A Cluster Randomized Controlled Trial of Prenatal Education to Improve the Use of Pain Management Strategies during Infant Immunization

by

Sarah Smart

A thesis submitted in conformity with the requirements for the degree of Master of Science
Graduate Department of Pharmaceutical Sciences
University of Toronto

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Abstract

Background: Unmitigated immunization pain in infants has the potential to impact long-term health outcomes. Teaching parents in the prenatal period may increase utilization of pain management (PM) strategies in clinical practice.

Objective: To assess the efficaciousness of teaching parents in the prenatal environment and its impact on the number of analgesic PM strategies utilized during the 2-month immunization appointment.

Methods: This partially blinded cluster randomized controlled trial enrolled mothers from prenatal classes at Mount Sinai Hospital. Classes were randomized to receive a presentation on either immunization PM or general immunization information.

Results: One hundred and ninety-seven mothers from 28 classes participated in this study. There was a statistically significant increase (p<0.01) in the use of one or more analgesic interventions in the group that received a presentation on immunization PM compared to those who received general immunization information.

Conclusions: Prenatal classes are a suitable environment to educate parents about immunization PM.
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Chapter 1

1 Introduction

1.1 Statement of the problem

1.1.1 Burden of pain

Adequate attention to the management of pain and anxiety in children undergoing immunization injections is extremely important, as unmitigated injection pain has the potential to produce adverse long-term effects, which include heightened pain sensitivity, the development of needle phobias and an increasing risk of morbidity and mortality due to non-compliance with health interventions such as subsequent immunization.\(^1\),\(^2\)

As the most commonly experienced painful procedure for healthy infants in the first year of life, immunization appointments represent a significant source of distress for all that are involved, including caregivers and health professionals. In fact, both have cited pain as a deterrent to adhering to recommended immunization schedules.\(^1\),\(^3\)-\(^8\)

1.1.2 Lack of parental knowledge regarding immunization pain management

Clinical practice guidelines\(^9\),\(^10\) recommend a variety of evidence-based and feasible interventions to reduce childhood immunization pain. These interventions span across three domains of pain management: Psychological, Physical, and Pharmacological interventions\(^11\)-\(^15\) (The 3 P’s of pain management), examples of which include sweet-tasting solutions,\(^14\),\(^15\) topical anaesthetics,\(^16\)-\(^20\) breastfeeding\(^21\)-\(^24\) and upright positioning.\(^25\),\(^26\) Unfortunately, even with significant evidence for their use, the translation of these techniques into clinical practice has been consistently demonstrated to be suboptimal.\(^27\),\(^28\) Thus, children are not benefitting from best practices and are at risk of unnecessary suffering and long-term adverse effects from unmitigated pain.

Directing knowledge translation activities to parents in order to improve current pain management practices is a novel approach that is ideally suited to address this current gap
between research evidence and clinical practice. Educating parents about pain-relieving interventions has the potential to increase utilization of analgesic strategies during immunization, and empower parents to take on a more active role in the management of their child’s health.

1.2 Study objectives and research questions

1.2.1 Primary objective

The primary objective of this study was to determine the impact of teaching parents about immunization pain management in prenatal education classes on their subsequent use of analgesic strategies during infant immunization.

1.2.2 Primary research question

Does teaching about immunization pain management in a hospital-run prenatal education class increase parent self-reported utilization of pain management strategies (defined as use of sugar water, topical anaesthetics and/or breastfeeding) at their infant’s two-month immunization appointment when compared to teaching about immunization in general?

1.2.3 Secondary research questions

1. Does education about pain management strategies for immunization in the prenatal education setting increase the number of pain reducing techniques parents intend to use at their infant’s two-month immunization appointment compared to control education on general immunization information?

2. Does the addition of an immunization pain management education module to the current prenatal education curriculum enhance the knowledge of these pain-relieving strategies for parents following the birth of their infant compared to those parents who receive the control education on general immunization information?

3. Does education about pain management strategies in the prenatal education setting result in less pain in infants during their two-month immunization injections compared to
control education on general immunization, based on parent self-report using the 11-point Numerical Rating Scale (NRS)?

4. Does education about pain management strategies in the prenatal education setting result in increased self-reported satisfaction with infant pain control for parents after their infant’s two-month immunization appointment compared to control education, as measured by a 5-point Likert Scale?

1.3 Research hypotheses and rationale

1.3.1 Hypotheses

We hypothesized that the addition of an immunization pain management education module to the standard hospital prenatal education curriculum would result in; (1) an increased utilization of analgesic pain management strategies at the two-month immunizations, (2) increased parental intent to use these strategies, (3) increased knowledge of pain management strategies, (4) decreased infant pain, and (5) increased parent satisfaction with infant pain control during immunization.

1.3.2 Hypotheses rationale

Previous study data from our research team indicated that passive teaching methods such as the inclusion of information sheets in patient discharge packages after the birth of an infant were ineffective in increasing the utilization of pain management strategies for infant immunization. Previous studies, however, demonstrated knowledge uptake from educational materials (factsheet and video) when reviewed by new parents. As expecting parents come to prenatal classes eager to learn and studies show parents are becoming increasingly more interested in expanding the amount of information related to parenting topics that is given in the prenatal period, we expected parents to enjoy receiving this information in an interactive classroom presentation. It was postulated that the addition of a formal presentation including this educational material would increase knowledge and utilization of pain management strategies at infants’ 2-month immunization appointments.
1.4 Literature review

1.4.1 Acknowledging infant pain

Significant advances in the recognition and treatment of pain in infants have occurred over the last two decades. Formerly, pain in infants was not well understood, with some believing that infants could not feel, process or remember pain at all due to the immaturity of their developing central nervous system.\(^{33-37}\) Nowadays we know this not to be true – a large body of scientific literature shows infants can and do feel pain, therefore it must be managed accordingly as pain relief is recognized as a basic human right.\(^{38}\) The importance of adequate pain management is further reinforced by substantial research evidence that suggests that exposure to pain early in life may influence the development of pain systems and contribute to alterations in long-term development and behaviour.\(^{39-42}\)

1.4.2 Effective strategies to reduce pain

A number of evidence-based strategies are recommended to alleviate immunization pain in young children and include pharmacological, physical and psychological modalities that can be employed alone or in combination by parents and healthcare providers. Recommendations for clinicians additionally include injection techniques such as fast injection without aspiration\(^{43}\) and injecting the least painful vaccine first when multiple injections are provided during a single visit.\(^{44}\)

The following options are recommended in an evidence-based clinical practice guideline (CPG) for the management of immunization pain in infants under 1 year of age.\(^{9}\)

1.4.2.1 Pharmacological Strategies

1.4.2.1.1 Sweet-tasting solutions

Sweet-tasting solutions such as sucrose or glucose (with or without non-nutritive sucking) have analgesic effects in infants.\(^{45-47}\) The mechanism of action is not well understood but it is hypothesized to involve the release of endogenous opioids while also serving as a method of distraction.\(^{47}\) Sweet-tasting solutions (or “sugar water”) are administered to the infant using a
pacifier, syringe, medicine cup or clean finger within 1-2 minutes before an injection. They are easy to prepare and are safe for infants to ingest. Adverse events such as coughing and gagging are relatively uncommon (<5% of cases).

Sucrose and glucose are the most commonly used sweet-tasting solutions, and are usually offered to the infant in 1-2 ml doses. A standardized concentration of sucrose solution does not exist at this time, but concentrations from 12% to 50% have been shown to be effective in the literature. Additionally, 24% sucrose is available commercially as TootSweet™ (Hawaii Medical, Natus Medical Incorporated) for institutional use.

The recommendation to use sweet-tasting solutions during immunization was based on “good evidence” from randomized controlled trials (Grade A Level I recommendation according to critical appraisal methods outlined by the Canadian Task Force on Preventive Health Care) in which a meta-analysis of data from 6 trials showed that sucrose solution with or without non-nutritive sucking significantly reduces acute pain from immunization compared to placebo (sterile water) as assessed by validated pain tools (SMD -0.56 95% CI -0.72 to -0.40, p<0.001). Of the 8 comparisons analyzed from the 6 studies included in this review (for sucrose versus placebo), 5 comparisons favoured sucrose while 3 showed no effect. In addition to its use for infant immunization, sucrose analgesia is also recommended for procedural pain management (for example heel lances or venipuncture) in newborn infants as described in a Cochrane Review by Stevens et al.

1.4.2.1.2 Topical anaesthetics

Topical anaesthetics such as lidocaine-prilocaine 5% (EMLA, available as a cream or gel), liposomal-lidocaine 4% cream (Maxilene), and amethocaine 4% gel (Ametop) are effective in reducing pain by numbing the skin around the area of injection. Their mechanism of action is proposed to involve reversible inhibition of the generation and transmission of pain impulses by blocking transmission of action potentials across nerve endings in the dermis. They are applied to the site of injection (for infants <1 year of age this is the upper outer thigh) approximately 20-60 minutes before the injection, depending on the formulation. Topical anaesthetics are available without a prescription and adverse events are usually limited to transient skin reactions such as reddening (erythema) or whitening (blanching) of the skin.
The recommendation to use topical anaesthetics during immunization was based on “good evidence” from randomized controlled trials (Grade A Level I recommendation\textsuperscript{48}) in which a meta-analysis of data from 4 trials showed that topical anaesthetics significantly reduce pain from immunization compared to placebo (placebo cream) as assessed using the Modified Behavioural Pain Scale (MBPS) specific to infants (SMD -0.43 95% CI -0.60 to -0.26, p=0.001). All four studies included in this review favoured topical anaesthetics.\textsuperscript{13} In addition to their use for infant immunization, topical anaesthetics are also recommended for pain management during circumcision in two systematic reviews and meta-analyses; one Cochrane Review by Brady et al\textsuperscript{50} and a separate systematic review by Taddio et al.\textsuperscript{51}

1.4.2.1.3 Breastfeeding

Breastfeeding continuously before, during and after an injection has been shown to alleviate pain in infants, providing a good latch is established and maintained throughout the procedure.\textsuperscript{9} Holding, skin-to-skin contact and the act of sucking may additionally contribute to the effectiveness of this combined intervention that provides analgesia through sweet taste and other chemicals found in breast milk. For infants that are fed expressed breast milk (EBM) or formula by bottle, sweet-tasting solutions are recommended in lieu of breastfeeding.\textsuperscript{9}

The recommendation to breastfeed during immunization was based on “good evidence” from randomized controlled trials (Grade A Level I recommendation\textsuperscript{48}) in which a meta-analysis of data from 4 trials showed that breastfeeding during immunization significantly reduce pain compared to not breastfeeding, as measured using validated pain tools (SMD -2.03 95% CI -2.26 to -1.80, p<0.001). All four studies included in this review favoured breastfeeding.\textsuperscript{13} Breastfeeding is also recommended as an effective pain management strategy for painful procedures in neonates, as described in a systematic review conducted by Shah et al.\textsuperscript{52}

1.4.2.2 Physical Strategies

1.4.2.2.1 Holding upright

Holding infants in an upright position in a hug or in a parent’s lap has been shown to reduce pain during injection when compared to infants who are injected lying down (supine position) on an examination table.\textsuperscript{26}
The recommendation to position infants upright during immunization was based on “good evidence” to recommend against supine positioning (lying down) for vaccine administration from randomized controlled trials (Grade E Level I recommendation\(^48\)) in which 3 of 4 included studies in systematic review and meta-analysis by Taddio et al\(^12\) reported greater pain scores for children immunized in the supine position over an upright position. In a more recent systematic review and meta-analysis conducted by Pillai Riddell et al,\(^53\) results showed there was limited evidence to suggest that holding was an ineffective intervention for pain reactivity in older infants (classified as infants aged 1-36 months) however only one large study was included in this analysis. Findings were similar for the effects of holding in the neonatal population for pain reactivity, however there was some evidence to suggest holding for pain-related regulation.

1.4.2.3 Psychological Strategies

1.4.2.3.1 Distraction

Parent- or clinician-directed distraction techniques have been shown to reduce pain from injections in children of all ages and show some effectiveness in reducing pain during injection in infants young as 1-2 months of age.\(^11,54-57\) Distraction methods include rocking, cuddling, singing, talking or distracting with age-appropriate objects or toys.

Although there was limited evidence for or against the use of parent or clinician-led distraction, the recommendation to use distraction were based on “fair evidence” from randomized controlled trials (Grade B Level I recommendation\(^48\)) for their potential to reduce pain-related distress.\(^9\) A recent Cochrane review by Pillai Riddell et al\(^53\) provides an update on this information for distraction techniques specific to toy and video distraction and suggests these distraction methods have limited effects on infant pain. Pillai Riddell et al found sufficient evidence to suggest that toy distraction was not more efficacious than no-treatment control for reducing pain reactivity in older infants (classified as infants aged 1-36 months) and limited evidence to suggest it was not efficacious for improving immediate pain regulation in this population.\(^53\) In the case of video distraction, some evidence was found to support its use in older infants due to its efficaciousness in reducing pain reactivity in one medium-sized study and
immediate pain regulation in a separate large study. No evidence was available to determine the effect of distraction on pain reactivity and regulation in the neonatal population.

1.4.3 Audits of pain management practices for immunization

Despite considerable progress in establishing safe and effective strategies to reduce pain combined with the development of pain care protocols in a wide range of institutions and settings, pain is still largely undermanaged in all populations of infants that experience skin-breaking procedures. In the immunization setting, strategies to reduce pain are used far more infrequently than in the hospital despite the fact that immunization is the most commonly experienced painful procedure for healthy children in the first year of life and evidence based reviews and clinical practice guidelines for immunization pain management are available and easily accessible.9-10

In a 2007 audit of analgesic practices for immunization pain in the greater Toronto area by Taddio et al,28 only 4 (1%) of the 278 included children 0-12 years of age were administered a topical anaesthetic (lidocaine-prilocaine) by a parent prior to an immunization to reduce pain; all 4 of these children were toddlers aged 1-5 years. When asked about the use of other pain management interventions, the majority of parents reported using distraction and holding to comfort their child, while very few used pacifiers, feeding (breast or bottle for infant) and sweet solutions.58 When pediatrician pain management practices were assessed in the same audit, 53% reported they never used topical anaesthetics in their practice.28 When injection techniques were addressed, 50% reported they used a fast injection technique to reduce pain but only one third of physicians injected intramuscular vaccines without aspirating28 (evidence shows aspiration is not necessary and increases pain from needle procedures44).

Similar findings were found in a more recent Toronto-based naturalistic observation study of parental pain management practices during 760 infant immunization appointments in the first year of life.59 Parents used topical anaesthetics (specifically EMLA) <1% of the time and 3 parent soothing behaviours categorized as offering food, offering toy and nursing (breastfeeding) <5% of the time at all appointment ages (2-, 4-, 6- and 12-months of age). Again, across all age categories, physical comfort, rocking and verbal reassurance were the most commonly observed parent soothing behaviours, although also utilized relatively infrequently.59
Besides these two Toronto-area studies, only one other study has looked at pain management practices in the immunization setting. Harrison et al surveyed 125 nurses regarding their pain management practices during early childhood immunization in Victoria, Australia and again found similar results to those discussed above. Topical anaesthetics and sucrose were almost never used for any infant, toddler or child and breastfeeding of infants 0-12 months was reportedly “occasionally” used (~50% of the time). Distraction techniques such as use of bubbles, toys and talking were described as the most commonly utilized pain management strategies in all age categories.

The results from these 3 studies as a whole confirm that immunization pain is undermanaged across all age groups of children by both parents and clinicians. There are a number of barriers that are repeatedly cited as reasons evidence based strategies to reduce pain are continually underutilized in the immunization setting. For clinicians, these include lack of time, the cost associated with analgesic interventions as well as parental (did not ask about pain management for immunization) and personal (do not value pain management) factors. For parents, the most commonly reported barrier to using pain management strategies during immunization is they are not informed of or told to do anything for injection pain by their healthcare provider. These reported barriers in combination represent the overarching problem that a knowledge gap between clinical practice and evidence-based research exists; put simply, parents and vaccinators alike are unaware that they can reduce pain from immunization in children of all ages and that a large body of research evidence shows there are effective and easily employed modalities in which to do so.

1.4.4 Disseminating immunization pain management information to parents

Regardless of reported barriers, we do know parents show interest in learning about this topic and it is well documented that parents are willing to pay for analgesics to reduce immunization pain for their children. In addition, we know health care providers view parents as the primary targets for education about pain management and that educational efforts aimed at providers positively impact practice in the short-term but these effects may not be sustained over time. As a result, the majority of recent knowledge translation research in the field of immunization pain management has been directed at parents.
After publishing a clinical practice guideline outlining evidence based strategies for alleviating pain from immunizations in children of various age groups, educational materials including a video and factsheet (pamphlet) were developed by our team in order to facilitate the uptake of information by target end-users (clinicians and parents). Subsequently, these materials were pilot-tested with parents of healthy newborns at Mount Sinai Hospital (Toronto, Ontario) in order to test knowledge acquisition from the educational materials and obtain feedback regarding how the information was presented. Results from pre- and post-test questionnaires illustrated high levels of knowledge acquisition from the educational materials, and parents provided useful feedback and suggestions for content and aesthetic changes in 20-minute interviews, including that the factsheet and video should be offered in combination for better learning. Multiple iterations of the educational tools were tested until parents were satisfied with the information and the way in which it was presented.

From here, our research team sought to investigate whether including the factsheet in hospital discharge packages after the birth of an infant would be effective in increasing the use of pain management strategies by parents in clinical practice. This passive dissemination strategy was chosen for its cost-effectiveness and ease of distribution. Results from this study showed increased use of sugar water (10.5% vs. 0%; p=0.005) and topical anaesthetics (5.3% vs. 0%; p=0.049) but no difference in breastfeeding (5.3% vs. 9.6%; p=0.551) between participants that reported reading versus not reading the pamphlet at the intervention site. Despite this significant increase in strategy use, only 21% (n=19) of intervention site participants reported reading the pamphlet therefore it was concluded that more “active” teaching or dissemination techniques for parent education should be investigated in future knowledge translation initiatives.

1.4.5 Identifying the appropriate environment for parent education

In order to identify an appropriate environment in which to educate parents about immunization pain management, we asked new mothers about their preferences. Almost all of the respondents indicated that they were interested in learning about ways to minimize the pain and distress their infant experienced during immunization, and a substantial percentage of these participants (10%) suggested that prenatal classes might be an effective gateway to educate parents about this topic.
In accordance with parents’ suggestions to offer the factsheet and video in tandem to promote better learning, we sought to identify the best method of teaching parents in an enriching manner that would include the use of both educational tools. The “Learning Pyramid”, adapted from Edgar Dale’s original “Cone of Experience” states that average learning retention rates (i.e. how much people remember) from reading material is merely around 10%. According to this theory the learning retention rate increases when the method of instruction changes and the pyramid thickens. The least retention is expected from lecture only (5-10%) and increases with the use of audio-visual materials (20%), demonstrations (30%), discussion groups (50%) and practice by doing (75%), while learning retention is expected to be the highest when an individual is teaching others (90%).

Therefore, for the purpose of this study we concluded that a combination of various instructional teaching methods would most likely yield the best results when teaching parents about immunization pain management, and that education in the prenatal period was worthy of investigation.

1.4.6 Theoretical framework: the theory of planned behaviour

In order for a health promotion intervention to be successful in changing a given behaviour, Icek Ajzen’s Theory of Planned Behaviour (TPB) suggests it is important that the intervention addresses peoples’ attitudes, subjective norms and perceived behavioural control regarding a particular health behaviour. The attitude towards a given behaviour is determined by a person’s evaluation of the outcomes associated with the behaviour and the strength of this association. Subjective norms are believed to be a function of beliefs that specific individuals or groups think the targeted individual should perform a given behaviour (i.e. family and friends or persons in a position of power/authority). Finally, perceived behavioural control refers to an individual’s perception of their ability to perform a given behaviour and can be influenced by many factors including the assessment of his/her skills, willpower and the presence of favourable or unfavourable external factors (such as the influence of an outside party who may block a given behaviour). This subjective perception is often one of the stronger predictors of behavioural intent and thus, behavioural performance. Alfred Bandura’s work on the concept of self-efficacy (similarly defined as the belief in one’s capabilities to achieve a goal or outcome) is
supportive of this notion and association between perceived behavioural control and behavioural performance.  

Each of the above three constructs play a significant role in dictating an individual’s behavioural intention, which according to the theory is the most important predictor of future behaviour. Individuals with a strong behavioural intention to perform a specific behaviour are much more likely to engage in the behaviour over those who possess a weaker behavioural intention. 

Ajzen first proposed the TPB in 1985 as an extension to the Theory of Reasoned Action (TRA) in which attitudes and social norms were seen as the predecessors of behavioural intent that would lead to a change in behaviour. With the addition of perceived behavioural control, the TPB was able to expand the theory’s application to behaviours that were more complex and often dependent on other factors such as availability of resources, skills, or the cooperation of others.

The TPB is regarded as being well supported by empirical evidence and to date over 1200 studies have used the TPB as a theoretical basis for understanding and promoting change in many types of behaviours. Overall, the TPB was chosen as the theoretical framework for this study based on its previous successful applications, and because we recognize changing parent behaviours in regards to immunization pain management is a complex notion that is well represented by the TPB model. More specifically, the use of pain management strategies is dependent on not only the attitudes, subjective norms and perceived behavioural control of the parent who is primed with this information, but also the cooperation of the infant (in order to breastfeed successfully, for example) and the healthcare provider providing the immunizations, which may alter an individual’s perceived behavioural control and thus the entire behavioural pathway in the TPB model.

1.4.7 Studies of educating parents about infant care topics in prenatal period

Historically, expectant women are prepared for pregnancy, birth and parenting through the teachings of women in their family and others around them. When giving birth became institutionalized, the health care system took on a more active role in preparing women for birth and early parenting. Today, prenatal education is offered through a variety of organizations,
including public health units, non-profit organizations, hospitals, community health centres and private businesses.\textsuperscript{76} The teaching philosophies, policies, and content differ amongst different education settings, however most programs cover topics such as healthy behaviour during pregnancy, signs and stages of labour, comfort measures and medical interventions for labour, breastfeeding and topics related to postpartum and baby care.\textsuperscript{76} These subjects are discussed using a wide-array of education strategies, including didactic lecture style teaching, handouts and videos and sometimes demonstrations with infant dolls (for example, when learning how to bathe a newborn infant).

Despite the inclusion of some parenting information in the majority of prenatal education curriculums, a number of studies have shown first-time parents believe they are unprepared to take on the role of parenting even after attending prenatal classes.\textsuperscript{77-80} This has sparked a number of research studies in recent years to examine changes in knowledge and behaviour with regards to various parenting topics when additional education is added to the usual prenatal teaching curriculum. We sought to compile this evidence to inform our study design and hypotheses and therefore conducted a systematic review and meta-analysis. A systematic review is recognized as an overview of primary literature that uses explicit and reproducible methods\textsuperscript{81} in order to summarize evidence surrounding a defined research question. A meta-analysis further combines quantitative results from two or more primary studies addressing the same question with similar or identical outcomes in a mathematical synthesis in order to obtain an estimate of overall treatment effect.\textsuperscript{81} Meta-analyses are considered to increase the precision of the overall conclusions or results from a systematic review in a quantitative manner.\textsuperscript{81} A summary of the conducted systematic review and meta-analysis is described below.

1.4.7.1 Overview of systematic review and meta-analysis of prenatal parenting education interventions

1.4.7.1.1 Study selection

Studies included in this review possessed the following characteristics: (1) education was targeted at healthy mothers (and available partners) who gave birth to healthy term infants; (2) study was conducted in a country of “developed region” status according to the UN guidelines;\textsuperscript{82} (3) involved only group prenatal education (i.e. no postpartum or 1-on-1 educational component)
and (4) was written or translated in English language. Studies were further excluded from the analysis if they were only published in abstract or letter form.

1.4.7.1.2 Search strategy

With the aid of a research librarian, a search of MEDLINE (1946 to February 2013), EMBASE (1947 to February 2013), CINAHL (1983 to February 2013), PsycINFO (1806 to January 2013), ERIC (1965 to January 2013) and CCTR databases, relevant journals and reference lists (hand searched in applicable studies) for prospective randomized controlled trials or quasi-experimental studies involving group education on infant care topics identified 10965 studies (as part of a larger parent education search strategy outlined in Appendix A). Two independent reviewers (the candidate and another student) examined titles and abstracts, and 22 papers were retrieved for further inspection. Of these, 10 studies were excluded: 1 study was published only in abstract form, 3 studies did not meet design requirements (i.e. were not quasi-experimental studies or randomized controlled trials) and the topics of 6 studies were outside the scope of this review (i.e. compared peer-led versus nurse-led instructional methods, examined parent-child interactions in the home, only collected participant feedback on presentations). The remaining 12 studies have been included in this systematic review and meta-analysis.

1.4.7.1.3 Data extraction and outcomes

Data was extracted by the candidate and confirmed for accuracy by a second reviewer (another student). Content extracted included: author and citation, setting of study, study design, population, type of education and comparator(s), outcome assessment methods and outcome data. The primary outcome of interest was change in behaviour, assessed after subjects received an added education intervention plus standard care (or standard prenatal education) relative to standard care or standard prenatal education alone. Due to the variability in topics studied, all measures of behaviour change including self-report, follow-up assessment by researcher or change in scores from previously validated scales were acceptable for inclusion. The secondary outcome of interest was change in knowledge, as assessed by comparing pre- and post-test knowledge scores in applicable studies.
1.4.7.1.4 Study characteristics

The most prevalent topic of group education amongst the 12 retrieved studies was breastfeeding (8 studies\textsuperscript{83-90}), while other topic areas included car safety (1 study\textsuperscript{91}), congenital toxoplasmosis (1 study\textsuperscript{92}) and general parenting information (2 studies\textsuperscript{93,94}). Methods of group education consisted predominantly of didactic, lecture style teaching with or without demonstration, while some studies included videos and/or informational handouts to supplement the group’s learning. Most studies were conducted in pre-existing prenatal classes in which an intervention was added to the standard curriculum, while others recruited subjects from prenatal care centres to attend an external group education intervention. The duration of outcome assessment varied according to the topic of education and all studies included a comparison group (standard care or standard prenatal education). Evidence from these studies was synthesized according to the topic and content of the prenatal education intervention. Table 1 provides a summary of the included studies.

1.4.7.1.5 Data synthesis

The retrieved breastfeeding studies measured similar outcomes, and data were meta-analyzed accordingly for initiation and duration of breastfeeding. All data were combined using a random-effects model in Review Manager 5.1.7. Breastfeeding duration measures were divided into short-term (<4 months) and long-term (4-6 months) outcomes, as defined in a previous meta-analysis of primary-care interventions to improve breastfeeding status conducted by the US Preventive Services Task Force.\textsuperscript{95} When data was collected at multiple time points within a given breastfeeding study, the time point closest to 4 months (short-term) or long-term (6 months) was chosen. We reported risk ratios (RR) and 95% confidence intervals (CI) for measures for effect. All other studies included in this review were described qualitatively.

Heterogeneity, a measure of variability amongst studies included in a meta-analysis\textsuperscript{96} was assessed using $I^2$ statistics. $I^2$ values of 75% to 100% are recognized in the Cochrane Handbook as representing considerable heterogeneity amongst studies.\textsuperscript{96} A sensitivity analysis was planned to assess the effect of excluding quasi-experimental studies given several high risk of bias ratings and only including randomized controlled trials with lower ratings for risk of bias.
Table 1: Randomized and quasi-experimental trials of prenatal group education on parenting topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Authors</th>
<th>Population</th>
<th>Setting (Country)</th>
<th>Intervention/ Comparison</th>
<th>Design</th>
<th>Outcomes of Interest (Measures Used)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF</td>
<td>Duffy et al(^{83})</td>
<td>Primiparous women ≥ 36 wks gestation (n=70)</td>
<td>H (AUS)</td>
<td>I: SPNE + 1x1-hour session on positioning and attachment of baby + demonstration (n=35) C: SPNE (n=35)</td>
<td>RCT*</td>
<td>• BF duration @ 6 wks PP</td>
<td>92% (I) versus 29% (C) BF @ 6 wks PP (p&lt;0.001)</td>
</tr>
<tr>
<td></td>
<td>Forster et al(^{84})</td>
<td>Primiparous women 20-25 wks gestation (n=981)</td>
<td>H (AUS)</td>
<td>I1: SC+ 1x1.5-hour class on BF skills (n=327) I2: SC+ 2x1-hour classes on BF “attitudes” (n=327) C: SC (n=327)</td>
<td>RCT</td>
<td>• BF initiation @ 2-4 d PP • Exclusive BF duration @ 6m PP</td>
<td>97%(I1) versus 96% (I2) versus 96% (C) initiated BF @ 2-4 d PP (no SSD) 55% (I1) versus 50% (I2) versus 54% (C) reported exclusive BF at 6m PP (no SSD)</td>
</tr>
<tr>
<td></td>
<td>Kistin et al(^{85})</td>
<td>Low-income African-American women &lt;24 wks gestation (n=130)</td>
<td>H (USA)</td>
<td>I1: SC+ 1x50-80 min group session on BF topics (n=38) I2: SC+ 1x15-30 min counseling session on BF topics with author (n=36) C: SC (n=56)</td>
<td>Q-RCT</td>
<td>• BF initiation in H • BF duration @ 2, 6, 12 wks PP</td>
<td>45%(I1) versus 50% (I2) versus 22% (C) initiated BF in H (p&lt;0.05) 36% (I2) versus 18% (C) BF @ 2 wks PP (p&lt;0.05) No SSD in BF @ 6 wks PP 15% (I1) versus 4% (I2&amp;C) BF @ 12 wks PP (p&lt;0.05)</td>
</tr>
</tbody>
</table>

BF=breastfeeding; CS=car safety; CT=congenital toxoplasmosis; PI=general parenting information
H= hospital; C=community (public health centres, Special Supplemental Nutrition Program for Women Infants and Children (WIC) clinics)
SPNE = Standard Prenatal Education (mothers enrolled in Prenatal Class); SC = Standard Care (mothers not enrolled in Prenatal Class at the time of study enrollment)
RCT= randomized controlled trial; Q-RCT= quasi-randomized/quasi-experimental trial; CRCT= cluster randomized controlled trial
SSD= statistically significant difference; PP=postpartum
*No mention of how randomization performed; **data analyzed separately due to significant differences in participant demographics between hospitals
<table>
<thead>
<tr>
<th>Topic</th>
<th>Authors</th>
<th>Population</th>
<th>Setting (Country)</th>
<th>Intervention/Comparison</th>
<th>Design</th>
<th>Outcomes of Interest (Measures Used)</th>
<th>Results</th>
</tr>
</thead>
</table>
| BF    | Kluka et al. | Primiparous women ≥28 wks gestation and planning to BF (n=209) | C (CAN) | I: SC+ Pre-workshop guide + attendance @ group workshop on BF topics (n=111)  
C: SC (n=98) | RCT | • BF duration @ 2, 12, 24 wks PP  
• BF confidence (BSES) @ baseline, 2, 12, 24 wks PP  
• BF satisfaction (MBFES) @ baseline, 2, 12, 24 wks PP  
• No SSD in BF duration @ 2, 12, 24 wks PP  
• No SSD in BF confidence scores @ baseline, 2, 12, 24 wks PP  
• No SSD in BF satisfaction scores @ baseline, 2, 12, 24 wks PP |
| BF    | Lavender et al. | Women ≥28 wks gestation and planning to BF (n=1312) | H (UK) | I: SC+ 1x2.5-hour educational BF support session (n=679)  
C: SC (n=633) | CRCT | • Proportion BF @ discharge  
• BF duration @ 4m PP  
• No SSD in proportion of women BF @ discharge  
• No SSD in BF duration @ 4m PP |
| BF    | Noel-Weiss et al. | Primiparous women planning to BF (n=101) | H (CAN) | I: SC+ 1x2.5-hour BF workshop + demonstration + video (n=50)  
C: SC (n=51) | RCT* | • BF self-efficacy (BSES-SF) @ baseline, 4, 8 wks PP  
• BF self-efficacy scores @ 4 wks PP higher in I group (p=0.004)  
• No SSD in BF self-efficacy scores @ 8 wks PP |

BF=breastfeeding; CS=car safety; CT= congenital toxoplasmosis; PI= general parenting information  
H= hospital; C=community (public health centres, Special Supplemental Nutrition Program for Women Infants and Children (WIC) clinics)  
SPNE = Standard Prenatal Education (mothers enrolled in Prenatal Class); SC = Standard Care (mothers not enrolled in Prenatal Class at the time of study enrollment)  
RCT= randomized controlled trial; Q-RCT= quasi-randomized/quasi-experimental trial; CRCT= cluster randomized controlled trial  
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*No mention of how randomization performed; **data analyzed separately due to significant differences in participant demographics between hospitals
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<tr>
<th>Topic</th>
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<th>Intervention/Comparison</th>
<th>Design</th>
<th>Outcomes of Interest (Measures Used)</th>
<th>Results</th>
</tr>
</thead>
</table>
| BF    | Reifsnider & Eckhart<sup>89</sup> | Pregnant WIC women planning to BF (n=47) | C (USA) | I: SC+ minimum 1 BF education class (of possible 2) (n=23)  
C: SC (n=24) | Q-RCT | • Initiation of BF | • No SSD in initiation of BF between I and C groups |
| BF    | Rossiter<sup>90</sup> | Immigrant Vietnamese women >12 wks gestation (n=194) | H (AUS) | I: SC+ 25-min video + 3X2-hour small group discussions on BF + BF pamphlets if requested (n=108)  
C: SC+ BF pamphlets if requested (n=86) | RCT* | • BF knowledge (pre-/post-test)  
• Initiation of BF after birth  
• Duration of BF @ 4 wks, 6m PP | • SSD in BF knowledge between I and C groups (p<0.001)  
• 70.2% (I) versus 37.8% (C) initiated BF after birth (p=0.001)  
• 50.0% (I) versus 25.6% (C) BF infant @ 4 wks PP (p=0.001)  
• No SSD in duration of BF @ 6m PP |
| CS    | Goodson et al<sup>91</sup> | Pregnant women and available partners (n=136) | H (USA) | I: SPNE + 1x 30 min lecture on child passenger seats + demonstration + video + pamphlet (n=78)  
C: SPNE (n=58) | Q-RCT | Use of child passenger seat for infant during last ride | • H1: 97.5% (I) versus 100% (C) used car seat during last ride (no SSD)  
• H2**: 94% (I) versus 60% (C) used car seat during last ride (p<0.001) |

BF=breastfeeding; CS=car safety; CT= congenital toxoplasmosis; PI= general parenting information  
H= hospital; C=community (public health centres, Special Supplemental Nutrition Program for Women Infants and Children (WIC) clinics)  
SPNE = Standard Prenatal Education (mothers enrolled in Prenatal Class); SC = Standard Care (mothers not enrolled in Prenatal Class at the time of study enrollment)  
RCT= randomized controlled trial; Q-RCT= quasi-randomized/quasi-experimental trial; CRCT= cluster randomized controlled trial  
SSD= statistically significant difference; PP=postpartum  
*No mention of how randomization performed; **data analyzed separately due to significant differences in participant demographics between hospitals
<table>
<thead>
<tr>
<th>Topic</th>
<th>Authors</th>
<th>Population</th>
<th>Setting (Country)</th>
<th>Intervention/Comparison</th>
<th>Design</th>
<th>Outcomes of Interest (Measures Used)</th>
<th>Results</th>
</tr>
</thead>
</table>
| CT    | Carter et al<sup>92</sup> | Pregnant women >28 wks gestation (n=432) | C (CAN) | I: SPNE + 1x 10 min presentation on cat, food & personal hygiene + pamphlet (n=201)  
C: SPNE (n=231) | RCT* | • Change in behaviour based on self-report hygiene scores | • No SSD for food, personal hygiene  
• SSD in cat hygiene for cat owners (n=32 (I), p<0.05) |
| PI    | Corwin<sup>93</sup> | Pregnant women and available partners (n=48) | H (USA) | I: SPNE+ infant development and coping information (n=24)  
C: SPNE (n=24) | RCT | • Parenting knowledge (researcher-designed instrument) | • I group knowledge scores significantly higher between pre- and post-test (p=0.01)  
• No SSD between post-test scores of I and C groups |
| PI    | Svensson et al<sup>94</sup> | Primiparous women and available partners (n=248) | H (AUS) | I: ‘Having a Baby’ program (SPNE+ new parenting material discussion + demonstration + group problem-solving activities) (n=124)  
C: SPNE (n=124) | RCT | • Maternal parenting self-efficacy (PES) @ baseline, 8 wks PP  
• Parenting knowledge @ baseline, post-class, 8 wks PP (researcher-designed instrument) | • SSD in postnatal self-efficacy scores between I and C groups (p<0.001)  
• Perceived knowledge increased for both groups after program (p<0.001), only I group scores higher than pre-program scores @ 8 wks PP (p<0.001) |

BF=breastfeeding; CS=car safety; CT=congenital toxoplasmosis; PI=general parenting information  
H= hospital; C=community (public health centres, Special Supplemental Nutrition Program for Women Infants and Children (WIC) clinics)  
SPNE = Standard Prenatal Education (mothers enrolled in Prenatal Class); SC = Standard Care (mothers not enrolled in Prenatal Class at the time of study enrollment)  
RCT= randomized controlled trial; Q-RCT= quasi-randomized/quasi-experimental trial; CRCT= cluster randomized controlled trial  
SSD= statistically significant difference; PP=postpartum  
*No mention of how randomization performed; **data analyzed separately due to significant differences in participant demographics between hospitals
1.4.7.1.6 Risk of bias

Risk of bias associated with sequence generation, allocation concealment, blinding of participants, study personnel and outcome assessors, incomplete reporting of outcome data, selective outcome reporting, and other sources of bias were assessed using methods described by the Cochrane Collaboration\textsuperscript{96} and the StaR Child Health Group.\textsuperscript{97} A rating of low, high or unclear risk of bias was assigned by two reviewers (including this author and another student) to each domain according to recommended criteria found in the Cochrane Handbook and a third reviewer (a PhD student) was called upon if there were any disagreements in bias judgments. Eleven of the twelve studies\textsuperscript{83-93} received at least one high risk of bias rating; 4 studies\textsuperscript{85,87,89,91} received a total of 3 high risk of bias ratings each. The most frequently rated high risk of bias domain was blinding of personnel, particularly because in most cases, the education was provided by study personnel who had to know group allocation in order to teach the assigned topic accordingly and hence this bias could not be avoided (unless an outside educator not involved with the study was used – which some studies did report). A complete list of risk of bias judgments is presented in Table 2.
<table>
<thead>
<tr>
<th>Author Year</th>
<th>Random Sequence Generation</th>
<th>Allocation Concealment</th>
<th>Blinding of participants and personnel</th>
<th>Blinding of outcome assessment</th>
<th>Incomplete Outcome Data</th>
<th>Selective Outcome Reporting</th>
<th>Other sources of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carter 1989</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Participants: Low Personnel: Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Corwin 1999</td>
<td>Low</td>
<td>Unclear</td>
<td>Participants: Low Personnel: Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Duffy 1997</td>
<td>Unclear</td>
<td>Low</td>
<td>Participants: High Personnel: Low</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Forster 2004</td>
<td>Low</td>
<td>Low</td>
<td>Participants: Unclear Personnel: High</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Goodson 1985</td>
<td>High</td>
<td>High</td>
<td>Participants: Low Personnel: Low</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Kistin 1990</td>
<td>High</td>
<td>Unclear</td>
<td>Participants: High Personnel: High</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Kluka 2004</td>
<td>Low</td>
<td>Low</td>
<td>Participants: High Personnel: High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Lavender 2005</td>
<td>Unclear</td>
<td>Low</td>
<td>Participants: High Personnel: High</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Noel-Weiss 2006</td>
<td>Unclear</td>
<td>Low</td>
<td>Participants: Unclear Personnel: High</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Unclear</td>
</tr>
<tr>
<td>Reifsnider &amp; Eckhart 1997</td>
<td>High</td>
<td>High</td>
<td>Participants: Low Personnel: High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
</tr>
<tr>
<td>Rossiter 1994</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Participants: Unclear Personnel: High</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
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</tr>
<tr>
<td>Svensson 2009</td>
<td>Low</td>
<td>Low</td>
<td>Participants: Low Personnel: Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
</tr>
</tbody>
</table>
1.4.7.2 Results for systematic review and meta-analysis of prenatal parenting education interventions

1.4.7.2.1 Primary outcome: change in behaviour

1.4.7.2.1.1 Breastfeeding education

Breastfeeding initiation and duration behaviour measures were meta-analyzed as shown below. Due to variation in the definition of breastfeeding amongst included studies we have combined all studies to show the effects of prenatal education interventions on “any” amount of breastfeeding (anywhere from at least one feed per day to exclusive breastfeeding). An additional meta-analysis compiled data from studies that examined exclusive breastfeeding separately.

1.4.7.2.1.1.1 Initiation of breastfeeding

Five\textsuperscript{84,85,87,89,90} of the 8 published papers included breastfeeding initiation after the birth of an infant as a primary or secondary outcome. Six comparisons from these five papers were meta-analyzed for breastfeeding initiation after a group education session on breastfeeding versus standard care (Figure 1). A total of 2318 expectant mothers were included. Results showed mothers who received prenatal breastfeeding education were no more likely than mothers who received standard care to initiate breastfeeding after birth (RR 1.06; 95% CI 0.99-1.14, p=0.12). Significant heterogeneity in studies was noted by an $I^2=78\%$ (p<0.01). Removing the two quasi-experimental studies from the meta-analysis (Reifsnider & Eckhart 1997 and Kistin et al 1990) from the analysis increased (but did not significantly affect) heterogeneity ($I^2=82\%, p<0.01$) and had no influence on the test for overall effect (RR 1.04; 95% CI 0.97-1.11, p=0.30). It is possible that the education had no effect on breastfeeding initiation in hospital because all mothers had access to a support system of healthcare providers to assist them in their attempts to start breastfeeding.
Four of the 8 published papers included short-term breastfeeding duration as a primary or secondary outcome. These four studies enrolling 911 expectant mothers were meta-analyzed to determine the impact of group breastfeeding education on short-term breastfeeding status (Figure 2). Breastfeeding status was measured anywhere from 2 weeks (minimum) to 3 months (maximum) postpartum and when multiple measures were collected in a single study, the data point closest to the maximum of the outcome range (up to 4 months as defined by the US Preventive Services Task Force) was inputted for analysis. Results showed mothers who received prenatal breastfeeding education were 2 times more likely to be breastfeeding within the first 3 months postpartum than mothers who did not receive any prenatal breastfeeding education (RR 2.01; 95% CI 1.06-3.80, p=0.03), however significant heterogeneity in studies was noted ($I^2=87\%$, p<0.01).

Removing the quasi-experimental study (Kistin et al 1990) that possessed a very large confidence interval had no impact on heterogeneity ($I^2=90\%$, p<0.01) and resulted in a non-significant effect for prenatal breastfeeding education over control (RR 1.81; 95% CI 0.93-3.52, p=0.08). Potential reasons as to why group education was ineffective in increasing short-term breastfeeding are unknown.
Figure 2: Breastfeeding status up to 3 months postpartum in participants receiving prenatal breastfeeding education versus standard care

Four of the 8 published papers included long-term breastfeeding duration as a primary or secondary outcome. Five comparisons from these four studies enrolling 2325 expectant mothers were meta-analyzed to determine the impact of group breastfeeding education on long-term (4-6 months as defined by the US Preventive Services Task Force) breastfeeding status (Figure 3). Long-term breastfeeding status was measured anywhere from 4 months to 6 months postpartum in the included studies. Results showed there was no difference in long-term breastfeeding status amongst those who received prenatal breastfeeding education and those that did not (RR 1.00; 95% CI 0.92-1.09, p=0.97) and heterogeneity between studies did not exist ($I^2=0\%$).

Figure 3: Breastfeeding status 4-6 months postpartum in participants receiving prenatal breastfeeding education versus standard care

Two of the 8 published papers studied long-term duration of exclusive breastfeeding. Three comparisons from these two studies enrolling 1193 expectant mothers were meta-analyzed in an additional analysis to determine the impact of group breastfeeding education on exclusive breastfeeding duration at 6 months postpartum (Figure 4). Results showed there was no difference in exclusive breastfeeding at 6 months postpartum amongst those who received prenatal breastfeeding education and those that
did not (RR 1.15; 95% CI 0.86-1.56, p=0.34) and heterogeneity between studies did not exist ($I^2=0\%$).

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Prenatal BF Education Events</th>
<th>Std Care/Std PNE Events</th>
<th>Total Events</th>
<th>Weight</th>
<th>Risk Ratio IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forster 2004a</td>
<td>25</td>
<td>297</td>
<td>322</td>
<td>299</td>
<td>1.19 [0.69, 2.05]</td>
</tr>
<tr>
<td>Forster 2004b</td>
<td>25</td>
<td>293</td>
<td>322</td>
<td>299</td>
<td>1.16 [0.67, 2.01]</td>
</tr>
<tr>
<td>Klaka 2004</td>
<td>29</td>
<td>96</td>
<td>22</td>
<td>82</td>
<td>1.13 [0.70, 1.80]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>686</td>
<td>680</td>
<td>100.0%</td>
<td>1.15 [0.86, 1.56]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.02, df = 2 (p = 0.99); I^2 = 0%

Test for overall effect: Z = 0.94 (p = 0.34)

Figure 4: Exclusive breastfeeding status at 6 months postpartum in participants receiving prenatal breastfeeding education versus standard care

It is possible that prenatal interventions for breastfeeding education have no impact on long-term breastfeeding status (for exclusive or any amount of breastfeeding) because of several uncontrollable factors. Previously reported reasons for weaning around 6 months postpartum in the literature include return to work, ‘insufficient’ milk production, a subsequent pregnancy or other personal reasons. Additionally it is possible that the intervention may not be successful in influencing long-term breastfeeding status because the intervention had little to no impact on breastfeeding initiation or short-term breastfeeding duration as shown in the previous meta-analyses (measurements which precede these long-term assessments of breastfeeding status).

1.4.7.2.1.2 Car safety education

One study enrolling 167 parents looked at the effects of educating parents about infant car safety prenatally in a quasi-experimental study. Classes were assigned alternatively at each study hospital (total=2) to a 30-minute lecture on child passenger seats and car safety added to their standard prenatal education class curriculum (intervention) or standard prenatal education alone (control). All parents were called between 4-6 months postpartum in order to assess how their infant rode (i.e. whether a child passenger seat was used) during their last car ride and data was analyzed separately between the two hospitals as there were statistically significant differences in participant demographics between study sites.
Results showed that group prenatal education on infant car safety had some impact on the use of child passenger seats for car travel. At Hospital A (where subjects were generally Caucasian with more education and higher family income), the use of a child safety seat was high for both study groups (97.5% in intervention group and 100% in control group, no statistically significant difference). Conversely, at Hospital B (where subjects were more multicultural with a lower family income than Hospital A), significantly more parents from the intervention group used a child safety seat during their last car ride versus those who were assigned to the control group (94% versus 60%, respectively, p<0.001). It was therefore concluded that this intervention was successful in increasing child safety seat use in a population that would otherwise use car safety seats infrequently.91

1.4.7.2.1.3 Congenital toxoplasmosis education

One study92 enrolling 432 women assessed the impact of prenatal group education regarding congenital toxoplasmosis on cat, food and personal hygiene behaviours in a randomized controlled trial. Congenital toxoplasmosis is a special case of *Toxoplasma gondii* infection in which the unborn fetus is infected through the mother’s placenta. The handling of cat feces and ingestion of uncooked meat frequently cause toxoplasmosis as it completes its reproductive cycle in the intestines of the domestic cat.101 Although the infection is predominantly mild in humans, it can cause serious harm to the unborn fetus.102 In this study, mothers were randomly assigned to receive standard prenatal education (control group) or an additional 10 minute presentation on cat, food and personal hygiene in addition to the standard prenatal education curriculum (intervention group). A researcher-designed hygiene behaviour questionnaire was given to all participants after the first (pre-test) and last (post-test) class of the prenatal education program.

Results showed that group prenatal education on congenital toxoplasmosis had some impact on cat, food and personal hygiene behaviours, specifically for cat owners (n=32 of intervention group population, p<0.05). It is possible this intervention had only limited effectiveness on hygiene behaviour changes due to participant recall of information as the
authors of this paper report only 5% of the women assigned to the intervention recalled receiving education about congenital toxoplasmosis in the post-test questionnaire.\textsuperscript{92}

1.4.7.2.2 Secondary outcome: change in knowledge

1.4.7.2.2.1 Breastfeeding education

One study\textsuperscript{90} enrolling 194 immigrant Vietnamese women assessed the impact of prenatal group breastfeeding education on breastfeeding knowledge in a randomized controlled trial. Mothers attending a prenatal clinic at one of three study hospitals were randomly assigned to receive standard care plus view a 25-minute video on breastfeeding and participate in three 2-hour small group discussions on breastfeeding (intervention group) or receive standard care alone (control group). Knowledge acquisition was assessed in pre- and post- knowledge tests (the same 18-item researcher designed questionnaire translated into the Vietnamese language).

Results showed that group prenatal education on breastfeeding that included the viewing of a video about breastfeeding significantly increased breastfeeding knowledge in the intervention group over the control group (p<0.001). It is hypothesized that the increased knowledge of intervention group participants contributed to their significantly higher breastfeeding initiation and increased duration up to 6 months postpartum.

1.4.7.2.2.2 General parenting education

Two studies\textsuperscript{93,94} enrolling 296 parents assessed the impact of group prenatal education on general parenting information on general parenting knowledge in two randomized controlled trials.

The first study by Corwin\textsuperscript{93} randomly assigned parents to standard prenatal education plus an added presentation on age-appropriate infant development, early parenting challenges and parent coping mechanisms (intervention group) or standard prenatal education alone (control group). Parenting knowledge was assessed using a 20-item researcher-designed instrument in a pre- and post- test for both intervention and control groups.
Results showed that group prenatal education on general parenting information had some impact on general parenting knowledge. There were no significant differences between post-test scores of intervention and control groups, however the intervention group’s knowledge scores increased significantly between pre- and post-test (p=0.01).

The second study by Svensson et al\textsuperscript{94} randomly assigned parents to a new program entitled the ‘Having a Baby’ program which included increased parenting content (intervention group) or standard prenatal education alone (control group). Parenting knowledge was measured using an 11-item researcher-designed instrument and assessed at baseline, immediately after education and at 8 weeks postpartum for both intervention and control groups.

Results from this study showed group education on general parenting information had a significant impact on general parenting knowledge. Scores for parenting knowledge increased for both groups at the conclusion of the program (p<0.001) however only the intervention group’s scores remained higher than pre-program scores when assessed at 8 weeks postpartum (p<0.001).

Due to differences in teaching topics and scales used to collect outcome data, these studies could not be meta-analyzed to look at the overall effect of parenting education on parent knowledge. Nevertheless, qualitatively these results show that although parenting knowledge may increase over time regardless of whether parents received additional education or not, long-term knowledge retention appears to be higher in those that receive additional education.

1.4.7.2.3 Supplemental measures that may have impacted breastfeeding behaviour

Several of the included studies measured other outcomes that may have impacted the initiation and duration of breastfeeding in the intervention group relative to the control group. These outcomes included breastfeeding confidence, self-efficacy, and attitudes and planned behaviour to breastfeed, although none were measured in more than one study. Furthermore, none of these studies statistically analyzed the association, if any,
that these factors had with breastfeeding initiation or duration thus their relevance to outcomes in the above meta-analyses are unknown.

1.4.7.3 Conclusions for systematic review and meta-analysis of prenatal parenting education interventions

Studies of group prenatal education on parenting topics show inconsistent results however it appeared that studies conducted in pre-existing prenatal education classes were more likely to obtain positive results than studies conducted in prenatal clinics where participants were receiving individualized care and were brought together after recruitment to deliver a group presentation. Further, shorter duration interventions (<1 hr sessions) appeared more likely to significantly influence results than longer programs (1-2.5 hours or more). Also, 3 studies were specifically directed at at-risk or low-income populations and 2 of the 3 saw significant intervention effects therefore tailored interventions specific to a study population may reinforce behaviour change and/or knowledge acquisition.

Further observations or conclusions beyond these are limited by several factors. In addition to varying definitions of breastfeeding status and length of outcome assessment for breastfeeding outcomes discussed previously, we could not differentiate between effects of education on mothers of different parity (i.e. primapara versus multipara), socio-economic or ethnic backgrounds (some interventions were designed for specific target populations) as well as those who were receiving standard care (no education at all) or standard prenatal education (some form of education) due to the lack of studies available. We also could not meta-analyze results of studies from other topics areas other than breastfeeding simply due to the lack of retrieved studies in those areas.

Lastly, assessing the quality of the included studies was proven difficult, as many did not report how randomization of subjects was performed and/or did not discuss concerns related to several forms of experimental bias. Potential bias may also exist in how participants were selected in a prenatal clinic versus an established prenatal education
class as well as who led or delivered the group education sessions (volunteer, nurse-practitioner, lactation consultant etc.). The conclusions of the effectiveness of prenatal education interventions aimed at behaviour change are therefore tentative, and further higher-quality research studies on this topic are warranted.

1.4.7.4 Informing research design and education methods

In addition to conducting this study in an established prenatal education setting with a short-duration (<1 hour), tailored intervention as discussed previously, the evidence also provides preliminary results for effective educational strategies and methods.

Most studies appeared to involve a didactic-lecture (but no indication of use of PowerPoint) and some used demonstration to reinforce presentation material (mostly with infant dolls but some utilized live infants for demonstration). Of the 8 studies that showed positive effects of a prenatal group education intervention on behaviour and/or knowledge, all 8 studies appeared to include a didactic lecture or discussion session, 4 studies included demonstration time or group problem solving activities, 3 studies used audiovisual materials and 2 studies used written materials to supplement learning.

Six of the 8 studies utilized 2 or more education strategies in combination (lecture/discussion plus other method(s)) therefore results from this review suggest the use of multiple educational methods may significantly influence behaviour change or knowledge acquisition. This conclusion was consistent with the postulates of the Learning Pyramid and agreed well with previous research by our team that has illustrated significant knowledge acquisition regarding infant pain management strategies when a pamphlet and video are offered in combination. Although none of the studies in this review specified the use of a PowerPoint presentation, it was decided that our intervention would include a PowerPoint presentation in addition to demonstration time and parents would watch our previously tested video and receive our previously tested immunization pain management factsheet (handout).
1.4.8 Measuring behaviour change through use of pain management strategies

The types and number of pain management strategies utilized by parents during infant immunizations were captured in a standardized survey that was modified in previous studies by our research team. The survey has demonstrated feasibility and discriminatory abilities that allow for identification and differentiation of knowledge between study participants (including both parents and healthcare providers) who are educated versus not educated on effective pain management strategies.104

Pain management strategies (both effective and ineffective) are listed in no particular order in the standardized survey and parents were asked to provide yes/no closed-ended answers to whether they implemented any of the strategies mentioned and were asked for the exact timing that the strategy was employed (before, during, after the injection(s) or any combination). By inquiring about timing of strategy utilization, we were able to identify parents who used each strategy correctly according to the information provided (factsheet, video, and through instructional presentation delivered to parents during their prenatal education class). Parents were then asked whether they found the strategy was effective in reducing the pain their infant experienced during the injection(s) and comments from parents regarding each strategy (if any) were recorded by the blinded research assistant conducting the survey, and were used to decipher any potential discrepancies in use of the listed pain management strategies.

1.5 Summary and strategy

1.5.1 Summary

Traditionally, prenatal education is focused on promoting a healthy pregnancy and preparing for labour and delivery74 yet a growing body of research has indicated that parents are interested in learning additional information related to baby care and other parenting topics during the prenatal period.30,31 Based on parent suggestion, this study was designed to investigate the impact of an immunization pain management teaching
module introduced into the current prenatal education curriculum on future parent use of pain management interventions during infant immunizations.

1.5.2 Strategy for study conduct

The prenatal period has been acknowledged as an excellent time for teaching because expectant mothers and their partners are especially open to learning and accepting suggestions for health promotion. With the Theory of Planned Behaviour, the Learning Pyramid and the results of our systematic review and meta-analysis in mind, our research team created a multi-faceted educational presentation to inform parents-to-be about the importance of reducing pain during infant immunization while teaching them how to do so. We then conducted a cluster randomized controlled trial in order to assess the efficaciousness of teaching classes of parents in the prenatal education environment and the impact it had on analgesic pain management practices during subsequent infant immunization.
Chapter 2

2 Methods

This chapter outlines the methods by which this study was conducted. This trial aimed to evaluate the efficaciousness of an immunization pain management education module when added to a prenatal education curriculum on increasing the use of pain management strategies by parents in the office setting. A control education module (general immunization information) was included to compare utilization between those who received the added education intervention of focus and those that did not.

2.1 Study design and setting

A partially blinded, cluster randomized controlled trial was conducted in the Prenatal Education Program of an academic teaching hospital that delivers approximately 6500 infants per annum (Mount Sinai Hospital, Toronto, Ontario).

A cluster randomized design was chosen for this study based on its feasibility in an established group education setting and its decreased risk of experimental contamination (the spread of information amongst groups) that might have occurred if the participants were individually randomized. The unit of randomization in cluster randomized trials is the cluster (group of individuals), which in this case represented the prenatal class that mothers and their available partners were enrolled in.

2.2 Ethics

The research ethics boards of Mount Sinai Hospital (protocol 12-0134-E, see Appendix B) and the University of Toronto (protocol 28245, see Appendix C) approved this study. The study was also registered with ClinicalTrials.gov (NCT01707212).
2.2.1 Ethical aspects and participant consent

The candidate obtained written, informed consent from all eligible expecting parents on the first day of their prenatal education series. In accordance with the International Conference on Harmonization-Good Clinical Practice\textsuperscript{106} and Tri-Council Policy Statement-2\textsuperscript{nd} Edition\textsuperscript{107} guidelines for informed consent, participants received information about the study and their freedom to withdraw at any time without any impact on their future care at Mount Sinai Hospital. Participants were also assured that any identifying personal information would be kept confidential.

When approached for recruitment, however, subjects were not told the details of the differences between the two presentations being studied. Subjects were informed that the two presentations differed slightly but both covered topics related to infant immunization and they were being tested to decide which presentation parents liked best.

Using deception was imperative to the unbiased conduct of this trial and to our ability to answer the defined research questions adequately and appropriately. According to Article 3.7 of the Tri-Council Policy Statement-2\textsuperscript{nd} Edition\textsuperscript{107} set forth by the Interagency Advisory Panel on Research Ethics, partial disclosure or deception is acceptable only when (1) the research involves no more than minimal risk to the participants; (2) the research does not involve a therapeutic intervention or other clinical or diagnostic intervention; (3) it is impossible or impracticable to carry out the research and to answer the research question properly if prior consent of the participant is required in full exposure; and (3) after participation, participants are debriefed and provided with additional pertinent information that was withheld during the conduct of the trial.\textsuperscript{107}

Accordingly, at the conclusion of follow-up data collection, parents were informed of the true purpose of the study and their group allocation. All parents were offered the immunization pain management factsheet given to the intervention group if they were interested in receiving it.
2.3 Study participants

All parents attending a weekend series of prenatal education classes were eligible for participation in this study. After ensuring that all parents would be attending the second day of class, as scheduled, the candidate (study coordinator) described the study and obtained consent. To determine their eligibility for follow-up measures, additional inclusion and exclusion criteria were assessed after the birth of each participant’s infant(s) and prior to follow-up data collection.

2.3.1 Inclusion criteria

- Mothers attending a weekend prenatal class series
- Delivery of a healthy newborn >35 weeks gestational age (multiples included)
- Available (and home) for infant’s two-month immunization

2.3.2 Exclusion criteria

- Mothers who did not plan to immunize infant
- Infant born with major birth defect(s) or hospitalized at time of immunization
- Mothers who needed to attend the second day of class at a separate time (for example, not on the weekend due to scheduling conflicts)

2.4 Randomization

The unit of randomization for this trial was the class (cluster) in which subjects were enrolled. An investigator (statistician) who was not directly associated with the execution of the trial utilized a computer random number generator to randomize each prenatal class (cluster) in blocks of four to receive either the intervention or control presentation. A research assistant who was not associated with this trial created sequentially numbered, opaque sealed envelopes containing group allocation according to the generated randomization code. Study personnel could not access the randomization code and the candidate opened the next available envelope after consent from all participants in each class was obtained.
2.5 Procedures for all groups

The weekend prenatal education courses offered at Mount Sinai Hospital consisted of two class days (approximately 6 hours/day) per series. The added education module (either intervention or control group presentation) was always administered on the second day of each session and lasted 20-30 minutes. All parents from each class were recruited for participation using the same standardized recruitment and introduction script during the first day of teaching and the number of eligible participants was recorded in an eligibility log.

Those who were willing to participate provided written consent. Demographics forms were completed for all participants whether they chose to participate or not (collecting minimal data from consenting individuals who refused to participate). Additionally, contact information for those who consented to participate was collected and recorded in a recruitment log.

Mothers (and available partners although they were not included in follow-up data collection unless they fulfilled the role of primary caregiver during infant immunization) were then randomized according to the prenatal class they were enrolled in (i.e. by cluster) to receive either (1) the control presentation on general immunization information or (2) the intervention presentation on immunization pain management, incorporated into the standard curriculum and allotted class time on the second day of the prenatal education series. Parents who did not consent to participate were given the option to sit in on the presentation their class was assigned to, or were able leave the classroom for 20-30 minutes while the study presentation was taking place.

After group assignment was determined, the candidate presented and distributed all teaching materials for the allocated presentation during participants’ second prenatal class. During the presentation period, the prenatal educator responsible for moderating and delivering the standard prenatal education curriculum often sat at the back of the class or right outside the classroom door for the duration of the class’ assigned presentation (either intervention or control). The prenatal educators and the candidate met
as a group before data collection began to discuss the study purpose and the content being presented to parents (in order to receive their feedback). The educators were given the opportunity to sit in on the presentation assigned to their class or leave the room while it was being administered (only one educator of five actually left the room during the conduct of the study for all of her classes), and were asked not to interject during the presentation or discuss any of the information presented during the study after the assigned education was delivered unless parents inquired directly to them after the candidate (study presenter) left the classroom. These methods ensured consistent delivery of the assigned class presentation.

Both educational sessions were created to include similarly structured materials (PowerPoint presentations, handouts, video clips, Q&A time) and were scripted in order to ensure consistency in treatment between groups. The intervention group, however, was provided with a demonstration of how to prepare pharmacological interventions and topical anaesthetic samples and occlusive dressings were passed around to participants for them to examine more closely if desired. The education (intervention and control) module components are included in Appendix D&E (Intervention and Control PowerPoint presentation slides, respectively), and Appendix F (Intervention handout). The Control handout, “Keep your children healthy! Protect them! Immunize them!” created by Toronto Public Health is available publicly at http://www.toronto.ca/health/cdc/pdf/child_immunization_brochure.pdf.

Participants allocated to each group completed the same questionnaires before and after the presentation regarding their attitudes and beliefs (intervention group) or their knowledge (control group) surrounding the material taught in class (see Appendices G&H, respectively). In the intervention group, participants also completed a self-efficacy questionnaire at the conclusion of the education module.

Using expected dates of delivery and mothers’ maiden names as a guide, the candidate accessed the electronic medical chart interface at Mount Sinai Hospital on a weekly basis in order to check delivery dates of all participants. This system was also used to assess
infant demographics for further inclusion/exclusion criteria before subsequent follow-up data collection.

Upon assessment of infant eligibility, participants were telephoned within a few days after the infant’s expected 2-month immunization appointment, regardless of what education intervention they received by one of two Research Assistants (RA1/RA2) from our team. At first contact over the phone, participants were addressed using a standardized introductory message from RA1 or RA2. Participants in both groups answered the same set of questions and completed a knowledge test regarding effective pain management strategies.

In a random sub-set (20%, 32 participants as per sample size calculation) of the study sample (equally distributed between groups), a third Research Assistant (RA3) observed the infant’s 2-month immunization injections at their doctor’s office to confirm reliability of parent self-report for pain management strategy utilization. Class numbers were chosen randomly from a hat and all participants in the corresponding class were called to discuss their infant’s immunization appointment that would be attended by a research assistant for observational purposes. Appointments were observed only when selected parents answered this preliminary telephone call and provided the information for their appointment date and time. This process continued until the sample size of 32 participants was obtained and a total of 14 class numbers were drawn to achieve this desired sample size.

RA3 attended infant immunization appointments in order to assess reliability of parent self-report of pain-management strategy utilization during telephone follow-up.

2.5.1 Intervention presentation structure

Classes that were randomized to receive the intervention (immunization pain management) presentation were provided with a 15-minute scripted PowerPoint presentation that discussed pharmacological, physical and psychological strategies for pain management during immunization and when they were best employed. The instructor also demonstrated how to prepare pharmacological agents such as sugar water
and topical anaesthetics. Parents were told they could make sugar water at home themselves (as manufactured formulations are currently not available to the public for purchase) by mixing 2 teaspoons of water with one teaspoon of sugar in a small medicine cup for transport to the appointment and the educator provided a demonstration. Parents were shown how to apply topical anaesthetics by placing two 1-inch strips of a cream (for the sake of demonstration, regular hand cream was used) on a dressing (Tegaderm™) and applying it to the upper outer thigh (for children <1 year old). Topical anaesthetic and occlusive dressing samples were also passed around the class for participants to examine their packaging if desired.

Following the presentation, the class viewed a 8-minute video produced by the Help Eliminate Pain in Kids (HELPinKIDS) Team and aboutkidshealth.ca (available at: http://www.youtube.com/watch?v=jxnDc2PxGUc&list=PLJH3y0duq2Z) that displayed the pain management strategies being used during actual immunization appointments with infants and young children. To conclude the presentation, parents were allotted approximately 5 minutes for question and answer time.

2.5.1.1 Theory of planned behaviour and the intervention presentation

Each of the TPB constructs and how they were targeted in our educational intervention on pain management for infant immunization are outlined below.

2.5.1.1.1 Attitudes

The presentation content targeted parents’ attitudes and beliefs by informing parents about the positive outcomes of using pain-reducing strategies for immunization and the evaluation of those outcomes (i.e. by reducing infants pain I am reducing anxiety, stress and the development of needle phobia in my infant).
2.5.1.1.2 Subjective norms

Although it remains a staple in the model of TPB, some researchers have argued the pathway between subjective norms and behavioural intention is the weakest in the TPB model.\textsuperscript{109} Regardless, the presentation content targeted parents’ subjective norms by showing credible people (pharmacists, physicians, psychologists and other parents) promoting the information in a supplemental video produced by our research team.

2.5.1.1.3 Perceived behavioural control

The presentation content targeted parents’ perceived behavioural control by increasing their self-efficacy through demonstration and discussion of how easily pharmacological agents are prepared and utilized, as well as encouraging parents to be advocates for their infant’s health and well-being.

2.5.2 Control presentation structure

Classes that were randomized to receive the control (general immunization) presentation were provided with a 10-minute scripted PowerPoint presentation that covered topics such as reasons for immunizing, vaccine safety and the current immunization schedule in Ontario as outlined by the Public Health Agency of Canada’s booklet “A Parents Guide to Immunization” available at: http://www.phac-aspc.gc.ca/im/iyc-vve/pgi-gpv/pdf/brochure-eng.pdf. Following the presentation, the class viewed a 3-minute video produced by the Public Health Agency of Canada that was released to the public in 2010 to promote immunization for infants and young children (URL: http://www.youtube.com/watch?v=vlVaoOU1Teg). Parents were also provided with some time to address any questions they might have had regarding immunization.

2.5.3 Take-home materials

All participants (in both control and intervention classes) received a take-home pamphlet about childhood immunization created by Toronto Public Health (public access at http://www.toronto.ca/health/cdc/pdf/child_immunization_brochure.pdf). Additionally,
participants in the intervention classes received a pamphlet previously designed by our research team\textsuperscript{108} (Appendix F) that highlighted the pain management strategies for immunization discussed in the presentation.

2.6 Blinding

- Study Personnel: The candidate, who fulfilled the role of the educator was responsible for delivering the presentation content and was aware of group assignment after consent was obtained.

- Parents: Parents were unaware of their group allocation and purpose of the study. In each participant’s consent form, parents were told that they would be viewing one of two possible presentations regarding infant immunization. Group allocation and purpose of the study were revealed to parents after data collection was complete as part of the study debriefing process.

- Outcome assessors: Research assistants who were blinded to group allocation were responsible for collecting telephone-survey and office visit data using structured questionnaires and/or checklists. There was no indication of group allocation in either data form.

2.7 Outcome measures

All outcomes of interest were selected based on previous research by our team and current challenges that have been identified in this area of research. The primary outcome of interest, analgesic pain management strategy utilization, was defined as use of sugar water, breastfeeding or topical anaesthetics because use of these strategies can be measured easily and objectively. We were specifically interested in seeing in an increase in use of these 3 strategies in particular as they are amongst the most effective strategies for immunization pain management and are the most uncommonly used techniques in clinical practice as exemplified by the immunization pain management audits discussed previously.\textsuperscript{28,59,60}
2.7.1 Primary outcome

2.7.1.1 Analgesic pain management strategy utilization

Utilization of analgesic strategies (sugar water, topical anaesthetics and breastfeeding) was assessed by a structured checklist that has been employed in previous research studies by our team. The types and number of analgesic strategies used were compared amongst intervention and control classes during the analysis of study data. Correct use of analgesic interventions was coded using a standardized coding grid (see Appendix I).

All participants self-reported on pain management strategy utilization during the follow-up telephone survey, and RA1/RA2 was responsible for asking participants about the specific timing in which each intervention was used (before/during/after injection or any combination). Additionally, parents reported whether they believed the intervention(s) they used was/were successful in reducing the pain and distress the infant may have experienced during immunization, as well as if they experienced any barriers to implementing these strategies.

For the subset of participants that were followed to their infant’s 2-month immunization appointment with their doctor, RA3 was present to record any pain management strategies that were utilized by the parent (including the timing in which the intervention was employed). This was later cross-referenced and compared to the strategies parents reported using during their telephone survey follow-up. This comparison allowed the candidate to ascertain the reliability of parent self-report for pain management strategy utilization, recalled after as many as 7-14 days after their infant’s immunization appointment (depending on when the participant was available to be contacted).
2.7.2 Secondary outcomes

2.7.2.1 Parental intent to use analgesic pain management strategies

Parental intent to use any pain management strategies to reduce infant pain during immunization was noted in an open-ended question included in the telephone survey data form and coded quantitatively for any analgesic strategies parents intended to use (this is the first time we have looked at parental intent in a quantitative manner). Reasons for their inability to carry out any of the discussed interventions such as time restrictions, lack of co-operation from health care provider, and restlessness or fussiness of the baby was also collected as previous research from our group has shown that what parents intend to do to manage their infant’s pain during immunization often differs from what they are actually able to employ during the appointment (unpublished data).

2.7.2.2 Knowledge of analgesic pain management strategies

Knowledge was assessed using a previously validated knowledge test on several evidence-based pain management strategies for infants, included in the telephone survey data form (see Table 3). For each strategy, the parent first answered a question about their belief in the effectiveness of its use in infants during painful procedures such as immunization with a traditional true/false response. If they answered true, participants were then asked to rate their certainty of their answer based on a five point Likert Scale (where 5=very sure, 1=very unsure), and were also asked to provide their insight as to whether this strategy is best used before, during, or after the injection (or any combination of the three time frames).
Table 3: Analgesic strategy knowledge test questions

<table>
<thead>
<tr>
<th></th>
<th>True</th>
<th>False</th>
<th>How sure are you on a scale of 1-5?</th>
<th>If True, when do you think it would work? (Circle any combination of the three)</th>
<th>How sure are you on a scale of 1-5?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giving the baby sugar water can reduce pain and distress</td>
<td></td>
<td></td>
<td>Before Inj</td>
<td>During Inj</td>
<td>After Inj</td>
</tr>
<tr>
<td>Using numbing (topical anaesthetic) medicines can reduce pain and distress</td>
<td></td>
<td></td>
<td>Before Inj</td>
<td>During Inj</td>
<td>After Inj</td>
</tr>
<tr>
<td>Breastfeeding the baby can reduce pain and distress</td>
<td></td>
<td></td>
<td>Before Inj</td>
<td>During Inj</td>
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2.7.2.3 Infant pain

Mother’s perception of infant pain during immunization was measured using the validated 11-point Numerical Rating Scale (NRS). The 11-point NRS is one of the most commonly used pain measures. Patients are asked to rate the intensity of their pain on an 11-point scale from 0 (“no pain”) to 10 (“worst possible pain”). The scale is sensitive and has been employed in several experimental studies with both adults and children. There is also some evidence to suggest its construct and criterion validity in assessing child pain by a parent or caregiver. Both control and intervention groups provided an estimation of their infant’s pain from immunization during follow-up over the telephone.

2.7.2.4 Parent satisfaction

Parents’ satisfaction with how their infant’s pain was controlled was assessed with each participant during telephone follow-up using a 5-point Likert Scale response (range 0=very satisfied to 4=very dissatisfied).
2.8 Other data collected from participants

2.8.1 Perceived self-efficacy measures in intervention group

A self-efficacy “ability inventory” (included at the end of the intervention group’s questionnaire, Appendix G) that addressed participants’ perceived confidence in being able to carry out any of the pain management interventions was created by the candidate to serve as a marker of parent understanding of the strategies taught at the conclusion of the intervention presentation. Participant’s responses were further examined to understand the relationship, if any, between these ratings and what pain management strategies parents actually employed during their infant’s two-month immunization appointment.

The perceived self-efficacy “ability inventory” modified by the candidate was designed based on standard methodological recommendations. Parents were required to rate the strength of their beliefs in their ability to execute each of the pain management strategies that were discussed in the teaching module in the context of their infant’s two-month immunization appointment. Their responses were recorded for each pain management strategy on a 100-point scale, ranging in 10-unit intervals from 0 (“cannot do”) to 100 (“highly certain can do”). This scale utilized a 0-100 response format as research has shown it is a stronger predictor of performance over a scale with a 5-interval response range for perceived self-efficacy.

2.8.2 Demographic data

Self-reported demographic data pertaining to the expectant mother including age, marital status, highest level of education completed and expected date of confinement were collected in a demographics form that was completed by the mother after written, informed consent was obtained on the first class day of each prenatal education series. Minimal information was also collected from parents who declined to participate (with their consent) in order to determine if parents who participated in the study were similar to those who did not participate. Information collected from these parents included age, expected date of confinement, plan to immunize their infant and reason(s) for refusal.
Subsequent demographic data related to the newborn(s) of each participating mother were collected during telephone follow-up, and included information regarding infant sex, birth weight, gestational age at birth and mode of delivery.

2.9 Sample size calculation

When calculating the sample size required to demonstrate a desired treatment effect in a cluster randomized controlled trial, two major factors must be considered. First, the standard formulas used to calculate sample size in patient-level randomized controlled trials cannot be employed as this will lead to an underestimation of the required sample size.118 Secondly, the sample size calculation must take into account the intracluster correlation coefficient (ICC), a measure of the degree of within-cluster variance119 as the calculation cannot assume individuals within a single cluster are completely unrelated. Intracluster Correlation Coefficients are usually quantified for a given sample size calculation based on previous research in a similar setting or, when no prior data exists, by utilizing a conservative estimate.

For this trial, an investigator (statistician) who was not directly associated with the execution of this study calculated the sample size based on the primary outcome of increasing the proportion of pain-management strategies utilized during the 2-month immunization appointment (specifically for breastfeeding, sugar water and topical anaesthetics) by 0.5, relative to sample data collected from 174 postpartum mothers (data unpublished29) in which the mean number of pain management strategies used was 0.1 (scored from 0 to 3) with a standard deviation of 0.3. This sample size was calculated using an ICC of 0.6 (a conservative estimate chosen because of no known ICC for the pain-management strategy utilization score in a similar setting) and standard deviation (SD) of 0.5 with the assumption of 5% significance level ($\alpha=0.05$), 80% power ($\beta=0.8$) and a minimum class size of 6 mothers (maximum class size of 10 mothers). A total sample size of 78 mothers per group (156 total) from 26 classes (13 control, 13 intervention) was calculated and accounted for 10% loss to follow-up due to telephone survey methods. Data for 28 clusters (14 control and 14 intervention) was collected in order to meet complete block randomization requirements.
2.10 Statistical analysis

All data were entered into an Excel Spreadsheet by the candidate, and were checked for accuracy by research assistants before data-analysis was conducted.

All statistical analyses were performed by the statistician in conjunction with the candidate. A significance level of 0.05 was used, and data analysis was performed on SPSS version 20 and SAS version 9.3.

The unit of analysis was the individual for all statistical analyses. Regression analyses were performed in order to assess the impact of the educational intervention on the primary and each secondary outcome. All regression models were fitted with Generalized Estimating Equations (GEE) to control for the correlation within clusters (ICC).

2.10.1 Primary outcome analysis

The utilization of sugar water, breastfeeding or topical anaesthetics at the two-month immunization appointment for each infant was compared between groups using a logistic regression model.

The original plan for analysis was to compare the mean score amongst intervention and control groups for utilization (score of proportion of strategies used 0-3) as detailed in the study protocol, however too little observations were seen for scores of 2 or 3 in both study groups (and therefore the data was not normally distributed violating the assumption of univariate analysis methods). The solution was to collapse and dichotomize observations for analysis into zero strategies used (score of 0) or one or more strategies used (score of ≥1) for each study group, as recommended by the study statistician.

2.10.2 Analysis of secondary outcomes

Intent to use any pain main management strategies (i.e., successful utilization and attempted but unsuccessful utilization) was modeled using logistic regression analysis to account for group allocation and obtain a measure of effect size.
Knowledge of analgesic pain management strategies and parent self-reported infant pain ratings were modeled using linear regression models. Parent satisfaction was modeled using a multinomial regression model.

An *a priori* secondary analysis was planned in which the influence of parental stress ratings on pain-management strategy utilization and self-reported NRS pain scores was to be analyzed through logistic and linear regression models, respectively.

A *post hoc* secondary analysis assessed the impact of perceived self-efficacy (confidence) scores for analgesic strategy use and participants’ attitudes and beliefs about pain on what analgesic strategies mothers in the intervention group utilized. This analysis was modeled using logistic regression.

### 2.10.3 Demographic data

Baseline characteristics were analyzed and compared using the Student’s t-test for continuous data or the $\chi^2$-test for categorical data, in order to ensure differences amongst participants did not exist and randomization was effective.

### 2.10.4 Interim analysis

No interim analyses were performed.
Chapter 3

3 Results

This chapter presents the findings of the study. It begins by describing and comparing the sample characteristics and participant flow through the trial. The results associated with the outlined primary and secondary outcomes are then reported.

3.1 Participant flow

Two hundred and sixty-four women and their available partners were approached for participation in this study during prenatal classes held between October 20th, 2012 and February 16th, 2013. Altogether, 197 women (75%) consented and received the intervention and 174 (88%) of these completed follow-up data collection. A summary of participant flow is depicted in Figure 4 below.
Figure 5: Participant flow

Eligible and approached for participation (n=264, 28 classes)

Consented and randomized by cluster (n=204, 28 classes)

Allocated to intervention (n=99, 14 classes)
  Received intervention* (n=96, 14 classes)
  Analyzed (n=88, 14 classes)
  Lost to follow-up (n=7)
  Excluded†(n=1)

Allocated to control (n=105, 14 classes)
  Received control** (n=101, 14 classes)
  Analyzed (n=86, 14 classes)
  Lost to follow-up (n=13)
  Excluded†† (n=2)

Declined to participate (n=60)

---

*n=3 missed second day of class when intervention presentation was administered
**n=4 missed second day of class when control presentation was administered
† n=1 mother excluded due to choice to delay infant immunization until later in life
†† n=1 infant born <35 weeks GA, n=1 mother declined to participate in follow-up measures
3.2 Characteristics of consenting versus non-consenting mothers

Mothers who declined to participate (n=60) and who agreed to provide minimal demographic information (n=33) were no different than those who consented to participate when maternal age and plans to immunize their infant were compared, as seen below in Table 4 (both p>0.05). Commonly cited reasons for choosing not to participate included lack of time, not interested or already participating in other studies.

Table 4: Characteristics of consenting versus non-consenting mothers

<table>
<thead>
<tr>
<th></th>
<th>Consenting individuals (n=197)</th>
<th>Non-consenting individuals (n=33)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (years)</td>
<td>33.5 (4.2)</td>
<td>33.6 (4.5)</td>
<td>0.96</td>
</tr>
<tr>
<td>Planned to immunize infant</td>
<td>166 (84)</td>
<td>24 (73)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Values are frequency (%) or mean (SD)

*Chi-square or Student’s t-test performed for analysis depending on type of data
3.3 Characteristics of groups

3.3.1 Baseline characteristics of participating mothers

The total sample size was 197 mothers; 96 mothers from 14 classes received the intervention presentation and 101 mothers from 14 classes received the control presentation. Demographic data of participating mothers are shown below in Table 5. All expectant mothers were primipara and the majority were married and had completed (at minimum) a college or university education.

Table 5: Baseline characteristics of participating mothers

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=96)</th>
<th>Control (n=101)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (years)</td>
<td>33.4 (3.9)</td>
<td>33.7 (4.2)</td>
<td>0.62</td>
</tr>
<tr>
<td>Married</td>
<td>87 (91)</td>
<td>88 (87)</td>
<td>0.44</td>
</tr>
<tr>
<td>Highest level of education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>completed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College or University</td>
<td>56 (58)</td>
<td>51 (50)</td>
<td>0.27</td>
</tr>
<tr>
<td>Post-graduate degree</td>
<td>40 (42)</td>
<td>47 (47)</td>
<td>0.49</td>
</tr>
<tr>
<td>Accompanied to class by partner</td>
<td>95 (99)</td>
<td>99 (98)</td>
<td>0.59</td>
</tr>
<tr>
<td>Planned to immunize infant</td>
<td>80 (83)</td>
<td>86 (85)</td>
<td>0.73</td>
</tr>
</tbody>
</table>

Values are frequency (%) or mean (SD)
*Chi-square or Student’s t-test performed for analysis depending on type of data
3.3.2 Infant birth characteristics

Birth characteristics were collected using electronic patient charts and were subsequently confirmed during telephone follow-up by parent self-report. Characteristics collected are displayed in Table 6. All infants were born singleton and the majority were female. There were significantly more female infants in the intervention group than the control group (p=0.02).

Table 6: Infant birth characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant sex (female)</td>
<td>50 (57)</td>
<td>33 (38)</td>
<td>0.02</td>
</tr>
<tr>
<td>Gestational age (GA) at birth (weeks)</td>
<td>39.7 (1.4)</td>
<td>39.5 (1.4)</td>
<td>0.28</td>
</tr>
<tr>
<td>Birth weight (kg)</td>
<td>3.4 (0.5)</td>
<td>3.4 (0.5)</td>
<td>0.55</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>59 (67)</td>
<td>61 (71)</td>
<td>0.58</td>
</tr>
<tr>
<td>Delivery at Mount Sinai Hospital</td>
<td>86 (98)</td>
<td>82 (95)</td>
<td>0.39</td>
</tr>
</tbody>
</table>

Values are frequency (%) or mean (SD)

* Chi-square or Student’s t-test performed for analysis depending on type of data
3.4 Outcome measurements

3.4.1 Primary outcome: analgesic pain management strategy utilization

One or more of the three analgesic strategies (sugar water, topical anaesthetics, breastfeeding) were implemented at infants’ 2-month immunization appointments in 34% and 17% of intervention and control group cases, respectively, as shown in Table 7 below. Five (6%) and two (2%) participants from the intervention and control groups, respectively, utilized two analgesic strategies in combination during their infant’s immunization appointment. One participant from the intervention group used all three analgesic strategies.

Upon examining specific strategy use amongst intervention and control groups, results showed increased use of topical anaesthetics (11%, n=10 in intervention group versus 0%, n=0 in control, p<0.01) and sugar water (11%, n=10 in intervention group versus 3%, n=3 in control, p=0.04) in particular. Breastfeeding use amongst groups did not differ between groups (19%, n=17 in intervention group versus 16%, n=14 in control, p=0.6).

Table 7: Utilization of analgesic strategies at routine 2-month immunizations

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>58 (66)</td>
<td>71 (83)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>≥1 (collapsed)</td>
<td>30 (34)</td>
<td>15 (17)</td>
<td></td>
</tr>
</tbody>
</table>

Values are frequency (%)  
*Modeled using logistic regression fitted with GEE

Results of an a priori logistic regression analysis adjusting for stress and group assignment (control or intervention) found that stress ratings were not predictive of strategy use (p=0.28) as no significant differences in stress ratings were seen amongst intervention and control groups. When adjusting for group assignment alone (control or intervention), the odds of the intervention group using one or more strategies was 2.45 times higher than the odds of the control group using one or more strategies (OR 2.45; 95% CI 1.25-4.80, p<0.01).

A post hoc logistic regression analysis of analgesic strategy utilization (in intervention group participants only) aimed to analyze the effects of knowledge, self-reported stress, perceived self-
efficacy and attitudes and beliefs about pain on analgesic strategy utilization. Correlations of these factors with use of $\geq 1$ analgesic strategies were analyzed amongst participants and results from the logistic regression model found knowledge ($p=0.08$), self-reported stress ($p=0.11$) and perceived self-efficacy to use any of the three strategies (all $p \geq 0.07$) were not significantly associated with utilization of one or more analgesic strategies during infants’ 2-month immunization appointments. Interestingly, participant answers for 1 of the 5 statements in the post-intervention questionnaire modeled from the Theory of Planned Behaviour (TPB) significantly predicted analgesic strategy use ($p=0.04$). The significant statement was that which was designed to capture participants’ social norm beliefs (i.e. whether they thought their peers would think it was important that they do everything they can to reduce their infants pain during immunization). Upon further analysis, the significant association existed between those who felt they “strongly-agreed” versus “agreed” with the aforementioned statement, but showed the odds of those who chose “strongly agree” for this statement to use one or more strategies were 0.27 times higher than the odds of those who chose “agree” for this statement to use one or more strategies (OR 0.27; 95% CI 0.08-0.95, $p=0.04$).
3.4.2 Parental intent to use analgesic pain management strategies

Several mothers described plans to utilize one or more of the analgesic interventions at follow-up despite the fact that some were unable to carry out the interventions(s) during the actual immunization appointment. Table 8 below captures mothers’ self-reported intent to use any of the analgesic interventions. Evidently, more than 50% of the mothers in the intervention group planned to utilize at least one of the interventions relative to 34% who were actually able to carry out the intervention as described above in Table 7.

Results of an a priori logistic regression analysis adjusting for group assignment (control or intervention) found the odds of the intervention group planning to use one or more strategies was 4.04 times higher than the odds of the control group planning to use one or more strategies (OR 4.04; 95% CI 2.13-7.66, p<0.01).

Table 8: Intended utilization of analgesic strategies at routine 2-month immunizations

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>41 (47)</td>
<td>67 (78)</td>
<td></td>
</tr>
<tr>
<td>≥1 (collapsed)</td>
<td>47 (53)</td>
<td>19 (22)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Values are frequency (%)
*Modeled using logistic regression fitted with GEE
Additionally, reported barriers to implementing any of the three analgesic strategies were collected from mothers’ experiences and are listed in Table 9. The most frequent barrier reported was that mothers were told the intervention of interest was “not recommended” by their primary care provider.

**Table 9: Reported barriers to strategy implementation by individual parents**

<table>
<thead>
<tr>
<th>Barriers Reported by Parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar water</td>
</tr>
<tr>
<td>• I asked my doctor about it and he said he didn’t have it and did not recommend it</td>
</tr>
<tr>
<td>• Doctor said rotavirus is sweet so no need for it</td>
</tr>
<tr>
<td>• I wanted to use sugar water but my doctor said no; he made me feel silly for asking</td>
</tr>
<tr>
<td>Topical anaesthetics</td>
</tr>
<tr>
<td>• Bought EMLA but pharmacist said it wasn’t recommended for babies &lt;3 months</td>
</tr>
<tr>
<td>• My doctor said it doesn’t work for intramuscular injections</td>
</tr>
<tr>
<td>• Package insert says not for use &lt;3 months</td>
</tr>
<tr>
<td>Breastfeeding</td>
</tr>
<tr>
<td>• I asked my doctor but he did not recommend; said it would make [the immunizations] “awkward”</td>
</tr>
<tr>
<td>• Nurse said she didn’t believe in it; too cumbersome</td>
</tr>
<tr>
<td>• Nurse said I could breastfeed after the shots but not during [because] dangerous to have baby on breast; may choke</td>
</tr>
</tbody>
</table>
3.4.3 Knowledge of analgesic pain management strategies

Knowledge test responses for both control and intervention group participants are displayed below in Table 10. Each participant was asked whether sugar water, topical anaesthetics and breastfeeding helped to reduce pain (true/false) and when these strategies were best employed (before/during/after injection or any combination). Results demonstrated that the intervention group scored significantly higher on the analgesic strategy knowledge test over the control group by 0.8 points on average (p<0.01).

Table 10: Mean number of correct responses on follow-up knowledge test of analgesic pain management strategies

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean number of correct responses</td>
<td>2.1 (0.8)</td>
<td>1.3 (0.9)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Values are mean (SD)
*Modeled using linear regression fitted with GEE
3.4.4 Infant pain

Mean overall 11-point NRS scores for intervention and control groups are reported in Table 11 below. Results demonstrated that the intervention group rated their infant’s pain 0.5 units lower than the control group, on average, although the difference was not statistically significant (p=0.11).

In an a priori analysis assessing the impact of stress ratings on pain measures reported by parents, results from a linear regression model showed for every 1 point increase in stress, participants had 1.3 times the odds of reporting a higher infant pain score (OR 1.30; 95% CI 1.14-1.48, p<0.01).

Table 11: Maternal self-reported 11-point NRS scores for infant at 2-month immunizations

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean overall pain experienced by infant</td>
<td>6.1 (2.0)</td>
<td>6.6 (2.1)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Values are mean (SD)
*Modeled using linear regression fitted with GEE
3.4.5 Parent satisfaction

Mothers most often reported that they were at least somewhat satisfied with how well their infant’s pain was controlled during the 2-month immunization appointment with their healthcare provider, as shown below in Table 12. As too few participants rated their procedural satisfaction as no opinion/somewhat dissatisfied/very dissatisfied, these options were collapsed into ‘dissatisfied’ as shown below for analysis purposes. Results demonstrated that the control group was significantly more likely to rate their satisfaction with their infant’s pain control in a higher satisfaction category compared to the intervention group.

Table 12: Reported procedural satisfaction

<table>
<thead>
<tr>
<th>Procedural Satisfaction</th>
<th>Intervention (n=88)</th>
<th>Control (n=86)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>52 (59)</td>
<td>65 (76)</td>
<td></td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>26 (30)</td>
<td>16 (19)</td>
<td>0.02</td>
</tr>
<tr>
<td>Dissatisfied (collapsed)</td>
<td>10 (11)</td>
<td>5 (5)</td>
<td></td>
</tr>
</tbody>
</table>

Values are frequency (%)
*Modeled using multinomial regression fitted with GEE
3.4.6 Reliability of parent self-report

For the 32 mothers who were accompanied to their infants’ immunization appointments by a research assistant from our team, reported use of any of the pain management strategies presented were compared to observer measures. As displayed in Table 13 below, there were no differences between what parents and the research assistant reported when objective strategies were addressed (i.e. sugar water, topical anaesthetic, breastfeeding).

Table 13: Reported use of pain management strategies by maternal self-report compared to observer measures

<table>
<thead>
<tr>
<th></th>
<th>Parent self-report (n=32)</th>
<th>Observer measures (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sugar water</td>
<td>1 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Topical anaesthetics</td>
<td>1 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>7 (22)</td>
<td>7 (22)</td>
</tr>
</tbody>
</table>

Values are frequency (%)
Chapter 4

4 Discussion

4.1 Summary of results

To our knowledge this is the first study to evaluate immunization pain management education in the prenatal period. The intervention was successful in increasing the utilization of one or more selected analgesic pain management strategies during infants’ 2-month immunization appointments, and in particular, significantly increased the use of sugar water and topical anaesthetics compared to the control group (both p<0.05). Qualitatively, mothers reported similar barriers to strategy implementation that have been discussed previously in the literature and their intent to use any pain management strategies was captured quantitatively, which prior to this study has never been investigated in this manner. Over 50% of mothers in the intervention group reported that they intended to use one or more of the analgesic interventions studied regardless of whether they were able to carry out the intervention or not (due to described barriers) and intervention group participants had 4 times the odds of intending to use one or more of the analgesic interventions than the control group participants (OR 4.04; 95% CI 2.13-7.66, p<0.01). Knowledge scores were significantly higher in the intervention group and there was no difference in mean infant pain scores reported by parents in either group. Lastly, control group participants reported higher satisfaction with the overall immunization appointment with their doctor and how well their infant’s pain was controlled.

4.2 Increased use of analgesic interventions

In this study, we examined the use of strategies that are employed during less than 5% of infant immunization appointments based on findings from pain audits in the primary care setting.28,59,60 The addition of a 30-minute interactive presentation on infant pain management strategies to the standard prenatal education curriculum significantly impacted the use of analgesic pain management strategies in the intervention group compared to the control group. Results showed mothers in the intervention group had nearly 2.5 times the odds of implementing one or more of
these strategies over the control group as determined using a logistic regression model (OR 2.45; 95% CI 1.25-4.80, p<0.01).

The intervention increased the use of topical anaesthetics (11%, n=10 in intervention group versus 0%, n=0 in control, p<0.01) and sugar water (11%, n=10 in intervention group versus 3%, n=3 in control, p=0.04), but breastfeeding use did not differ (19%, n=17 in intervention group versus 16%, n=14 in control, p=0.6). These results represent a notable increase in use of analgesic strategies for immunization pain management compared to previous studies by our research team. The results demonstrate that the education was efficacious in improving subsequent utilization of sugar water and topical anaesthetics. It was not, however, efficacious in improving utilization of breastfeeding. Many mothers that successfully breastfed reported being encouraged by their healthcare provider to breastfeed during the appointment and this support may have been highly influential in the corresponding ~15-20% use of breastfeeding reported by both groups, as we know parents regard their healthcare provider as a trusted source of information in regards to the care of their child. The structure and content of the intervention presentation may explain why no difference was seen for breastfeeding. Specifically, the use and effectiveness of sugar water and topical anaesthetics for infant pain management may have been reinforced more strongly than the use and effectiveness of breastfeeding due to the demonstration time during the presentation that was allotted to show parents how to prepare sugar water and apply topical anaesthetic agents. It is possible that a breastfeeding demonstration from an outside volunteer or a more in-depth discussion regarding breastfeeding strategy during infant immunization could have increased breastfeeding use more substantially in the intervention group than what was seen. All classes in the prenatal education program at Mount Sinai Hospital also receive general education on breastfeeding as part of the standard curriculum therefore this education may have also contributed to the comparable breastfeeding rates among groups during their infant’s two-month immunization appointment.

Regardless of the success of this intervention, 66% of participants (n=58) did not use any of the analgesic strategies they were taught during their infants’ 2-month immunization appointment and 47% (n=41) of these did not mention any intent to utilize these interventions when probed during telephone follow-up. When questioned about analgesic strategy use, some parents
explained that they “wanted to see how the first immunization appointment would go” before using any analgesic interventions and therefore it is not known whether participants would have chosen to utilize the strategies they had learned during subsequent immunization appointments after they witnessed the distress their infant experienced during the 2-month appointment. Studies that quantify and monitor long-term pain management strategy use by parents beyond the 2-month immunization appointments are therefore warranted.

4.2.1 Comparison of results with previous studies of prenatal education interventions designed to impact behaviour change

Relative to the studies of group prenatal education interventions aimed at promoting behaviour change that were discussed earlier in a systematic review and meta-analysis, this intervention was designed shorter in length than most studies (approximately 20-30 minutes versus 1-2.5 hours in many of the included studies) but combined more teaching methods and materials (i.e. video, demonstration time etc.) than what the studies included in this review explicitly described. It is possible that the shorter presentation time maintained parents’ attention and/or interest better than the longer educational interventions examined in other studies and that the increased number of educational methods and materials utilized in this study contributed to a positive learning experience and increased knowledge.

Additionally, the participants in this study were well educated to begin with and generally represented a population with moderate to high socioeconomic status (SES) while some of the included studies in the systematic review and meta-analysis targeted at-risk or low-income populations. It is therefore difficult to compare this population studied to more at-risk populations because higher SES populations may possess a stronger support system that may influence behaviour change and may also have better access to additional educational resources (or be more likely to seek them out).

In summary, the provision of education on infant pain management in the prenatal period resulted in significant behaviour change in regards to the use of pain management strategies by parents in clinical practice. The novelty of the information presented to parents in combination with its delivery in an established setting for education are likely two important factors that contributed to the success of this intervention in promoting behaviour change. The strength of
scientific rigor present in this study relative to the studies of group prenatal education reviewed previously further validates these findings.

4.3 Barriers to pain management strategy utilization

Despite significant increases in the use of analgesic interventions by parents during their infant’s 2-month immunization appointment, several parents reported being blocked from using pain management strategies by clinicians, consistent with previous research by our team. Results showed that over 50% (n=47) of participants in the intervention group planned to utilize at least one analgesic pain management strategy for their infant’s immunization appointment (compared to 22%, n=19 in the control group, p<0.01).

Although it was stressed to parents in the intervention presentation that not everyone is educated about effective strategies for pain management and therefore they should feel comfortable in advocating for their use, parents still reported being told by their healthcare provider that the interventions they intended to use were “not necessary” for immunization and therefore they did not use one or more of the strategies they were taught. Some parents in this study even reported feeling belittled or “silly” for enquiring about pain management strategy use.

Notably, this is the first study by our team that has been able to capture parents’ intent to use analgesic pain management strategies for immunization quantitatively. The data obtained has important implications for future research because it asserts that the proportion of parents’ who have plans to utilize analgesic pain management strategies they learn about is higher than the proportion of parents who are actually able to employ the interventions in practice therefore our educational interventions may have a greater affect if welcomed by health care providers.

Overall these results reinforce the need for continuing professional education for healthcare providers regarding immunization pain management so that the barriers parents are frequently experiencing when it comes to pain management strategy implementation can be minimized.

4.4 Impact of education on analgesic strategy knowledge

As exemplified in previous research by our team, knowledge regarding effective pain management strategies for infant immunization is significantly increased with the provision of
educational materials such as a factsheet (pamphlet) and video. This study additionally provided an interactive presentation on infant pain management and this likely contributed to the slight increase in correct analgesic knowledge scores over previous studies. When planning this study, it was not known whether knowledge retention would be lost due to the multitude of topics discussed in the prenatal period during prenatal education classes; however this study proves knowledge was retained even after the birth of an infant. As discussed in previous research by our team, it is not known exactly how long knowledge is retained for, nor if mothers who utilize strategies at their infant’s 2-month immunization appointment plan to use these strategies again at further immunization appointments. Future research may look to examine these issues.

4.5 Infant pain ratings

No significant differences were found in 11-point NRS ratings of infant pain by parents during follow-up measures. This may be a result of several factors including possible reporting bias in participants exposed to the educational intervention or parents’ lack of experience with assessing and quantifying their infant’s pain. Firstly, during the pain management education intervention, parents were provided with information about effective pain management strategies that have been shown through research to markedly reduce the pain infants experience during immunization. Primed with this knowledge, parents from the intervention group who chose not to utilize any of the interventions (66%) they were taught may have reported high ratings of pain because they knew pain would only be decreased if they utilized the interventions presented. This mentality represents a potential for reporting bias in pain measures by intervention group participants. Additionally, previous research has noted parents report strong emotional connections with their children when they are subjected to painful procedures and feel unprepared to measure and quantify pain. As the 2-month immunization appointment may be the first encounter parents of healthy infants have with procedural pain, they may report consistently higher reports of pain simply because they lack a reference point to compare the pain experienced by immunization.

Results of an a priori analysis found higher parent self-reported stress ratings (in regards to how nervous/stressed/anxious they were about their infant having an immunization) significantly correlated with higher ratings of infant pain using the 11-point NRS. These findings are
supported by research conducted by Cohen et al who also found a similar correlation in these ratings.\textsuperscript{123}

4.6 Parent satisfaction ratings

Priming intervention group mothers about immunization pain may have contributed to their lower satisfaction scores with regards to how well they believed their infant’s pain was controlled. As a result, mothers in the control group were significantly more likely to rate their satisfaction with how well their child’s pain was controlled in a higher satisfaction category compared to the mothers in the intervention group (p=0.02). Intervention group mothers’ lower satisfaction scores may also be attributed to not being able to carry out the interventions they planned to utilize, as it was found that in the intervention group alone, over 50% of participants planned to utilize one or more analgesic interventions at their infant’s 2-month immunization appointment, but only 34% were able to follow-through with their use.

4.7 Applicability of the chosen theoretical framework

Results obtained from the logistic regression model found no effect of self-efficacy ratings or stronger attitude and belief ratings in regards to infant pain on the utilization of analgesic interventions during infants’ 2-month immunization appointment. Nevertheless, we did see an increase in behavioural intent as discussed above which led to, in the majority of cases, utilization of one or more of the analgesic strategies parents were taught. This suggests that the intervention, designed with the Theory of Planned Behaviour in mind, had some effect on behaviour change providing preliminary support for the application of this theory. Attitudes, beliefs and feelings of self-efficacy were consistently rated high after the administration of the educational intervention and we cannot be sure that these ratings parents provided are valid and not just rated highly because they believed they were expected to feel that way because of the provided education. Accordingly, establishing the applicability of the theory of planned behaviour and behavioural self-efficacy to the context of infant procedural pain education requires further research.
4.8 Strengths of study design

Strengths of this cluster randomized controlled study include randomizing participants, concealing treatment allocation, blinding the participants to group assignment and study purpose, using a single educator for all presentations, blinding all outcome assessors to group assignment and study hypotheses and high follow-up rates.

Firstly, parallel two-group randomized controlled trials are considered to possess strong internal validity relative to other study designs\(^{124}\) and randomizing by cluster (i.e. class) instead of on an individual level minimized possible contamination bias between participants.

Concealing treatment allocation using sequentially numbered opaque sealed envelopes was also a strong methodological quality of this project that prevented the candidate from knowing group allocation prior to recruiting eligible participants (dampening the potential for an exaggerated treatment effect in intervention group participants\(^{125}\) if more “desirable” participants were recruited for intervention group assignment). Although the educator could have predicted the assignment of every 4\(^{th}\) class due to knowledge of the block randomization strategy employed, it is unlikely that this influenced recruitment as all classes were recruited continuously over the given study period (i.e. no weekends were missed) and all participants were recruited as a class using the same standardized recruitment script.

Blinding participants to group allocation and study purpose through use of partial disclosure techniques allowed for a reduction in contamination and reporting bias during outcome assessment at follow-up. Similarly, blinding outcome assessors to group allocation and study hypotheses allowed for unbiased outcome assessment during telephone follow-up.

By using a single educator to deliver the intervention and control presentations to all classes, we were able to standardize the delivery procedures to ensure consistency in the information each study group was provided and increase treatment fidelity. This also assisted in ensuring all groups, regardless of allocation, were treated equally so as to limit performance bias.

Additionally, collecting observational data during a subset of participants’ infants’ 2-month immunization appointments in order to confirm reliability of parent self-report was another significant strength of this study, as the unknown reliability of parent self-report during
telephone follow-up has been a significant study limitation of previous studies in this area of research.\textsuperscript{29}

Finally, the follow-up rate for this study was high (88%) and response rate was similar between study groups (n=88 and n=86 completed follow-up from intervention and control groups, respectively) thereby limiting attrition bias. therefore the potential for attrition bias is low. This follow-up rate is also substantially greater than previous studies conducted by our team that utilized telephone follow-up.\textsuperscript{29}

### 4.9 Study limitations

Several limitations to the study design should be considered when interpreting the results, including the analysis methods employed and the overall generalizability of the study findings.

The analysis for this study was done per-protocol rather than by intent-to-treat (ITT), a recognized gold standard in outcome reporting in randomized controlled trials because it provides an unbiased estimate of treatment effect.\textsuperscript{126,127} Only data from subjects who attended their class’ assigned presentation (i.e. received their allocated intervention) and completed follow-up data collection were analyzed and it is possible that those who did not receive their assigned intervention or those who did not complete study follow-up may differ from those who completed the study in its entirety. Despite this, outcome data were available from 85% of the total population recruited (n=204) and dropout and attrition rates were comparable amongst groups.

The homogenous population enrolled in this study may not represent the demographic characteristics of women in prenatal classes in general, or of pregnant women. This may reduce the generalizability of the study findings. The convenience sample obtained was highly educated, predominately married and there was little ethnic diversity amongst participants (the majority were Caucasian as noted anecdotally by the candidate). Further, mothers and their available partners who registered for Mount Sinai Hospital’s prenatal education program were charged a fee of $220 to attend. As such, the results obtained in this study may not be generalizable to the broader population in the Greater Toronto Area (GTA) or those mothers who may register for prenatal classes where a fee for attendance is not paid (i.e. perhaps in classes at a public health centre). Additionally, this study was conducted at an urban academic teaching hospital in
Toronto, Ontario and therefore the results may not be generalizable to community hospitals or other centres that offer prenatal education (i.e. public health centres, non-profit agencies etc.).

Finally, although it was noted as a strength of study design above, using a single educator to administer the study presentations may also have hindered external validity because this does not mimic a “real-world” scenario, even though study designs of this nature are preferred in efficacy trials.\textsuperscript{128} It is difficult to envision that one educator would deliver this intervention if it were employed in the real world when there are a multitude of staff (each with different healthcare backgrounds) who teach the prenatal classes at the centre this study was conducted at alone. Although this would have required extensive standardization and training, using a group of educators rather than a single educator may have produced more generalizable results and this could be investigated in a pragmatic trial in the future.

### 4.10 Summary and future research

In summation, the addition of a 30-minute interactive presentation on infant immunization pain management to the standard prenatal education curriculum at Mount Sinai Hospital was efficacious in increasing the use of one or more selected pain management interventions (sugar water, breastfeeding, or topical anaesthetics) by parents at their infants’ 2-month immunization appointments relative to a control group who received a presentation on general immunization information. On top of this, 97% of participants recommended that the pain management education intervention they received should be shown to all parents in future prenatal classes. The success of this project provides preliminary support for its widespread implementation in prenatal education programs across Ontario to raise awareness and promote infant immunization pain management to first-time parents. Before this, the intervention’s efficaciousness in impacting analgesic pain management strategy use should be investigated in other potentially more generalizable populations and prenatal education settings and should subsequently be followed up with a large-scale rollout study to determine its effectiveness in the “real world” setting.

Additionally, studies evaluating the impact of combining educational efforts in the prenatal and postnatal period to inform new parents about immunization pain management are warranted. With the substantial decrease in the length of stay after the birth of an infant (sometimes as little
as 24 hours), priming parents before the birth of an infant may be the opportune time for “active”
teaching that can be combined and reinforced with education in the postnatal period such as the
provision of educational materials including the previously designed factsheet and video for
parents. 

At present, there is no study or statistics available that detail how many women and their partners
attend prenatal education classes on the provincial level, however individual health units in
Ontario report anywhere from 30 to 72% of women attend at least once. At Mount Sinai
Hospital in particular, approximately 1415 mothers attended prenatal education classes in the
2012/2013 fiscal year; up from approximately 1300 in the previous fiscal year (data provided by
the Prenatal Education Coordinator at Mount Sinai Hospital via email correspondence) but lower
than the attendance rates provided by individual health units when considering approximately
6500 infants are born per year at Mount Sinai Hospital. Targeting parents prenatally in
established prenatal education classes therefore will capture a substantial percentage of expecting
parents but not this population in its entirety, therefore other means to spread information to
parents about immunization pain management prenatally should be hypothesized and considered.

Ultimately, prenatal education about immunization pain management is promising but it is well
established that parents see their healthcare provider as the primary source of information when
it comes to care for their child and therefore education for healthcare providers and parents
should occur simultaneously. Continuing professional education and further dissemination of
guidelines such as that produced by the Help Eliminate Pain in Kids (HELPinKIDS) team should be paramount so as to limit the barriers parents encounter when they express interest in
employing pain management strategies to reduce their infant’s pain during routine immunization.
Chapter 5

5 Conclusions

A multi-faceted education module added to a standard prenatal education curriculum was efficacious in increasing the use of specific pain management interventions (breastfeeding, sugar water, topical anaesthetics) for immunization pain management. This study is the first of its kind to examine education regarding immunization pain management practices in the prenatal period. Parents identified both successful and unsuccessful attempts of implementing pain management strategies in the presence of their healthcare provider, and known challenges were consistent with previous research. Future research endeavors to increase the use of pain management strategies for immunization in clinical practice should continue to strive to educate and support clinicians in the uptake of these evidence-based strategies into their practice. Also due to the success of this project, research regarding the efficaciousness of prenatal education for parents about immunization pain management is warranted in other settings such as within public health centres as well as hospitals that offer prenatal education to a more diverse population. In addition, prenatal education on immunization pain management should be combined with other postnatal education endeavors in order to ensure that educational materials are accessible and readily available for all parents in all settings in order to ensure and improve the quality of pain care that young children are entitled to.
References


81. Greenhalgh, T. How to read a paper: papers that summarize other papers (systematic reviews and meta-analyses). *BMJ*. 1997; 315(7109): 672-675.


Appendix A

The searches for your topic were run using the OvidSP search platform in the following databases: MEDLINE, EMBASE, EBM Reviews – Cochrane Central Register of Controlled Trials (CCTR), PsycINFO, Eric and EBSCOHost search platform in the following database CINAHL to include articles indexed as of February 6, 2013. The search strategy retrieved a total of 13795 references. All references were saved in an EndNote library used to identify the 2868 duplicates. The remaining 10927 unique references were forwarded for review against your inclusion criteria. Included in this group of 10927 are approximately 1757 are on breast feeding. I have saved and will send as a separate group.

The following tables record the search strategies and terms used in each of the databases. Search results were limited to English Language articles and age group (children 0-23 months) as available.

**MEDLINE:**

The search strategy for OvidSP MEDLINE (1946 to February 6, 2013) retrieved 3389 references of which 3320 were unique and not duplicated in our other searches. I used a combination of MeSH and free text terms for

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EMBASE

The search strategy for OvidSP Embase Classic+Embase <1947 to 2013 Week 05> retrieved **6541** references of which **5061** were unique and not duplicated in our other searches. I used a combination of EMBASE and free text terms for

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**EMB Reviews - Cochrane Central Register of Controlled Trials**

The search strategy for OvidSP EBM Reviews - Cochrane Central Register of Controlled Trials < January 2013> retrieved **545** references of which **276** were unique and not duplicated in our other searches. English language articles were removed manually as there is no language limit
available in this database. I used a combination of primarily MeSH, EMBASE and free text terms for

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Appendix B

Research Ethics Board
600 University Avenue, Room 19-311
Toronto, Ontario, Canada, MSG 1X5
t: (416) 586-4875 f: (416) 586-4715
www.mtsinai.on.ca

Notification of REB Initial Approval ( Expedited)

Date: October 3, 2012

To: Dr. Vibhuti Shah
Department of Pediatrics
Division of Neonatology
Mount Sinai Hospital
600 University Avenue, Room 775A
Toronto, Ontario

Re: 12.0134-E
A Prenatal Education Module for Parents to Improve the Use of Pain-Management Strategies for Immunization in Two-month Old Infants: A Randomized Trial of Knowledge Translation

Sponsor: No Funding Required
REB Review Type: Expedited
REB Initial Approval Date: 03 October, 2012
REB Expiry Date: 03 October, 2013

Documents Approved:
- Consent Form (dated 2012/08/01)
- Protocol (dated 2012/10/02)

Documents Acknowledged:
- Recruitment Script (dated 2012/08/01)
- Participant Identification Log (dated 2012/08/01)
- Participant Demographics Form (dated 2012/08/01)
- Q&A Guide (dated 2012/08/01)
- Questionnaires: Intervention Group (dated 2012/08/01)
- Questionnaires: Control Group (dated 2012/08/01)
- Telephone Follow-up Script (dated 2012/08/01)
- Follow-up Demographics & Birth Details Form (dated 2012/09/18)
- Immunization Observation Data Form (dated 2012/09/18)

Health Records Access: Yes

The above named study has been reviewed and approved by the Mount Sinai Hospital Research Ethics Board. Data transfer off-site in contingent upon approval of any necessary agreements by Mount Sinai Hospital. If, during the course of the research, there are any serious adverse events, confidentiality concerns, changes in the approved project, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the REB. In the event of a privacy breach, you are responsible for reporting the breach to the MSH REB and the MSH Corporate Privacy Office (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the MSH REB requires reports of inappropriate/unauthorized use of the information.

If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.


Sincerely,

Ronald Hesegarve, PhD
Chair, Mount Sinai Hospital Research Ethics Board
Appendix C

PROTOCOL REFERENCE # 28245

October 19, 2012

Dr. Anna Taddio  Miss Sarah Smart
FACULTY OF PHARMACY  FACULTY OF PHARMACY

Dear Dr. Taddio and Miss Sarah Smart,

Re: Administrative Approval of your research protocol entitled, "A prenatal education module for parents to improve the use of pain-management strategies for immunization in two-month old infants: A randomized controlled trial of knowledge translation"

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative approval to the above-named research protocol. The level of approval is based on the following role(s) of the University of Toronto (University), as you have identified with your submission and administered under the terms and conditions of the affiliation agreement between the University and the associated TAHSN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-identified Personal Information (date)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University's involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

Daniel Gyewu
REB Manager

Brought to you by the University of Toronto, Leslie Dan Faculty of Pharmacy, AboutKidsHealth, The Hospital for Sick Children & The Women’s and Infant’s Ambulatory Health Programs, Mount Sinai Hospital

Immunization is the safest way to protect your baby’s health.
Vaccines are safe

- Vaccines are constantly monitored and tested around the world and in Canada before they are approved for use.

- Severe reactions from vaccines are extremely rare.

- Normal reactions to the vaccine include low fever, mild redness or swelling around the injection site and crankiness or fatigue.

Ontario’s immunization schedule

Publicly Funded Immunization Schedules for Ontario – August 2011

Publicly funded vaccines may be provided only to eligible persons and must be free of charge.

<table>
<thead>
<tr>
<th>Schedule 1: Routine Schedule for Children Beginning Immunization in Early Infancy (Starting at 2 months of age)</th>
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</thead>
<tbody>
<tr>
<td>Age at vaccination</td>
</tr>
<tr>
<td>2 months old</td>
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<td>4 months old</td>
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<td>12 months old</td>
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<td>18 months old</td>
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<td>4-6 years old</td>
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<td>Grade 7 students</td>
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<tr>
<td>Grade 8 females</td>
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<td>14-16 years old (10 years after 4-6 year old booster)</td>
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<td>Every year (for adults)</td>
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</tbody>
</table>

*DTaP/IPV: administered at 2, 4, and 6 months of age; MMR: administered at 4-6 years of age; Pneumovax: administered at 6 months of age; cervical cancer: administered in 23v strain. **Does not include those who are pregnant. ***For those who are pregnant. ****For those who are not pregnant.
Vaccine injections can be painful and stressful for babies and parents, but you can really make a difference.

Immunization = Children in Pain
Why is it important to reduce pain?

- Increase in Stress and Anxiety
- Needle Phobias
- Changes in Future Pain Response
- Avoidance of Medical Care

How can parents reduce pain?

- Using the 3 P’s of Helping your Baby during Vaccinations:
  - **Step 1:** Pharmacological (Pain Medicine)
  - **Step 2:** Physical (Body Position & Activity)
  - **Step 3:** Psychological (Thoughts & Behaviors)
Step 1: Pharmacological

Apply topical anaesthetics

Step 1: Pharmacological

Give sugar water
Step 2: Physical

Hold upright

Step 2: Physical

Breastfeed
Step 3: Psychological

Deep breaths

Step 3: Psychological

Distract
On the day of your baby’s vaccination

• Make a *pain management plan*; what are you going to do to reduce your baby’s pain during immunization?

• Bring your baby’s yellow card

• If you have questions for your doctor, make a list and be sure to ask them before the injections are given
Appendix E

Immunization: Your Infant’s Best Shot

Getting the facts out to new parents

Brought to you by Toronto Public Health & The Women’s and Infant’s Ambulatory Health Programs, Mount Sinai Hospital

Presentation overview

• Why should my baby be immunized?
• What is a vaccine and how does it work?
• Vaccine Safety
• The immunization schedule in Ontario
• What to prepare on the day of vaccination
Why should my baby be immunized?

- It is the safest way to protect your baby’s health

- Just as growing babies have to learn how to eat by themselves, their immune systems have to learn how to recognize and fight diseases

What are vaccines and how do they work?

- A vaccine is the medicine in the needle when your baby is immunized

- They are made from killed or weakened germs that help your baby’s immune system learn how to protect itself
Vaccines are safe

• Vaccines are constantly monitored and tested around the world and in Canada before they are approved for use

• Severe reactions from vaccines are extremely rare

• Normal reactions to the vaccine include low fever, mild redness or swelling around the injection site and crankiness or fatigue

Vaccines are safe

• Vaccines are *much* safer than the diseases they prevent

• Your baby’s natural immune system will have no problem tackling and destroying the weak or dead germs in the vaccine
Ontario’s immunization Schedule

Publicly Funded Immunization Schedules for Ontario – August 2011
Publicly funded vaccines may be provided only to eligible persons and must be free of charge.

<table>
<thead>
<tr>
<th>Age at vaccination</th>
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<td><em>DTaP-IPV</em> (preferably given at 2 years of age, administered to children 0-11 years old, see Schedule B. The <em>DTP</em> vaccine is given at 6 years of age)</td>
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On the day of your baby’s vaccination

- Be sure to bring your baby’s yellow card
- Try to make sure the baby is well-fed and rested before they go in for their appointment
- Make a list of any questions you want to ask your doctor and be sure to ask them before the vaccines are given
Appendix F

The 3 P’s of Helping your Baby during Vaccinations
A Parent’s Guide: Babies up to 1 year old

Vaccine injections can be painful and stressful for babies and parents, but you can really make a difference.

For your baby’s next vaccine injection, plan with your health care provider to:

1. Apply topical anaesthetics to numb the skin – these are medicines you can buy at a pharmacy without a prescription.
2. Give your baby sugar water for comfort – make sugar water at home or at the clinic by mixing 1 teaspoon of sugar with 2 teaspoons of water.
3. Distract your baby – choose an age-appropriate item to bring.

Read the 3 P’s of vaccination pain management below and combine these strategies to improve pain relief.

For more information and a video, visit the SickKids (The Hospital for Sick Children, Toronto, Canada) website: www.aboutkidshealth.ca/pain-free-injections

**STEP 1: PHARMACOLOGICAL (PAIN MEDICINE)**

**TOPICAL ANAESTHETICS**
- Available products: lidocaine (Maxilene™), tetracaine (Ametop™), lidocaine-prilocaine (EMLA™).
- Apply to either the upper outer part of the leg (infants less than 1 year), or upper arm (infants 1 year old). 30 to 60 minutes before injection – check product instructions.
- If 2 or more injections are planned, apply to both legs or arms.
  - May cause temporary reddening or whitening of skin – this is normal. If there is a rash, talk to your doctor – it could be an allergic reaction.
  - Avoid acetaminophen (Tylenol™), ibuprofen (Advil™), ice and cold sprays before injection – they have not been proven to reduce injection pain. After injection, acetaminophen or ibuprofen may be used to relieve fever or discomfort.

**STEP 2: PHYSICAL (BODY POSITION AND ACTIVITY)**

**HOLD**
- Hold your baby close during injection – in a hug or on your lap. This feels good and helps your baby stay still.
- Avoid holding your baby too tightly – this can increase pain and distress.

**BREASTFEED**
- Start breastfeeding your baby before injection and continue during and after injection.
- If 1 injection is planned, position your baby to expose 1 leg; expose both legs for 2 or more injections.
- If the baby cannot be breastfed, offer a bottle or pacifier starting before injection and continue during and after injection.

**STEP 3: PSYCHOLOGICAL (THOUGHTS AND BEHAVIOURS)**

**BREATHE DEEPLY**
- Stay calm and use your normal speaking voice. This helps your baby stay calm – babies look to their parents for how to act and feel.
- If you are nervous, take a few slow, deep breaths to calm yourself before and during injection – breathe so your stomach expands, not your chest. You can do this while holding your baby.

**DISTRACT**
- Help keep your baby’s attention away from the injection.
- Distractions you can use: rocking, cuddling, singing, talking, sucking (breastfeeding or pacifier). Distract with objects or toys (bubbles, pop-up books, rattles) when your baby is calm enough to do so; otherwise, distress can be increased.

These are scientifically proven ways of reducing pain in babies during vaccine injections. Think about what worked and plan ahead to make the next vaccination less painful.

See over for children over 1 year old
Appendix G

Questionnaire 1 – Pain-Management Pre-Presentation Questionnaire

WE’D LIKE TO GET YOUR OPINION ON SOME GENERAL QUESTIONS BEFORE THIS PRESENTATION

1  I think preventing pain in children during immunization injections is important:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree

2  I think I should do everything I can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree

3  I think my doctor/nurse should do everything they can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree

4  I think that my family members and friends would think it is important to do everything I can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree

5  I am confident that I can control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree
WE’D LIKE TO GET YOUR OPINION ON SOME GENERAL QUESTIONS AFTER VIEWING THIS PRESENTATION

1. I think preventing pain in children during immunization injections is important:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Neither Disagree Strongly Agree
   Agree Disagree

2. I think I should do everything I can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Neither Disagree Strongly Agree
   Agree Disagree

3. I think my doctor/nurse should do everything they can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
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4. I think that my family members and friends would think it is important to do everything I can to control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Neither Disagree Strongly Agree
   Agree Disagree

5. I am confident that I can control my child’s pain during immunization injections:
   a. □   b. □   c. □   d. □   e. □
   Strongly Agree Neither Disagree Strongly Agree
   Neither Disagree Strongly Agree
   Agree Disagree
Questionnaire 2 – Pain-Management Post-Presentation Questionnaire

ABILITY INVENTORY

Listed below are the pain-management strategies you learned about in today’s presentation. In the column Confidence, rate how confident you are that you can do each of these strategies as of now.

*Rate your degree of confidence by recording a number from 0 to 100 using the scale given below:*

<table>
<thead>
<tr>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
</tr>
</thead>
</table>

- Cannot do at all
- Moderately certain can do
- Highly certain can do

**Pharmacological Strategies**

1. Sugar Water __________________
2. Topical Anaesthetics (Numbing Creams) __________________

**Physical Strategies**

3. Holding Upright __________________
4. Breastfeeding or Bottle-feeding __________________

**Psychological Strategies**

5. Deep Breathing __________________
6. Distracting your Baby __________________
Appendix H

Questionnaire 1 – Immunization Pre-Presentation Questionnaire

TELL US WHAT YOU KNOW NOW ABOUT IMMUNIZING YOUR CHILDREN

1 Vaccination is one of the best tools we have to protect a child’s health:
   a. □       b. □       c. □       d. □       e. □
   Strongly Agree Neither Disagree Strongly
   Agree

2 Immunization and vaccination mean the same thing:
   a. □       b. □       c. □       d. □       e. □
   Strongly Agree Neither Disagree Strongly
   Agree

3 One injection can protect your baby from multiple diseases:
   a. □       b. □       c. □       d. □       e. □
   Strongly Agree Neither Disagree Strongly
   Agree

4 Infant immunization records (Yellow Card) are kept at the doctor’s office:
   a. □       b. □       c. □       d. □       e. □
   Strongly Agree Neither Disagree Strongly
   Agree

5 Infants may receive multiple vaccine injections during a single visit with their doctor:
   a. □       b. □       c. □       d. □       e. □
   Strongly Agree Neither Disagree Strongly
   Agree
Questionnaire 2 – Immunization Post-Presentation Questionnaire

TELL US WHAT YOU KNOW NOW ABOUT IMMUNIZING YOUR CHILDREN

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3 One injection can protect your baby from multiple diseases:
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4 Infant immunization records (Yellow Card) are kept at the doctor’s office:
   a. □ b. □ c. □ d. □ e. □
   Strongly Agree Neither Disagree Strongly Agree Disagree

5 Infants may receive multiple vaccine injections during a single visit with their doctor:
   a. □ b. □ c. □ d. □ e. □
   Strongly Agree Neither Disagree Strongly Agree Disagree
Questionnaire 2 – Immunization Post-Presentation Questionnaire

6 This presentation has helped me feel better prepared to immunize my infant in the future.

   a. □    b. □    c. □    d. □    e. □
   Strongly Agree Neither Disagree Strongly Agree
   Agree Disagree

7 I feel other expecting parents should receive education on this topic in prenatal classes through a presentation such as the one presented to me.

   a. □    b. □    c. □    d. □    e. □
   Strongly Agree Neither Disagree Strongly Agree
   Disagree
Appendix I

If they answered the question the following way their answer was marked correct:

<table>
<thead>
<tr>
<th></th>
<th>YES, before (only or combined with during)</th>
<th>YES, during (only or includes)</th>
<th>YES, before only</th>
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<tbody>
<tr>
<td>Sugar Water</td>
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<tr>
<td>Breastfeeding</td>
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