj: Canadian Medical Association Journal, 182*(2), E68–E72.
- Bueno, M., Yamada, J., Harrison, D., Khan, S., Ohlsson, A., Adams-Webber, T., ... Stevens, B. (2013). A systematic review and meta-analyses of nonsucrose sweet solutions for pain relief in neonates. *Pain Research and Management, 18*(3), 153–161.
- Campbell-Yeo, M., Dol, J., Disher, T., Benoit, B., Chambers, C. T., Sheffield, K., ... & Stinson, J. (2017). The Power of a Parent's Touch. *The Journal of Perinatal & Neonatal Nursing, 31*(4),

341-349.

Canadian Institute of Health Research (CIHR). (2016). Knowledge Translation. Retrieved February 7, 2019, from <http://www.cihr-irsc.gc.ca/e/29418.html>

Centers for Disease Control and Prevention. (2017). Vaccines & Immunizations. Retrieved 08.2018, from https://www.cdc.gov/vaccines/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fdefault.htm

Centers for Disease Control and Prevention. (2018). Nationwide Breastfeeding Goals. Retrieved February 7, 2019, from <https://www.cdc.gov/breastfeeding/data/facts.html>

Cerminara, C., Santarone, M. E., Casarelli, L., Curatolo, P., & El Malhany, N. (2014). Use of the DISCERN tool for evaluating web searches in childhood epilepsy. *Epilepsy & Behavior, 41*, 119–121.

Chambers, C. T. (2019). Solutions for Kids in Pain (SKIP). Retrieved 07.2019 from <https://www.kidsinpain.ca/>

Chambers, C. T., Taddio, A., Uman, L. S., McMurtry, C. M., & Team, Help. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review. *Clinical Therapeutics, 31*, S77–S103.

Chan, S., Pielak, K., McIntyre, C., Deeter, B., & Taddio, A. (2013). Implementation of a new clinical practice guideline regarding pain management during childhood vaccine injections. *Paediatrics & Child Health, 18*(7), 367–372.

Charnock, D., & Shepperd, S. (2004). Learning to DISCERN online: applying an appraisal tool to health websites in a workshop setting. *Health Education Research, 19*(4), 440–446.

Chen, S. L., Harrison, D., Huang, R. R., Zhang, Q., Xie, R. H., & Wen, S. W. (2016). Efficacy of

sweet solutions in relieving pain caused by vaccination in infants aged 1 to 12 months: a systematic review. *Chinese Journal of Contemporary Pediatrics*, 18(6), pp.534-540.

Department of Health and Human Services, Government of U.S. (2019). Healthy People 2020

Objectives. Retrieved February 7, 2019, from <https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives>

Dillman, D. A., & Bowker, D. K. (2001). The web questionnaire challenge to survey methodologists. *Online Social Sciences*, 53–71.

Dol, J., Richardson, B., Boates, T., & Campbell-Yeo, M. (2018). Learning to parent from Google? Evaluation of available online health evidence for parents of preterm infants requiring neonatal intensive care. *Health Informatics Journal*, 25(4), 1265–1277.

Drozd, B., Couvillon, E., & Suarez, A. (2018). Medical YouTube videos and methods of evaluation: literature review. *JMIR medical education*, 4(1), e3.

Farkas, C., Solodiuk, L., Taddio, A., Franck, L., Berberich, F. R., LoChiatto, J., & Solodiuk, J. C. (2015). Publicly Available Online Educational Videos Regarding Pediatric Needle Pain. *The Clinical Journal of Pain*, 31(6), 591–598.

Franck, L. S., Berberich, F. R., & Taddio, A. (2015). Parent participation in a childhood immunization pain reduction method. *Clinical Pediatrics*, 54(3), 228–235.

France L., Zhang P., (2013). Barriers and facilitators: Strategies for identification and measurement. In Straus, S. E., Tetroe, J., & Graham, I. D, *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 3.3a, pp.121-136). New Jersey, USA: John Wiley & Sons.

Gabarron, E., Fernandez-Luque, L., Armayones, M., & Lau, A. Y. (2013). Identifying measures used for assessing quality of YouTube videos with patient health information: a review of current

- literature. *Interactive Journal of Medical Research*, 2(1), e6.
- Gayes, L. A., & Steele, R. G. (2014). A meta-analysis of motivational interviewing interventions for pediatric health behavior change. *Journal of Consulting and Clinical Psychology*, 82(3), 521.
- Government of Canada, Public Health Agency of Canada. (2019). National Advisory Committee on Immunization (NACI) - Immunization & Vaccines - Public Health Agency of Canada. Retrieved 07.2019 from <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html>.
- Graham, I. D., Logan, J., Harrison, M. B., Straus, S. E., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: time for a map? *Journal of Continuing Education in the Health Professions*, 26(1), 13–24.
- Graham, I. D., Tetroe, J., & Group, KT Theories Research Group. (2007). Some theoretical underpinnings of knowledge translation. *Academic Emergency Medicine*, 14(11), 936–941.
- Graham, P., Evitts, T., & Thomas-MacLean, R. (2008). Environmental scans: How useful are they for primary care research? *Canadian Family Physician*, 54(7), 1022–1023.
- Grimshaw, J., Eccles, M., Thomas, R., MacLennan, G., Ramsay, C., Fraser, C., & Vale, L. (2006). Toward Evidence-Based Quality Improvement. *Journal of General Internal Medicine*, 21(S2), S14–S20. <https://doi.org/10.1111/j.1525-1497.2006.00357.x>
- Gupta, S., & McKibbon, A. (2013). Informatics interventions. In Straus, S. E., Tetroe, J., & Graham, I. D., *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 3.4e, pp. 189-197). New Jersey, USA: John Wiley & Sons.
- Harrison, D. (2014). Be Sweet to Babies. Retrieved August, 2018, from <https://www.youtube.com/watch?v=L43y0H6XEH4&list=PLlZczt8t4Ac8cW3pbuRKJAes3SoC5y8MB>.

- Harrison, D., Beggs, S., & Stevens, B. (2012). Sucrose for procedural pain management in infants. *Pediatrics, 130*(5), 918–925.
- Harrison, D., Elia, S., Manias, E., & Royle, J. (2014). Sucrose and lollypops to reduce immunisation pain in toddlers and young children: Two pilot randomised controlled trials. *Neonatal, Paediatric & Child Health Nursing, 17*(1), 19.
- Harrison, D., Elia, S., Royle, J., & Manias, E. (2013). Pain management strategies used during early childhood immunisation in Victoria. *Journal of Paediatrics and Child Health, 49*(4), 313–318.
- Harrison, D., Larocque, C., Reszel, J., Harrold, J., Aubertin, C. (2017). Be Sweet to Babies during painful procedures. *Advances in Neonatal Care, 17*(5), 372–380.
- Harrison, D., Modanloo, S., Desrosiers, A., Poliquin, L., Bueno, M., Reszel, J., & Sampson, M. (2018). A systematic review of YouTube videos on pain management during newborn blood tests. *Journal of Neonatal Nursing, 24*(6), 325-330.
- Harrison, D., Reszel, J., Bueno, M., Sampson, M., Shah, V. S., Taddio, A., ... Turner, L. (2016). Breastfeeding for procedural pain in infants beyond the neonatal period. *Cochrane Database of Systematic Reviews 2016*, Issue 10. Art. No.: CD011248.
- Harrison, D., Sampson, M., Reszel, J., Abdulla, K., Barrowman, N., Cumber, J., ... Pound, C. M. (2014). Too many crying babies: a systematic review of pain management practices during immunizations on YouTube. *BMC Pediatrics, 14*(1), 134.
- Harrison, D., Stevens, B., Bueno, M., Yamada, J., Adams-Webber, T., Beyene, J., & Ohlsson, A. (2010). Efficacy of sweet solutions for analgesia in infants between 1 and 12 months of age: a systematic review. *Archives of Disease in Childhood, 95*(6), 406–413.
- Harrison, D., Wilding, J., Bowman, A., Fuller, A., Nicholls, S. G., Pound, C. M., ... Sampson, M. (2016). Using YouTube to disseminate effective vaccination pain treatment for babies. *PloS*

One, 11(10), e0164123.

Harrison, D., Yamada, J., Adams-Webber, T., Ohlsson, A., Beyene, J., & Stevens, B. (2015). Sweet tasting solutions for reduction of needle-related procedural pain in children aged one to 16 years.

Cochrane Database Systematic Reviews, 2015:5.CD008408

Kassab, M., Foster, J. P., Foureur, M., & Fowler, C. (2012). Sweet-tasting solutions for needle-related procedural pain in infants one month to one year of age. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD008411

Systematic Reviews 2012, Issue 12. Art. No.: CD008411

Kassab, M., Sheehy, A., King, M., Fowler, C., & Foureur, M. (2012). International Journal of Nursing Studies A double-blind randomised controlled trial of 25 % oral glucose for pain relief in 2-month old infants undergoing immunisation. *International Journal of Nursing Studies*, 49(3), 249–256.

Katrak, P., Bialocerkowski, A. E., Massy-Westropp, N., Kumar, V. S. S., & Grimmer, K. A. (2004).

A systematic review of the content of critical appraisal tools. *BMC Medical Research Methodology*, 4(1), 22.

Kitson, A., and Straus, S. (2013). Identifying knowledge to action gaps. In Straus, S. E., Tetroe, J., & Graham, I. D, *Knowledge translation in health care: Moving from Evidence to Practice*. (2nd ed., Chapter 3.1, pp. 97-110). New Jersey, USA: John Wiley & Sons.

Kraut, R., Olson, J., Banaji, M., Bruckman, A., Cohen, J., & Couper, M. (2004). Psychological research online: report of Board of Scientific Affairs' Advisory Group on the Conduct of Research on the Internet. *American Psychologist*, 59(2), 105.

Kumar, V. S., Subramani, S., Veerapan, S., & Khan, S. A. (2014). Evaluation of online health information on clubfoot using the DISCERN tool. *Journal of Pediatric Orthopaedics B*, 23(2), 135–138.

- Lundahl, B. W., Kunz, C., Brownell, C., Tollefson, D., & Burke, B. L. (2010). A meta-analysis of motivational interviewing: Twenty-five years of empirical studies. *Research on Social Work Practice, 20*(2), 137–160.
- O’Neill, M. C., Ahola Kohut, S., Pillai Riddell, R., & Oster, H. (2019). Age Related Differences in the Acute Pain Facial Expression During Infancy. *European Journal of Pain, 2019*; 00:1-12.
- Public Health Agency of Canada (2015). Vaccine coverage in Canadian children: Results from the 2011 Childhood National Immunization Coverage Survey. Retrieved 7/2019, from http://publications.gc.ca/collections/collection_2018/aspc-phac/HP40-156-2018-eng.pdf
- Public Health Agency of Canada (2016.). Publicly funded immunization programs in Canada - routine schedule for infants and children including special programs and catch-up programs. Retrieved 7/2019 from <http://www.phac-aspc.gc.ca/im/ptimprog-progimpt/table-%0A1-eng.php>.
- Quach, S., Pereira, J. A., Russell, M. L., Wormsbecker, A. E., Ramsay, H., Crowe, L., ... Kwong, J. (2013). The good, bad, and ugly of online recruitment of parents for health-related focus groups: lessons learned. *Journal of Medical Internet Research, 15*(11), e250.
- Riddell, R. P., Taddio, A., McMurtry, C. M., Chambers, C., Shah, V., & Noel, M. (2015). Psychological interventions for vaccine injections in young children 0 to 3 years: systematic review of randomized controlled trials and quasi-randomized controlled trials. *The Clinical Journal of Pain, 31*(Suppl 10), S64.
- Riddell, R. R. P., Racine, N. M., Gennis, H. G., Turcotte, K., Uman, L. S., Horton, R. E., ... Lisi, D. M. (2015). Non-pharmacological management of infant and young child procedural pain. *Cochrane Database of Systematic Reviews 2015, Issue 12*. Art. No.: CD006275.
- Russell, K., & Harrison, D. (2015). Managing pain in early childhood immunisation. *Kai Tiaki: Nursing New Zealand, 21*(2), 22.

- Ryan, G. S. (2013). Online social networks for patient involvement and recruitment in clinical research. *Nurse Researcher*, 21(1), 35–39.
- Rycroft-Malone, J., & Bucknall, T. (2010). Using theory and frameworks to facilitate the implementation of evidence into practice. *Worldviews on Evidence-Based Nursing*, 7(2), 57–58.
- Saarinen, H. L. (2010). Breastfeeding During Infant Immunization. (Doctoral dissertation), North Dakota State University, USA.
- Sampson, M., Cumber, J., Li, C., Pound, C. M., Fuller, A., & Harrison, D. (2013). A systematic review of methods for studying consumer health YouTube videos, with implications for systematic reviews. *PeerJ*, 1, e147-e147.
- Sarkies, M. N., Bowles, K. A., Skinner, E. H., Haas, R., Lane, H., & Haines, T. P. (2017). The effectiveness of research implementation strategies for promoting evidence-informed policy and management decisions in healthcare: a systematic review. *Implementation Science*, 12(1), 132.
- Schechter, N., Bernstein, B., & Zempsky, W. (2010). Educational outreach to reduce immunization pain in office settings. *Pediatrics*. 126(6), e1514-e1521.
- Schein, R., Wilson, K., & Keelan, J. E. (2011). Literature review on effectiveness of the use of social media: a report for Peel Public Health. Retrieved from <https://www.peelregion.ca/health/resources/pdf/socialmedia.pdf>
- Shah, P. S., Herbozo, C., Aliwalas, L. L., & Shah, V. S. (2012). Breastfeeding or breast milk for procedural pain in neonates. *Cochrane Database of Systematic Reviews*, (12). Issue 12. Art. No.: CD004950.
- Shah, V., Taddio, A., McMurtry, C. M., Halperin, S. A., Noel, M., Riddell, R. P., & Chambers, C. T. (2015). Pharmacological and combined interventions to reduce vaccine injection pain in children and adults: systematic review and meta-analysis. *The Clinical Journal of Pain*,

31(Suppl 10), S38.

Stacey, D., & Hill, S. (2013). Patient-direct and patient-mediated KT interventions. In *Knowledge Translation in Health Care: Moving from Evidence to Practice*, Chapter 3.4f (pp.197–211).

John Wiley & Sons, New Jersey, USA.

Stevens, B., Yamada, J., Gy, L., & Ohlsson, A. (2013). Sucrose for analgesia in newborn infants undergoing painful procedures - The Cochrane Library - Stevens - Wiley Online Library.

Cochrane Database of Systematic Reviews 2013, (1), 1–3. <https://doi.org/CD001069>

[pii]r10.1002/14651858.CD001069

Straus, S. E., Tetroe, J. M., & Graham, I. D. (2011). Knowledge translation is the use of knowledge in health care decision making. *Journal of Clinical Epidemiology*, 64(1), 6–10.

Sudsawad, P. (2007). *Knowledge translation: Introduction to models, strategies, and measures*.

Austin, TX: Southwest Educational Development Laboratory, National Center for the Dissemination of Disability Research.

Taddio, A., Chambers, C. T., Halperin, S. A., Ipp, M., Frpc, C., Lockett, D., ... Glasgow, F. (2009).

Inadequate Pain Management During Routine Childhood Immunizations: The Nerve of It.

Clinical Therapeutics, 31(C), S152–S167.

Taddio, A., Hogan, M.-E., Gerges, S., Girgis, A., Moyer, P., Wang, L., ... Ipp, M. (2012).

Addressing parental concerns about pain during childhood vaccination: is there enough time to include pain management in the ambulatory setting? *The Clinical Journal of Pain*, 28(3), 238–242.

Taddio, A., Ilersich, A. L., Ipp, M., Kikuta, A., Shah, V., & Team, Help. (2009). Physical interventions and injection techniques for reducing injection pain during routine childhood immunizations: systematic review of randomized controlled trials and quasi-randomized

- controlled trials. *Clinical Therapeutics*, 31, S48–S76.
- Taddio, A., Ipp, M., Thivakaran, S., Jamal, A., Parikh, C., Smart, S., ... Katz, J. (2012). Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine*, 30(32), 4807–4812.
- Taddio, A., Ipp, M., Vyas, C., Parikh, C., Smart, S., Thivakaran, S., ... Shah, V. (2014). Teaching parents to manage pain during infant immunizations: laying the foundation for better pain management practices. *The Clinical Journal of Pain*, 30(11), 987–994.
- Taddio, A., Manley, J., Potash, L., Ipp, M., Sgro, M., & Shah, V. (2007). Routine immunization practices: use of topical anesthetics and oral analgesics. *Pediatrics*, 120(3), e637-e643.
- Taddio, A., McMurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., ... Mousmanis, P. (2015). Reducing pain during vaccine injections: clinical practice guideline. *Canadian Medical Association Journal*, 187(13), 975–982.
- Taddio, A., MacDonald, N. E., Smart, S., Parikh, C., Allen, V., Halperin, B., & Shah, V. (2014). Impact of a parent-directed pamphlet about pain management during infant vaccinations on maternal knowledge and behavior. *Neonatal Network*, 33(2), 74-82.
- Taddio, A., Parikh, C., Yoon, E. W., Sgro, M., Singh, H., Habtom, E., ... Shah, V. (2015). Impact of parent-directed education on parental use of pain treatments during routine infant vaccinations: a cluster randomized trial. *Pain*, 156(1), 185–191.
- Taddio, A., Shah, V., Leung, E., Wang, J., Parikh, C., Smart, S., ... Sgro, M. (2013). Knowledge translation of the HELPinKIDS clinical practice guideline for managing childhood vaccination pain: usability and knowledge uptake of educational materials directed to new parents. *BMC Pediatrics*, 13(1), 23.
- Taddio, A., Smart, S., Sheedy, M., Yoon, E. W., Vyas, C., Parikh, C., ... Shah, V. (2014). Impact of

prenatal education on maternal utilization of analgesic interventions at future infant vaccinations: A cluster randomized trial. *Pain*, 155(7), 1288–1292.

- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., ... Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology*, 10(1), 1.
- Topolovec-Vranic, J., & Natarajan, K. (2016). The use of social media in recruitment for medical research studies: a scoping review. *Journal of Medical Internet Research*, 18(11), e286.
- Tustin, J. L. (2016). The Internet and Childhood Immunizations in Canada. (Doctoral dissertation), University of Toronto, Canada.
- Tustin, J. L., Crowcroft, N. S., Gesink, D., Johnson, I., & Keelan, J. (2018). Internet exposure associated with Canadian parents' perception of risk on childhood immunization: cross-sectional study. *JMIR Public Health and Surveillance*, 4(1), e7.
- Tustin, J. L., Crowcroft, N. S., Gesink, D., Johnson, I., Keelan, J., & Lachapelle, B. (2017). Facebook recruitment of vaccine-hesitant Canadian parents: cross-sectional study. *JMIR Public Health and Surveillance*, 3(3), e47.
- Valeri, B. O., Holsti, L., & Linhares, M. B. M. (2015). Neonatal pain and developmental outcomes in children born preterm: a systematic review. *The Clinical Journal of Pain*, 31(4), 355–362.
- Venegas, C. L., Taljaard, M., Reszel, J., Dunn, S., Graham, I. D., Harrold, J., ... & Harrison, D. (2019). A Parent-Targeted and Mediated Video Intervention to Improve Uptake of Pain Treatment for Infants During Newborn Screening: A Pilot Randomized Controlled Trial. *The Journal of Perinatal & Neonatal Nursing*, 33(1), 74-81.
- Vieira, A. C., Harrison, D. M., Bueno, M., & Guimarães, N. (2018). Use of the Facebook social network in data collection and dissemination of evidence. *Escola Anna Nery*, 22(3).
- Wiley, K. E., Steffens, M., Berry, N., & Leask, J. (2017). An audit of the quality of online

immunisation information available to Australian parents. *BMC Public Health*, 17(1), 76.

World Health Organization. (2015). Weekly epidemiological record Relevé épidémiologique

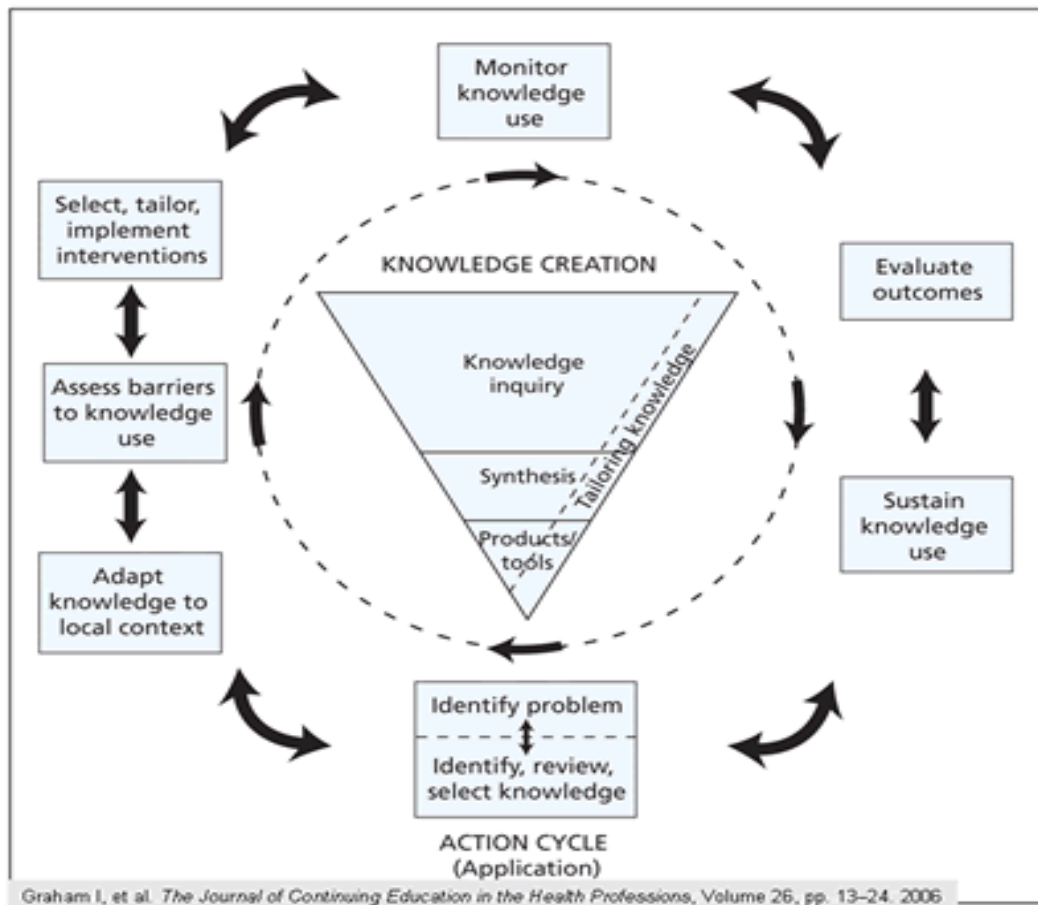
hebdomadaire. Retrieved February 2, 2018, from <http://www.who.int/wer>

Wormald, B. (2012). Video Length, Pew Research Center. Retrieved from

<https://www.journalism.org/2012/07/16/video-length/>

Appendices

Appendix A. Knowledge to Action Framework



Source of Figure: Graham I, et al. The Journal of Continuing Education in the Health Professions, Volume 26, pp 13-24, 2006. Publicly available at https://journals.lww.com/jcehp/Abstract/2006/26010/Lost_in_knowledge_translation__Time_for_a_map_.3.aspx#pdf-link

Appendix B. Advertisements Scripts

School of Nursing
Faculty of health sciences
University of Ottawa



IS YOUR BABY DUE FOR HIS/HER VACCINATION AT 2-,4-, OR 6-MONTH?
ARE YOU INTERESTED IN KNOWING MORE ABOUT REDUCING PAIN DURING
VACCINATION?

If the answer is “YES”, Parents of babies are invited to participate in a research study about ways to reduce needle pain during vaccination pain in babies

This research study aimed to increase your knowledge, confidence, and use of recommended pain management strategies of breastfeeding OR sweet solutions (very small volumes of sugar water) and upright secure holding during your baby vaccination.

This study will be done through online surveys that you can complete at your convenient time and place with any digital devices (computer, smartphone, tablet, etc.) in a two-time sitting. This study is being conducted in English, and therefore participants must be fluent in English. Participants will be invited to watch a brief video showing babies having their vaccination while being breastfed or given sugar water and being held securely, read a brief pamphlet about the pain reduction strategies and fill out a couple of brief surveys.

In appreciation for your time, you will receive a \$10.00 Tim Hortons e-gift card, sent to your email address.

For further question contact the principal investigator Shokoufeh Modanloo at;
School of Nursing, University of Ottawa, Children’s Hospital of Eastern Ontario, 401 Smyth Road,
Ottawa, Ontario, K1H 8L1

Phone: xxx

Email: xxx

The ethical component of this study has been reviewed and approved by the University of Ottawa
Research Ethics Board (REB).



Appendix C. Consent Form

Université d'Ottawa | University of Ottawa

Consent Form

Title of the study

Feasibility, Acceptability and Preliminary Effectiveness Evaluation of a Parent-targeted Intervention Followed by Motivational Interviewing based Questions in Vaccination Pain Management of Infants.

Name of investigators

Principal Investigator (PI)	Shokoufeh Modanloo, PhD Candidate	School of Nursing, University of Ottawa, Children's Hospital of Eastern Ontario, 401 Smyth Road, Ottawa, Ontario, K1H 8L1 Phone: [REDACTED] Email: [REDACTED]
Research Supervisor	Denise Harrison, RN, PhD Chair in Nursing Care of Children, Youth and Families	Children's Hospital of Eastern Ontario 401 Smyth Road Ottawa, Ontario, K1H 8L1 Phone: 613-737-7600 ext 4140 Email: dharrison@cheo.on.ca
Co- Investigator	Dawn Stacey RN, PhD, CON(C) Research Chair in Knowledge Translation to Patients	School of Nursing, University of Ottawa, 451 Smyth Rd, Phone: 613-562-5800 ext 8422; Room RGN 3038 Email: dstacey@uottawa.ca
Co- Investigator	Sandra Dunn, RN PhD Knowledge Translation Specialist	Children's Hospital of Eastern Ontario 401 Smyth Road, Ottawa, Ontario, K1H 8L1 Email: sdunn@bornontario.ca

I am invited to participate in the above mentioned research study conducted by Shokoufeh Modanloo and supervised by Denise Harrison. The purpose of the study is to evaluate the acceptability, success and usefulness of an informational video, pamphlet with or without some motivational statements before my infant vaccination. It aims to promote the use of recommended pain management strategies (breastfeeding, sweet solution, and upright secure

holding) during vaccinations of my infant. Before agreeing to take part in this study, it is important that I read and understand this document.

I have been asked to take part in this study because I have a baby scheduled to receive her/his 2, 4, or 6-month routine vaccination as per the childhood immunization schedule of Canada province I am living in, and I can read, speak and understand English sufficiently.

My participation in the study will consist of three steps,

Before my baby's vaccination

- Completing two brief online surveys asking me questions about me (age, sex, job, education, ethnicity, marital status), and my baby (boy/girl, weight of my baby etc.). Also, my previous awareness and intention to use any of specified recommended pain management strategies (breastfeeding, sweet solution (sucrose) and secure upright holding) in my baby's future vaccination episodes. I will be invited to provide an email address to be contacted for the following steps of the study.
- Watching an informational brief video produced by Be Sweet to Babies team and reading a pamphlet explaining the effect of these pain management strategies in reducing my babies' pain while a vaccination is being done by health care providers.

After my baby's vaccination

- Completing another brief online survey asking questions about the use of any of these pain management strategies during my baby's vaccination. Following that, my views about these surveys and study procedure will be asked and if I faced any problems about asking for, or using the pain management strategies during my baby vaccinations.

This is a low risk study. The study researchers do not expect any risks, side effects or discomforts associated with watching the video, reading a pamphlet or completing the study surveys for me and my baby.

My participation in this study will help me to be informed of pain management strategies for my baby and promote my involvement in vaccination pain care of my baby. Participating in

Université d'Ottawa | University of Ottawa

the study may improve my knowledge, confidence and experience in using these strategies during my baby's vaccination.

I have received assurance from the investigators that the information I will share will remain strictly confidential. I understand that the contents will be used only for research purposes. In order to minimize the risk of security breaches and to help ensure my confidentiality, I could use standard safety measures such as signing out of my internet account, closing the browser and locking my screen or device when I have completed the study. My anonymity will be protected by the research team asking the least possible identifying information (i.e no name is needed), restricted access to data collection databases and assigning a unique ID number to allow each participant to be identified by study code numbers. While my name will not be collected or linked to the data, personal email address and postal codes will be.

During the data collection and retention periods, maximum security checks will be taken including changing passwords and maintenance check on a routine basis. All digitally collected data will be kept in a secure manner through an online system (REDCap) and there will be no hard copies of any records available. Only the study PI has access to this data collation database, merely through her personal laptop secured by using a username and an updated password. In addition, the laptop will be stored securely in a locked cabinet at her office. The laptop will never be left unattended in the office, car, or any other insecure places. This research project database will be terminated after 5 years following the final publication of study results. My baby and I will not be identified in any presentation or publication of this study.

My participation in this study is voluntary and I am free to withdraw from the study at any time and there will be no penalty to me. If I choose to withdraw, my data will be removed and destroyed unless I give researchers permission to use it. Reasons for withdrawal will be recorded for consideration in designing a future larger study.

Following the study completion or after the withdrawal, I will be re-offered the Be Sweet to Babies vaccination educational videos and pamphlet as well as a summary of the study results, written in a user-friendly format, if I would like to receive it. If I have not completed the questionnaires after 2 weeks, up to three reminder emails will be sent to me.

Université d'Ottawa | **University of Ottawa**

To compensate for my time spent on this study, I will receive a \$10.00 Tim Horton E-Gift card. This Card will be delivered to me through my email address directly and I can spend it at any Tim Horton's branches across Canada, by just showing the scan code on my phone or any electronic devices. If I choose to withdraw from the study, I will still receive this gift.

The University of Ottawa Research Ethics Board (REB) has reviewed and approved the ethical component of this research project. 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

I keep a copy of this consent form for my personal records.

Confidential

Page 6 of 6

-
- 1) I agree to participate in the above research study conducted by Shokoufeh Modanloo, in the School of Nursing, Faculty of Health Sciences, University of Ottawa. This research is under the supervision of Professor Denise Harrison. I agree
-
- 2) Are you interested in receiving the final results of this study? Yes
 No
-
- 3) The collected data of this study may be used for designing a larger full-scale research project in the future. I allow the researchers to use this data for the future study. Yes
 No

Appendix D. Demographic Survey

Please complete the survey below asking information about you and your baby.

Thank you!

Where did you see the advertisement post for this study?

Facebook
 Twitter
 Telegram/WhatsApp
 Email
 Online Parents Forum
 Other

Please specify _____

What was your age in years when your baby was born?

(Please provide numerical values only!)

What is your relationship to this baby?

Mother
 Father
 Other

Please Specify _____

What is your employment status?

Employed outside the home - Full time
 Employed outside the home - Part time
 Full-time homemaker
 Student: Part time/Full time
 Self-employed
 Casual
 Unemployed
 I prefer not to answer

Which city in Canada are you living in?

Please provide the first three digits of postal code of the neighborhood in which you live:

(Please provide in this format: Letter-Number-Letter)

What is the highest level of education you have completed?

Less than 8th grade
 High School
 College
 University degree: Undergraduate, Graduate: Masters/ PhD
 I prefer not to answer

Confidential

Page 2 of 3

What is your ethnicity?

- Caucasian
- Hispanic
- African
- Asian
- Indigenous Canadian
- Middle Eastern
- Mixed race
- I prefer not to answer
- Other

Please specify:

What is your current marital status?

- Single
- Married
- Divorced
- Separated
- Widowed
- Common law relationship
- I prefer not to answer

What is the date of birth of your baby?

What scheduled time-point is the upcoming vaccination episode of your baby at? (according to standard routine vaccination schedule of the Canadian province you live in)

- 2 months
- 4 months
- 6 months

What is the sex of your baby?

- Male
- Female
- Not sure

What was the weight of your baby at birth?

(Please write which scale you are referring to (kg/g or lbs/oz))

What type of delivery did you have?

- Vaginal
- Caesarean Section
- I prefer not to answer

Are you breastfeeding?

- Yes, I am currently breastfeeding
- No, I am not currently breastfeeding but I did in the past
- No, I never breastfed
- I prefer not to answer

If yes,

- Exclusively breastfeeding
- Combination feeding - formula and breastfeeding

Apart from this baby, do you have other children?

- Yes
- No

Confidential

Page 3 of 3

If yes, how many other children do you have?

- 1
- 2
- 3
- 4
- 5
- 6
- > 6

Appendix E. Baseline Knowledge Survey

Please complete the survey below asking questions about your previous knowledge of recommended pain management strategies for babies.

Thank you!

Have you ever seen any of the "Be Sweet to Babies" videos before? Yes
 No
 Not sure

If yes, where? YouTube
 Conference
 Webinar
 University
 Other

Please specify: _____

Did you know that breastfeeding is effective at reducing pain during vaccination for babies? Yes
 No
 Not sure

Did you know that upright secure holding is effective at reducing pain during vaccination for babies? Yes
 No
 Not sure

Did you know that a small amount of sugar water (a sweet solution such as sucrose or glucose) is effective at reducing pain during vaccination for babies? Yes
 No
 Not sure

Have you personally used any of these pain management strategies (breastfeeding, upright secure holding, and/or sweet solutions) for your baby during needle-related procedures before? Yes
 No
 Not sure

Do you intend to use one of the three pain management strategies (breastfeeding, upright secure holding, and/or sweet solutions) in your baby's upcoming vaccination? Yes
 No
 Not sure

If yes, which one? (Select all that apply) Breastfeeding
 Sweet solution
 Upright secure holding

If no or unsure, briefly explain why? _____

Would you recommend these pain management strategies to other parents? Yes
 No
 Not sure

Confidential

Page 2 of 2

If yes, which one? (Select all that apply)

- Breastfeeding
- Sweet solution
- Upright secure holding

If no or unsure, please explain why?

Appendix F. AS&Q

Please read each statement and complete the survey below about your confidence and readiness to use any of the recommended pain management strategies (breastfeeding, sweet solutions, and upright secure holding) for your baby during vaccination.

Thank you!

-
- 1) Thinking about the information you have been given in the "Be Sweet to Babies" videos and the pamphlet, how important to you is it to use breastfeeding, sweet solutions or upright secure holding as pain management strategies during your baby's 2, 4 or 6-month vaccination?

Rate the importance on the scale below, from 1= Not important at all, to 5= Very important.

1 (Not important at all) 2 3 4 5 (Very important)

-
- 2) Recognizing your confidence will help you to discuss pain management for your baby during vaccination. How confident are you to inform your doctors or nurses that you want to use your preferred pain management strategy?

Rate your confidence on the scale below, from 1= Not Confident, to 5 = Very Confident.

1 2 3 4 5

-
- 3) How ready are you to use your choice of these pain management strategies during your baby's vaccination?

Rate your readiness on the scale below, from 1= Not Ready at all to 5 = Very Ready

1 2 3 4 5

For the next questions, think about possible answers. If you wish, you can take notes for yourself. Please be aware that you do not need to write or submit your answers for these questions.

Imagine a scenario in which you are taking your baby to a health clinic to get vaccinated, and you are willing to use one of the recommended pain management strategies.

- 4) What could help support you to use these pain management strategies during your baby's vaccination?

- 5) What do you think the benefits of using these pain management strategies may be?

- 6) What might hold you back or get in your way to use your preferred/most applicable pain management strategy?

- 7) How could you overcome any potential obstacles to using your preferred pain management strategies?

Appendix G. Reducing Pain during Vaccination Tip Sheet



Reducing Pain During Vaccination

Vaccines help to keep children healthy by protecting them against serious infections. However, vaccinations may be painful and may cause stress for you and your child. It is important that you stay calm and provide encouragement to your child when they are being vaccinated. Some of the tips listed below may also help to reduce your child's fear of injections and pain during vaccinations.

Tips for Infants

Breastfeed

- Breastfeed your baby five minutes before the injection, as well as during and after vaccinations, to reduce pain and to provide comfort.

Hold comfortably

- Hold your baby close to your body, in a front-to-front position with both legs exposed. This reassuring close contact can help to reduce pain.

Offer sugar water

- For babies 12 months old or less, who are not breastfed, give a few drops of sugar solution (on the tip of the infant's tongue) one minute before the injection. Repeat administration of a few drops of sugar solution just before the injection. The sweet solution provides a few minutes of pain relief during vaccination.
- Purchase a pre-mixed sugar solution at a pharmacy or prepare one at home by mixing 5 mL (one teaspoon) sugar with 10 mL (two teaspoons) water. Do not use honey.
- Never use sugar water at home to calm a fussy or crying baby, as this can lead to tooth decay.
- Feed the baby or give sips of water to clean the baby's mouth after vaccination.



Tips for Toddlers and Older Children

Prepare your child ahead of time

- Read stories about what happens when you visit the doctor.
- Offer an honest explanation about the procedure: Prepare young children (under 4 years old) just before the injection; prepare older children the day before.
- Describe how vaccination will feel (e.g. like a pinch).
- Tell your child what they can do to ease the pain (e.g. sit still, breath deeply, relax the arm).

Distract your child

- Draw your child's attention away from the needle. This is one of the best ways that you can help your child.
- Use age-appropriate tactics that may help to distract your child, such as a favourite toy or blanket, a book, music, singing, or telling a joke or a story.
- Tell your child to take a deep breath and to blow it out slowly. Blowing bubbles or blowing on a pinwheel can help also.



Appendix H. Knowledge Utilization Survey

Please complete the survey below about your knowledge of recommended pain management strategies.

Thank you!

Did you watch the "Be Sweet to Babies" videos that we provided to you before in the first survey? Yes
 No
 Not sure

If no, please watch them here if your baby is below 2 months of age;

Please watch if your baby is older than 2 months of age;

Did you read the pamphlet that was provided to you before in the first survey? Yes
 No
 Not sure

Do you remember what the videos and pamphlet in the first survey were about? Yes I remember from the first survey
 Yes, I just watched/read them again
 No I do not remember
 Not sure

Did you use any of the pain management strategies presented in the videos and pamphlet during your baby's last vaccination? Yes
 No
 Not sure

Confidential

Page 3 of 3

If yes, which one? (Select all that apply please!)

- Breastfeeding
- Sweet solution
- Upright secure holding

If no, please explain why?

After watching the videos and reading the pamphlet, did you feel more confident about how you could help reduce your baby's pain during her/his vaccination?

- Yes
- No
- Not sure

If no, please explain why?

After watching the videos and reading the pamphlet, would you recommend these pain management strategies to other parents?

- Yes
- No
- Not sure

If yes, which one? (Select all that apply please!)

- Breastfeeding
- Sweet solution
- Upright secure holding

If no, please explain why?

After watching the videos and reading the pamphlet, do you intend to use one of the three pain management strategies in your baby's future vaccination episodes?

- Yes
- No
- Not sure

If yes, which one? (Select all that apply please!)

- Breastfeeding
- Sweet solution
- Upright secure holding

If no or unsure, briefly explain why?

Appendix I. Acceptability Survey

Please complete the survey below about this study's surveys, information given, and the processes.

Thank you!

It was easy to read, understand and complete each of the surveys, listed below in the study, Please choose your answer from the 5 given items (strongly disagree, disagree, not sure, agree, strongly agree).

	Only click here, if you like to see a preview again	Only click here, if you did not receive this survey	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
Demographic Information Survey	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Knowledge Awareness Survey	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Motivational Interviewing Affirmative Statement and Questions (MIAS&Q)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Knowledge Utilization Survey	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barriers and Facilitators Survey	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Here is the link again;

[Attachment: "DemographicInformationQuestion.pdf"]

Here is the link again;

[Attachment: "BaselineKnowledgeAwarenessSurv.pdf"]

Here is the link again;

[Attachment: "MotivationalInterviewingAffirm.pdf"]

Here is the link again;

[Attachment: "KnowledgeUtilizationQuestionna.pdf"]

Here is the link again;

[Attachment: "BarriersAndFacilitatorsQuestio.pdf"]

I was satisfied with the time requirements for completing the surveys.

- Strongly Disagree
 Disagree
 Not Sure
 Agree
 Strongly Agree

Appendix J. CDC Clear Communication Index Tool

CDC Clear Communication Index Score Sheet

Name of material _____

Name of person scoring _____

Date ____ / ____ / _____

Before you begin, identify your primary audience, their health literacy skills, your primary communication objective, and main message. You must know these 4 pieces of information to score the material accurately. If you don't have this information, wait until you do to score the material.

Note about translated materials: If the audiences for the English and non-English versions are different, you should create and score the materials separately to account for audience differences.

1. Who is your primary audience? _____

Note: See Appendix B of the User Guide for a list of common public health audiences.

2. What do you know about the health literacy skills of your audience?

List as many relevant characteristics about your audience as you can. Try and include evidence about their literacy and numeracy skills; words, numbers, and health concepts they find familiar; their prior experience with the topic; and their ability to comprehend different information formats, such as graphs. If you don't have any information at all, assume average to low health literacy skills.

3. What is your primary communication objective?

A communication objective is what you want your audience to think, feel, or do after they receive the message or material. Example 1: Increase the proportion of women between 18-25 years who intend to increase consumption of folic acid. Example 2: Increase the proportion of sexually active adults with favorable attitudes about taking an HIV test.

4. What is the main message statement in the material?

The main message statement is the one thing the audience must remember. The statement may be 1-3 short sentences.

If you are reviewing an existing material with multiple messages, list all possible messages.

CDC Clear Communication Index Score Sheet

Using the Score Sheet

The Index has a total of 20 items in 4 parts. These 20 items are presented as questions.

- Questions 1-11 in Part A **apply to all materials**.
- Questions 12-20 in Parts B, C, and D may not apply to all materials.
- Choose one answer for each item you score.
- Only score a point when **all** instances of an item in the material meet the criteria.

More detailed descriptions and examples of each item can be found in the User Guide.

Part A: Core	
The items in this section (1-11) apply to all materials.	
Questions	Score <i>(Check one per question)</i>
Main Message and Call to Action	
<p>1. Does the material contain one main message statement?</p> <p><i>A main message is the one thing you want to communicate to a person or group that they must remember. A topic, such as heart disease or seasonal flu, isn't a main message statement. If the material contains several messages and no main message, answer no. (User Guide page 5)</i></p> <p>NOTE: If you answered No to Question 1, score 0 for Questions 2-4 and continue to Question 5.</p>	<p>Yes = 1</p> <p>No = 0</p>
<p>2. Is the main message at the top, beginning, or front of the material?</p> <p><i>The main message must be in the first paragraph or section. A section is a block of text between headings. For a Web material, the first section must be fully visible without scrolling. (User Guide page 6)</i></p>	<p>Yes = 1</p> <p>No = 0</p>
<p>3. Is the main message emphasized with visual cues?</p> <p><i>If the main message is emphasized with font, color, shapes, lines, arrows or headings, such as "What you need to know," answer yes. (User Guide page 7)</i></p>	<p>Yes = 1</p> <p>No = 0</p>
<p>4. Does the material contain at least one visual that conveys or supports the main message?</p> <p><i>For example, count photographs, line drawings, graphs and infographics as visuals. If the visual doesn't have a caption or labels, answer no. If the visual has human figures who aren't performing the recommended behaviors, answer no. (User Guide page 8)</i></p>	<p>Yes = 1</p> <p>No = 0</p>
<p>5. Does the material include one or more calls to action for the primary audience?</p> <p><i>If the material includes a specific behavioral recommendation, a prompt to get more information, a request to share information with someone else, or a broad call for change, answer yes. If the call to action is for someone other than the primary audience, answer no. (User Guide page 10)</i></p>	<p>Yes = 1</p> <p>No = 0</p>

CDC Clear Communication Index Score Sheet

Language	
6. Do both the main message and the call to action use the active voice? <i>If only the main message or only the call to action uses the active voice, answer no. If you answered no to #1 or #5, answer no. (User Guide page 11)</i>	Yes = 1 No = 0
7. Does the material always use words the primary audience uses? <i>If all specialized or unfamiliar terms are explained or described (not just defined) the first time they are used, answer yes. Acronyms and abbreviations must be spelled out and explained if unfamiliar to the audience. (User Guide page 12)</i>	Yes = 1 No = 0
Information Design	
8. Does the material use bulleted or numbered lists? <i>If the material contains a list with more than 7 items, and the list is not broken up into sub-lists, answer no. If the list is for additional information or references only or at the end of the material, answer no. (User Guide page 14)</i>	Yes = 1 No = 0
9. Is the material organized in chunks with headings? <i>This item applies to prose text and lists. If the chunks contain more than one idea each, answer no. If the headings don't match the information chunks, answer no. (User Guide page 15)</i>	Yes = 1 No = 0
10. Is the most important information the primary audience needs summarized in the first paragraph or section? <i>The most important information must include the main message. A section is a block of text between headings. For a Web material, the first section must be fully visible without scrolling. (User Guide page 17)</i>	Yes = 1 No = 0
State of the Science	
11. Does the material explain what authoritative sources, such as subject matter experts and agency spokespersons, know and don't know about the topic? <i>If the material addresses both, answer yes. If the material addresses only one (what is known or not known), answer no. (User Guide page 18)</i>	Yes = 1 No = 0
Part A score	Total _____ / 11

Comments

CDC Clear Communication Index Score Sheet

Part B: Behavioral Recommendations

Answer this question to determine if items 12-14 apply to the material.

Does the material include one or more behavioral recommendations for the primary audience?

- If **yes** – score items 12-14.
- If **no** – skip to Part C.

Questions	Score <i>(Check one per question)</i>
12. Does the material include one or more behavioral recommendations for the primary audience? <i>If no, STOP here and don't score Part B. (User Guide page 19)</i>	Yes = 1 No = 0
13. Does the material explain why the behavioral recommendation(s) is important to the primary audience? <i>If you offer only numbers to explain the importance of the behavioral recommendation with no other relevant information for the audience, answer no. (User Guide page 20)</i>	Yes = 1 No = 0
14. Does the behavioral recommendation(s) include specific directions about how to perform the behavior? <i>This may include step-by-step directions or a simple description (for example: Look for cereal with 100% daily value of folic acid). If the material includes information about when and how to contact a medical provider or health official, answer yes. If the material mentions when and how often to perform a behavior, answer yes. (User Guide page 21)</i>	Yes = 1 No = 0
Part B score	Total _____ / 3

Comments

CDC Clear Communication Index Score Sheet

Part C: Numbers

Answer this question to determine if items 15-17 apply to the material.

Does the material include one or more numbers related to the topic?

- If **yes** – score items 15-17.
- If **no** – skip to Part D.

Questions	Score <i>(Check one per question)</i>
<p>15. Does the material <u>always</u> present numbers the primary audience uses? <i>Many audiences find numbers distracting or confusing. Make sure the numbers in the material are both familiar and necessary to support or explain the main message statement. If not, delete them. Whole numbers are used by most audiences. The types of numbers used will vary for each audience. (User Guide page 22)</i></p>	<p>Yes = 1 No = 0</p>
<p>16. Does the material <u>always</u> explain what the numbers mean? <i>For example, "The amount of meat recommended as part of a healthy meal is 3 to 4 ounces – it will look about the same size as a deck of cards." (User Guide page 23)</i></p>	<p>Yes = 1 No = 0</p>
<p>17. Does the audience have to conduct mathematical calculations? <i>Adding, subtracting, multiplying, and dividing involve calculations. Calculating a common denominator for the purposes of comparison is a mathematical calculation. Use the same denominator, even for absolute risk (example: 1 out of 3), throughout the material so that audiences don't have to calculate. (User Guide page 24).</i></p>	<p>Yes = 0 No = 1</p>

NOTE: for this item, Yes is scored 0 and No is scored 1.

Part C score **Total** _____ / 3

Comments

CDC Clear Communication Index Score Sheet

Calculate the Score for the Material

- **Step 1:** The total points that the material earned (this is the numerator).
» A: _____ B: _____ C: _____ D: _____ = _____
- **Step 2:** The total possible points that the material could have earned (this is the denominator).
» A: 11 B: _____ C: _____ D: _____ = _____
- **Step 3:** The numerator divided by the denominator multiplied by 100 to get the total score.

$$\underline{\hspace{2cm}} / \underline{\hspace{2cm}} \times 100 = \underline{\hspace{2cm}}$$

How to Interpret the Score

The purpose of the Index is to improve the clarity of communication products.

If the total score is 90 or above:

Excellent! You have addressed most items that make materials easier to understand and use.

If the total score is 89 or below:

Note which items scored 0 points. Use the descriptions and examples in the User Guide to revise and improve the material. Then apply the Index again to check your work. You can use the Index as many times as you need to revise the material to get a score of 90 or above.

Additional Comments

Appendix K. CDC Social Media Guideline and Best Practice

Social Media Guidelines and Best Practices

CDC YouTube Channel

CDC YouTube Channel

This document is designed to provide guidance to Centers for Disease Control and Prevention (CDC) employees and contractors on the process of preparing videos for uploading to the CDC's [YouTube channel](#). For assistance with video production and information to be placed on CDC-TV, an online video delivery service available through CDC.gov, contact the Division of Communication Services (DCS).

Background

Online video sharing sites, such as YouTube, MSN, Google, AOL and Yahoo are popular and powerful media for exchanging information. Using these sites, anyone with Internet access can upload, share, view and comment on video footage. Sometimes the process of sharing videos among individuals and groups is called "viral video sharing."

YouTube, which launched in 2005, can be a powerful mechanism to support CDC program in disseminating science and health messages. In 2011, YouTube had more than 1 trillion views—approximately 140 views for each person on earth. Over 800 million unique users visit YouTube each month, with 1/5 of global YouTube views coming from mobile devices.

The CDC YouTube channel, managed by the Office of the Associate Director for Communication (OADC), Division of News and Electronic Media (DNEM), Electronic Media Branch (EMB), was launched in April 2007. To date, the CDC YouTube channel houses almost 450 videos, has more than 8,700 subscribers, and has logged more than 8.4 million video views.

Communications Strategy

Use of online video, as with other social media channels and tools, is intended to be part of a larger integrated health communications strategy or campaign developed under the leadership of the Associate Director for Communication Science (ADCS) in the Health Communication Science Office (HCSO) of CDC's National Centers, Institutes, and Offices (CIOs).

Clearance and Approval

Please note that all CDC videos should be placed on CDC's official YouTube channel. CIOs should not develop individual YouTube accounts.

As per the [CDC Enterprise Social Media policy](#):

- All YouTube video content must be cleared through the clearance channels determined by a programs HCSO office.
- All YouTube videos must be Section 508 compliant, meaning that CDC YouTube videos must be captioned.
- Once the video has been approved for release, OADC must be contacted to post the video and will work with the program to ensure all technical and content requirements (see below Appendix B and C) are met. Please contact socialmedia@cdc.gov for assistance in posting YouTube videos.



Social Media Guidelines and Best Practices

CDC YouTube Channel

Branding

All videos will be branded with the appropriate CDC.gov and/or HHS logos. Co-branding and the use of additional logos may also be incorporated in accordance with [CDC Brand Identity Standards](#).

Comment Policy

As the Agency's YouTube channel manager, OADC EMB maintains an official [comment policy](#) for the CDC YouTube channel. OADC EMB moderates all comments received on the CDC YouTube channel and will work with the program to determine how to best respond to the comments. Comments that violate CDC's policy will be deleted.

Consultation

The Electronic Media Branch (EMB) provides consultation on the planning and development of YouTube videos and other social media tools. It is recommended that you consult with EMB prior to the creation of a video for YouTube posting to ensure that content and technical requirements for YouTube can be met. Please submit a [Create-IT](#) request for social media consultation or contact socialmedia@cdc.gov. Your CIO's [Social Media Council representative](#) can also provide assistance.

For assistance in video production (e.g. filming, captioning, editing) please contact the OADC Division of Communication Services.

Planning Recommendations

When developing videos for posting on YouTube, programs should consider the following recommendations:

- 1. Clearly Define Your Objectives:** It is important to have clearly defined objectives before beginning to develop your video. Do you want to highlight content, spark action, or encourage awareness of an issue? Clarify the objectives first and determine if a video on YouTube is the ideal channel to help you meet larger communication goals.
- 2. Know Your Target Audience(s):** As with any communications activity, it is important to define your intended target audience(s) in order to develop and communicate messages that resonate with your audience and prompt them to take action.
- 3. Determine Moderating Capacity:** Determine if you have the appropriate staffing resources to review and potentially respond to comments received on CDC YouTube videos. It is important to designate a point of contact to work with OADC EMB on content moderation, especially for controversial or popular topics that may generate many comments and questions.
- 4. Establish an Evaluation Plan:** Evaluation is an integral component of measuring the success of all social media activities, including YouTube. Basic YouTube metrics include monitoring the number of times each video has been viewed and reviewing viewer comments and questions that have been posted to the video. YouTube Insights is an analytics and reporting product that provides additional metrics about uploaded videos. To request this information, contact OADC EMB at socialmedia@cdc.gov.



Social Media Guidelines and Best Practices

CDC YouTube Channel

Best Practices

Programs should consider the following best practices when developing YouTube videos:

1. **Keep Your Video Content Simple, Short, and Engaging:**
 - Use of jargon, technical information, or detailed charts and graphs should be avoided.
 - Simple, easy-to-follow “stories” work best, with a single message or call to action.
 - EMB recommends that most CDC videos should be 3 minutes or shorter.
 - For examples of the most popular videos on CDC’s YouTube channel, visit www.youtube.com/cdcstreaminghealth, click on “Videos,” and sort by “Most Popular.”
2. **Identify the Best Web Link:**
 - Include a specific URL at the end of the video to guide the user to additional information on the topic. In most cases, this should be a CDC URL.
3. **Establish Promotion Plan:** Ongoing promotion of YouTube videos is strongly recommended. Example promotion activities include:
 - Work with OADC EMB to promote the video to channel subscribers. Contact socialmedia@cdc.gov for more information.
 - Embed the YouTube URL in your CDC homepage and secondary features.
 - Embed the video, including a thumbnail and link, on high-profile topic-specific pages, campaign materials or blogs.
 - Send content-specific GovDelivery email updates.
 - Send promotional emails to partners and grantees.
 - Cross-promote the videos on other CDC social media channels. See the [CDC social media page](#) for the full list of channels.

Preparing Video for Posting to CDC’s YouTube Channel

If you have questions about the process for posting videos to CDC’s YouTube channel, please submit a [Create-IT](#) request to schedule a consultation or contact socialmedia@CDC.gov

1. **Review the Technical and Other Requirements:** Carefully review Appendix B and C to ensure a clear understanding of the steps required to be able to post videos to CDC’s YouTube channel.
2. **Develop and Clear Video Concept, Plan, and Content:** All YouTube video content must be cleared through the program’s established communication clearance channels.
3. **Develop and Clear Video Information Content:** Refer to Video Information in Appendix B of this document, technical requirements, section 3, for complete details. This content should also be cleared through the program’s established communication clearance channels.
4. **Ensure Video is Section 508 Compliant:** Coordinate the video captioning process to meet Section 508 compliance. Refer to the [CDC Web Video Standard](#) for more information.
5. **Coordinate Posting:** Send socialmedia@cdc.gov the cleared captioned video file and required posting information described in the Appendices.



Social Media Guidelines and Best Practices

CDC YouTube Channel

Appendix A: Points of Contact and Resources

Points of Contact and Resources

1. YouTube Posting POC: socialmedia@cdc.gov
2. YouTube Technical POC: NCHMwebrequests@cdc.gov
3. [CDC Web Video Standards](#)
4. [CDC Enterprise Social Media policy](#)
5. [CDC Brand Identity Standards](#)



Last updated October 16, 2012

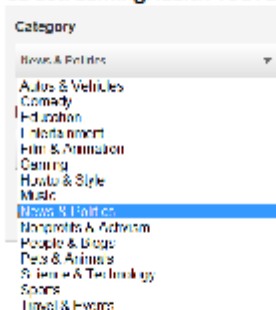
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Social Media Guidelines and Best Practices

CDC YouTube Channel

Appendix B: Technical and Other Requirements

1. Existing CDC URL
 - A CDC URL to the video currently on the Web site: www.cdc.gov is required.
2. File Types
 - Video source at the highest resolution possible under 1GB in size in a MP4, MOV or WMV format
 - Caption source in a XML or SRT format
3. Video Loaded to FTP Folder
 - To access ftp site, Right-click "Start" select "Explore"
 - Search: <ftp://sftp.cdc.gov/>
User Name: **youtubecdc**
Password: **Z18bBjqn**
4. Video Information
 - **Launch Date:** Provide the date the program would like to have the video live on YouTube
 - **Video Title:** A descriptive heading describing the content of the video that allows users to understand the video's purpose and content. (55 Character Limit)
 - **Video Description:** A brief explanation of the video. For promotion purposes, develop a description that is accurate and interesting and allows potential viewers to distinguish from other videos. (1,000 Character Limit) Example: *"It may shock you to know that one of every eleven teens reports being hit or physically hurt by a boyfriend or girlfriend in the past 12 months. Why is that and how can we change it? In Break the Silence: Stop the Violence, parents talk with teens about developing healthy, respectful relationships before they start dating."*
 - **Video Tags:** Tags are keywords used by viewers to easily locate your video and are also used by search engines to determine the video search results ranking (450 Character Limit) Example: For example, a cooking video may be tagged "food," "nutrition," and "healthy eating." Multiple tags can be used and are separated by spaces. Videos placed on the CDC YouTube channel will automatically list the following tags: CDCStreamingHealth; Centers for Disease Control and Prevention, and eHealthCDC.
 - **Video Category:** The video category is the YouTube group classification of videos by common characteristics. The "News & Politics" category is used for all videos uploaded to the CDCStreamingHealth YouTube Channel:



Social Media Guidelines and Best Practices

CDC YouTube Channel

- **Thumbnail picture:** The thumbnail picture is used to identify the video on YouTube and within search results. The image can either be an uploaded file or chosen at random from the video footage. It is recommended that you use a representative image which includes the title. File should be jpg format at a resolution of 640x840.
 - **Map Location:** The location for CDC YouTube videos is set at listed as Atlanta, Georgia. If another location is needed, please provide the location.
 - **Playlists:** Indicate whether or not the video is or will be part of a YouTube playlist. A playlist is a grouping of related videos based on topical categories. New playlists may be created in consultation with OADC EMB.
4. **508 Compliance and Captions** CDC YouTube videos must be captioned in order to meet 508 compliance requirements to make information accessible to persons with disabilities. For complete details on technical requirements, Frequently Asked Questions and recommended vendors, refer to [CDC Web Video Standards](#). The caption file must be submitted with the other required video content to socialmedia@cdc.gov.



Social Media Guidelines and Best Practices

CDC YouTube Channel

Appendix C: You Tube Videos Technical Tips

Embedding YouTube Videos on a Web page

Best practice: IFrame embeds are the recommended method for embedding a YouTube player because the IFrame will select the appropriate player based on the client's capabilities and available YouTube file formats.

IFrame embeds using <iframe> tags

The <iframe> tag's height and width parameters specify the dimensions of the player. If you are creating the <iframe> element yourself (rather than using the IFrame Player API to create it), you can append player parameters directly to the end of the URL. The URL has the following format:

[http://www.youtube.com/embed/\[VIDEO_ID\]](http://www.youtube.com/embed/[VIDEO_ID])

The <iframe> tag below would load a 640x390px player that would play the YouTube video u1zgF1Cw8Aw. Since the URL sets the autoplay parameter to 1, the video would play automatically once the player has loaded.

```
<iframe id="ytplayer" type="text/html" width="640" height="390"
src="http://www.youtube.com/embed/u1zgF1Cw8Aw?autoplay=1&origin=http://example.com" frameborder="0"/>
```

Steps to Embed

- Go to YouTube and open the video or playlist of videos to embed.
 CDC Streaming Health: <http://www.youtube.com/user/CDCStreamingHealth>

- Play the video and click on Share button on the bottom options



- Copy the code to embed the video on your page
<http://youtu.be/-WrWwUsKKN8>



Social Media Guidelines and Best Practices

CDC YouTube Channel

4. In your page insert a Div tag, and then paste the code from YouTube

```
<div><iframe width="560" height="315" src="http://www.youtube.com/embed/WrWwUsKKN8" frameborder="0" allowfullscreen></iframe></div>
```

5. Test your page

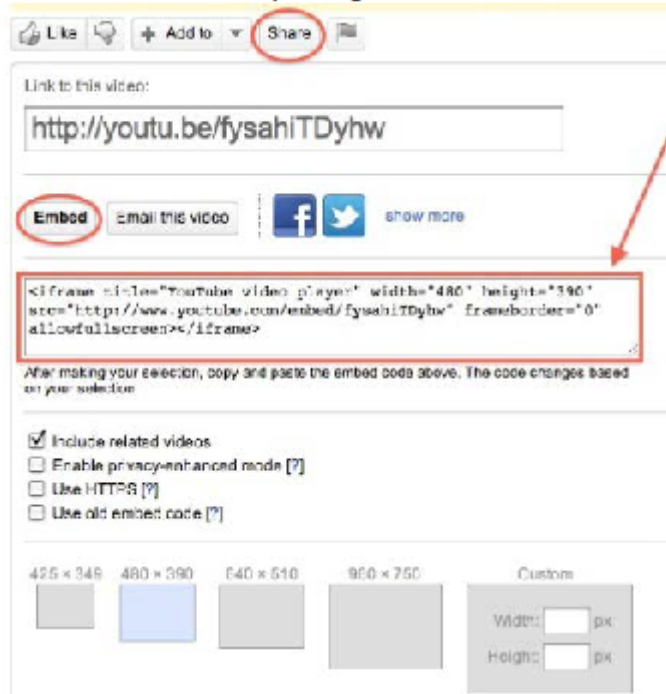


Social Media Guidelines and Best Practices CDC YouTube Channel

Turning off related videos

In order to embed a video into another website or blog:

1. Click the Share button located under the video.
2. Click the Embed button.
3. Copy the code provided in the expanded box.
4. Paste the code into your blog or website.



You may also customize your own embeddable player by clicking on the embed code. When you click on the embed code the space below it will expand and reveal customization options such as:

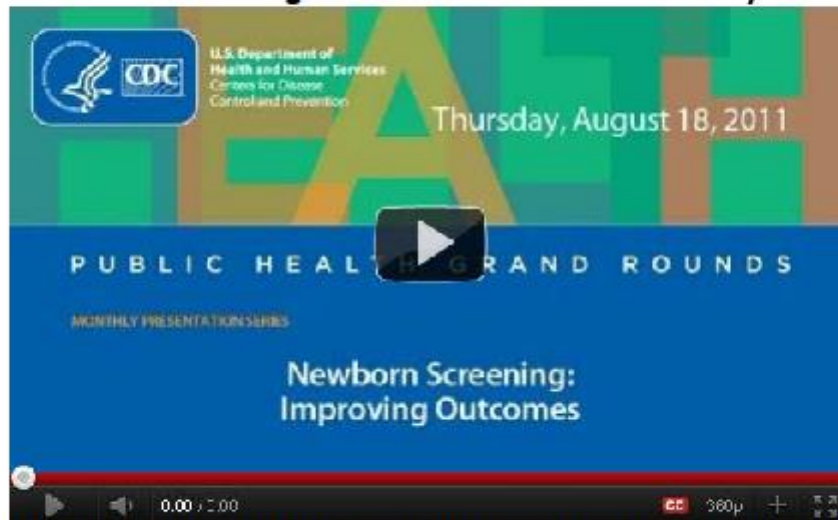
- whether or not to include related videos
- whether or not to enable privacy-enhanced mode
- whether or not to use the old embed code
- the size



Social Media Guidelines and Best Practices

CDC YouTube Channel

How to Remove YouTube's Logo from Embedded Videos and Players



So, although this is not a default option within the embed code box on YouTube videos, this can be done quite simply by adding the following to the end of a YouTube embed URL: `?modestbranding=1`

So for example, the standard iFrame embed code you would get for a video would be:

```
<iframe width="560" height="349" src="http://www.youtube.com/embed/[VIDEOID]"
frameborder="0" allowfullscreen></iframe>
```

In this case, you merely need to add `"?modestbranding=1"` to the end of the `src=` tag like so:

```
...src="http://www.youtube.com/embed/VIDEOID?modestbranding=1"...
```

You would do the same, adding `"?modestbranding=1"` to each instance of the YouTube player URL for the old embed code -> like this

```
<iframe width="560" height="349"
src="http://www.youtube.com/embed/VIDEOID?modestbranding=1&" frameborder="0"
allowfullscreen></iframe>
```



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Last updated October 16, 2012

Social Media Guidelines and Best Practices
 CDC YouTube Channel

Changing the start time of a video



Starting a video at a particular time can easily be achieved just by adding information to the end of the url. For instance, if you want to make a video start at 3 minutes and 22 seconds (03:22) all you would have to do is add #t=03m22s to the end of the url. (#t=XmYYs for XX minutes and YY seconds).

Below is the embed code for the video above:

```
<iframe width="560" height="345" src="http://www.youtube.com/embed/JFg6ocfeG1A#t=03m22s"
frameborder="0" allowfullscreen></iframe>
```



U.S. Department of Health and Human Services
 Centers for Disease Control and Prevention

Last updated October 16, 2012