Routine immunization is the most commonly encountered painful experience among healthy children worldwide. Evidence from past literature suggested that recurrent pain could have long-term undesirable effects on children and the community if left unmanaged. Although children are repeatedly exposed to immunization pain, the need for immunization pain management is often under-recognized in the Maternal and Child Health Centre (MCHC). On the other hand, use of Eutectic Mixture of Local Anesthetics (EMLA) has been cited in many literatures as an option for pain relief when undergoing immunizations for children. This dissertation therefore intends to conduct a critical appraisal on EMLA to affirm its effectiveness as pain relief measure for immunization so that an evidence-based practice (EBP) guideline on pre-vaccination EMLA could be
formulated for children undergoing immunizations in MCHC.

Three electronic databases were used to identify relevant research studies for critical appraisal, with seven studies targeting the use of pre-vaccination EMLA on children below 6 years of age being selected for review. Data from the selected studies were synthesized to reveal that application of EMLA on vaccination site for at least 60 minutes prior to immunization could effectively reduce pain response in children, as manifested by the shortening of crying duration and reduction in pain assessment scores in the intervention groups.

Investigation on the implementation potential of pre-vaccination EMLA in MCHCs was then carried out by conducting cost-benefit analysis and examining the transferability and feasibility of pre-vaccination EMLA to affirm its practicability as immunization pain relief among children in the MCHCs. An EBP guideline with six recommendations on the timing, duration and evaluation method of pre-vaccination EMLA was also formulated to guide the practice change. A communication plan was then set up to engage support from stakeholders and a pilot study plan was also formulated to test the feasibility of implementing pre-vaccination EMLA in a designated MCHC. An evaluation plan using Modified Behavioral Pain Scale, Visual Analog Scale, satisfaction questionnaires as well as level of utilization as outcome measures was also set up.
to assess the efficacy of pre-vaccination EMLA in the local setting. It is expected that pre-vaccination EMLA patch application could reduce the pain response in vaccinated children in the designated MCHC and is worthwhile to be generalized to other MCHCs in the Department of Health.
An evidence-based guideline for applying EMLA cream prior to vaccination to reduce immunization pain for children in the Maternal and Child Health Centre

by

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BNurs. (Hons) HKU

A dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Nursing at The University of Hong Kong.

July 2015
Declaration

I declare that this dissertation represents my own work, except where due
acknowledgement is made, and that it has not been previously included in a thesis,
dissertation or report submitted to this University or to any other institution for a
degree, diploma or other qualifications.

Signed

LO PUI YEE
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# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CFCS</td>
<td>Child Facial Coding System</td>
</tr>
<tr>
<td>CG</td>
<td>Control group</td>
</tr>
<tr>
<td>CHEOPS</td>
<td>Children’s Hospital of Eastern Ontario Pain Scale</td>
</tr>
<tr>
<td>CNS</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence-based practice</td>
</tr>
<tr>
<td>FHS</td>
<td>Family Health Service</td>
</tr>
<tr>
<td>FPS</td>
<td>Face Pain Scale</td>
</tr>
<tr>
<td>HIS</td>
<td>Health Information Section</td>
</tr>
<tr>
<td>HK</td>
<td>Hong Kong</td>
</tr>
<tr>
<td>HKD</td>
<td>Hong Kong dollar</td>
</tr>
<tr>
<td>IG</td>
<td>Intervention group</td>
</tr>
<tr>
<td>MBPS</td>
<td>Modified Behavioral Pain Scale</td>
</tr>
<tr>
<td>MCHC</td>
<td>Maternal and Child Health Centre</td>
</tr>
<tr>
<td>MFCS</td>
<td>Modified Neonatal Facial Coding Score</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>NO</td>
<td>Nursing Officer</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trials</td>
</tr>
<tr>
<td>RNs</td>
<td>Registered nurses</td>
</tr>
<tr>
<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Chapter 1  Introduction

Background

Immunization and its Benefits

Ever since the launch of the Expanded Programme on Immunization by the World Health Assembly in 1974, immunization programmes have been set up in many countries to protect children against various infectious diseases (World Health Organization [WHO], 2014a). Being recognized by the Centers for Disease Control and Prevention (CDC) as one of the greatest achievements for public health in the twentieth century, vaccination safeguards the well-being of children by reducing morbidity and mortality through eradicating, eliminating and controlling the transmission of communicable diseases (CDC, 1999a; CDC, 1999b; WHO, 2014a). It could also offer indirect protection to unvaccinated individuals and minimize their risk of exposure to communicable diseases by developing herd immunity in the community (Fine, 1993; Fox, Elveback, Scott, Gatewood, & Ackerman, 1971).

Despite the benefits it has brought about, undergoing immunization is still considered by parents and healthcare providers as an unpleasant experience for the pain it inflicted on children receiving the vaccines.
Pain and Immunization: Need for Pain Control

Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain, 2014). Although children at different developmental levels might have slight variations in their response to pain, they have already possessed fully-developed pain transmission pathways before birth and are capable of expressing pain through facial expressions, body movements and crying (Craig, McMahon, Morison, & Zaskow, 1984; Gevirtz, 2008; Johnston & Strada, 1986; Puchalski & Hummel, 2002).

Immunization is defined as “the process to induce or provide immunity artificially in order to prevent infectious diseases” (Public Health Nursing Division, 2014, p.1). With continuous introduction of new vaccines into the current immunization programmes, routine immunization has become the most commonly encountered painful experience among healthy children worldwide (Taddio et al., 2009a).

Pain, when left unmanaged, could have undesirable effects on children. Thus pain control measures should be provided for children undergoing vaccinations to minimize the deleterious effects of immunization-induced pain (Young, 2005). This paper will outline the current immunization practice and pain management
strategy in Hong Kong (HK) as well as illustrating the adverse effects of unmanaged pain to affirm the need for immunization pain control in the Maternal and Child Health Centre (MCHC). Summary and synthesis of data from selected studies will then be conducted to gather high-quality evidence for the formulation of an evidence-based pain control guideline in the MCHCs.

**Affirming the Need**

**Current Immunization Programme in HK**

A comprehensive immunization programme has been set up in HK in the 1950’s to protect children from infectious diseases (Family Health Service [FHS], 2014a). In the year 2015, a total of 14 vaccinations are being delivered to children by eighteen months of age for protection against 11 types of infectious diseases, among which 12 of them are administered in the MCHCs (Appendix A). Children with incomplete immunizations could also return to MCHCs for catch-up immunizations before six years of age. By providing immunization free of charge to eligible persons, HK is able to maintain a high immunization coverage rate of over 95% for all vaccines (Department of Health [DH], 2014; WHO, 2014b).

With the introduction of pneumococcal vaccine in 2009 and the launch of varicella vaccine in 2014, children are required to receive multiple vaccines during routine visits, such that as many as three vaccines might be administered...
during a single visit to the MCHCs (FHS, 2014a). Under the ever-growing immunization programme, children in HK are repeatedly exposed to the acute pain induced by immunizations. This is where the clinical issue of this paper lies as recurrent pain could have long-term adverse effects on children and the community if left unmanaged (Page, 2004).

**Undesirable Effects on Children**

Acute pain could alter the central nervous system (CNS)’s response to subsequent painful stimuli by decreasing one’s pain threshold, leading to hypersensitivity to pain and reduced effectiveness of analgesics in future medical procedures (Gevirtz, 2008; Puchalski & Hummel, 2002; Taddio, Katz, Ilersich, & Koren, 1997; vonBaeyer, Marche, Rocha, & Salmon, 2004; Weisman, Bernstein, & Schechter, 1998). It could also compromise the development of CNS and create detrimental effect on children’s growth and development, resulting in increased risk of attention deficit and somatic complaints when they grow up (Mitchell & Boss, 2002). Besides, immunization pain could lead to the development of needle phobia in children and elicit anticipatory anxiety towards future medical procedures, resulting in avoidance of medical care as well as greater risk of delayed diagnosis and treatment in adulthood (Craig et al., 1984; Hamilton, 1995; Pate, Blount, Cohen, & Smith, 1996).
Undesirable Effects on Community

Recurrent pain induced by administration of multiple vaccines during a single visit has elicited much stress for parents (Madlon-Kay & Harper, 1994; Parvez et al., 2010). In order to minimize the sufferance of their children, parents may postpone some of the vaccinations so that vaccines could be administered in separate visits (Taddio et al., 2009a). Such non-adherence to the immunization schedule would put the health of the community at risk as it may lower the overall immuno-protection of the population and threaten the integrity of the herd immunity, leading to resurgence of communicable diseases (Feikin et al., 2000; Taddio et al., 2009a).

Current Pain Control Practice in HK

Although children are repeatedly exposed to immunization pain, the need for immunization pain management is often under-recognized by the nursing staff (Harrison, Elia, Royle, & Manias, 2013; Puchalski & Hummel, 2002). A similar phenomenon is also occurring in the MCHCs in HK.

The immunization guidelines currently in use in the MCHCs mainly focus their emphasis on the safe administration of vaccines and on managing post-vaccination adverse reactions without mentioning the need for pain control. The absence of pain management guideline makes it difficult to standardize
nursing care on pain relief during immunization procedures in the MCHCs. In current practice, little is done by nursing staff to minimize immunization pain for children. During vaccinations, nursing staff solely rely on parents or caregivers in managing the pain of their children. As a result, inconsistent methods such as smacking hardly on the child’s thigh before delivery of vaccines are being used, with many of these methods being not evidence-based and ineffective.

Nursing staff’s knowledge deficit on pain control also contributes to the underuse of pain relief measures in the MCHCs (Park, Fulton, & Senthuran, 2000; Taddio et al., 2009a). While many studies have revealed that children already have fully-developed perception and memory for pain, many nursing staffs still are unaware of it (Ornstein, Manning, & Pelphrey, 1999; Rodkey & Riddell, 2013; vonBaeyer et al., 2004). They perceive immunization pain control as unnecessary as they believe that children would not be able to remember the painful experience when they grow up (Page, 2004).

With the absence of pain management guideline and the underuse of pain relief measures by nursing staff, it is clear that a gap between knowledge of immunization pain and the actual practice of pain relief during vaccination delivery is existing in the MCHCs. Being the advocate for our clients, it is nursing staff’s responsibility to generate the best health outcome and do no harm to them.
Thus it is the obligation of the nursing staff in the MCHCs to counteract the devastating effects of pain for children by minimizing pain during immunization procedures. In order to fulfill this obligation, there is an obvious need for the development of an evidence-based practice (EBP) guideline on immunization pain management in the MCHCs.

The Innovation: Use of Eutectic Mixture of Local Anesthetics (EMLA)

EMLA is a topical anesthetic composed of a 1:1 mixture of lidocaine and prilocaine (Dutta, 1999). Appears either in cream formulation or in a single unit dose patch, it could penetrate under the skin and establish its pain relief effect by temporarily blocking the pain transmission in the nerve bundles when applied half to one hour before medical procedures (Dutta, 1999; Nilsson, Boman, Wallin, & Rotstein, 1994; Park et al., 2000).

The effectiveness of EMLA in relieving pain has been demonstrated in a wide range of medical procedures such as venipuncture, circumcision, lumbar puncture as well as in many dental procedures (Fan et al., 2013; Gilboy & Hollywood, 2009; Lim & Julliard, 2004; Weise & Nahata, 2005). Although there were studies carried out to investigate the ability of EMLA in reducing pain for immunization, no systematic review has been conducted to affirm its effectiveness, its use as immunization pain relief thus becomes restricted (Abuelkheir et al.,
2014; Gupta et al., 2013; Taddio et al., 2007). It is therefore necessary to collect and synthesize data in the existing researches to determine the effectiveness and feasibility of incorporating the use of EMLA as immunization pain control in the MCHC setting.

**Objectives and Significance**

**Objectives**

1. To determine the effectiveness of EMLA in reducing pain for children during immunization procedures
2. To explore the feasibility of using EMLA as pain control measure under the MCHC setting

**PICO**

In order to formulate answerable research questions for this review paper, foreground questions were developed using the PICO framework (Santos, Pimenta, & Nobre, 2007). The four PICO components were described as below:

P (Patient) : Children below 6 years of age

I (Intervention) : Application of EMLA prior to immunization procedure

C (Comparison) : Current pain control practice in MCHC

O (Outcome) : Reduced pain response
Research Questions

1. When compared with current pain control practice, how effective is pre-vaccination EMLA application in reducing immunization pain among children below six years of age in the MCHC?

2. Is it feasible for the use of EMLA to be implemented under the MCHC setting?

Significance of Resolving Immunization-Induced Pain

Immunization pain has caused much distress for parents and nursing staff as they witnessed the children suffered (Ives & Melrose, 2010; Taddio et al., 2009a; Woodin et al., 1995). As demonstrated in a study conducted by Meyerhoff, Weniger and Jacobs (2001), parents were even willing to pay a considerable amount of money to reduce the immunization pain for their children. Reducing immunization pain by the use of EMLA could help to alleviate such stress so that parents will be more willing to adhere to the recommended immunization schedule. In this case, the immunization coverage in HK could be maintained and the integrity of the herd immunity could also be safeguarded.

Pain relief by the use of EMLA could also reduce the amount of stress experienced by the nursing staff as children would become less agitated during delivery of vaccines and safety of immunization administration could thus be
ensured. Apart from this, with effective pain management intervention available, parents are more willing to let their children receive multiple vaccinations in one single visit. As a result, with much time and administrative work being saved, the efficiency of immunization procedures could eventually be increased (Taddio et al., 2009a).
Chapter 2  Critical Appraisal

Search and Appraisal Strategies

Search Strategies

In order to identify relevant studies for critical appraisal, criteria for selecting the studies were set up, electronic databases for searching were identified and the keywords used to locate relevant studies were developed.

Inclusion criteria.

Participant characteristics. To be in accordance with the target group of MCHCs, healthy children below six years of age undergoing routine immunization will be included.

Intervention and control. Studies using pre-vaccination EMLA cream or EMLA patch to compare with the use of placebo will be included.

Outcome measures. Studies with duration of crying and the use of pain assessment tools as outcome measures to determine the level of pain will be included.

Exclusion criteria. Studies meeting the following criteria will be excluded from the critical appraisal:

1. Studies conducted in hospital setting

2. Studies conducted on pre-term infants
Electronic databases and keywords for searching. Three electronic databases, CINAHL Plus, Google Scholar and PubMed were used for searching relevant studies.

Four sets of keywords were used to locate eligible studies for critical appraisal:

(1) “children” or “infant” or “childhood”

(2) “eutectic mixture of local anesthetics” or “EMLA” or “lidocaine prilocaine”

(3) “immunization” or “vaccination” or “injection”

(4) “pain”

Manual searches by screening the reference lists of eligible studies were also carried out to identify additional studies for critical appraisal.

Data Extraction

For more thorough cross-study comparison, data from selected studies were extracted and tabulated in the table of evidence based on the format suggested by the Scottish Intercollegiate Guidelines Network (SIGN) (SIGN, 2011).

Appraisal Strategy

Selected studies were then critically appraised using appropriate appraisal tools. As all the studies included in this review paper were randomized controlled trials (RCTs), the SIGN Methodology Checklist for Controlled Trials was used to
assess the quality of the studies. The Checklist is a critical appraisal tool for conducting quality assessment on RCTs. It consists of two sections, with the first section reviewing the internal validity of the studies and determining the risk of bias in the methodologies used, while the second section of the checklist includes an overall assessment of the studies with ratings assigned according to their methodological qualities (SIGN, 2012). Levels of evidence ranging from 1++ to 4 were also allocated to the selected studies using the grading system recommended by SIGN to determine the strength of study results (SIGN, 2011) (Appendix B).

Results

Systematic Search Result

Searches for eligible studies were conducted between 5 May 2014 and 31 July 2014 using three electronic databases: CINAHL Plus, Google Scholar and PubMed. The initial keyword search using a combination of the four sets of keywords previous described generated a total of 949 citations. After removing duplicated studies from the search, 793 citations remained for further screening. Among the 793 citations identified, 778 of them were excluded after screening the titles and abstracts for eligibility. The remaining 15 studies were further assessed for eligibility by thorough reading of the full text, with 8 of them excluded due to non-adherence to eligibility criteria. Manual searches were also performed by
screening the reference lists of the eligible studies with no additional studies identified. As a result, a total of seven studies were selected for systematic review. A summary of the search strategy is included in Appendix C and the flow of systematic search is presented in Appendix D using the PRISMA Flow Diagram (Moher, Liberati, Tetzlaff, Altman, & the PRISMA Group, 2010).

**Data Extraction**

Data from the seven studies were then extracted and presented in a table of evidence. Data such as the study design, source of funding, subject characteristics, description of the intervention and comparison groups, outcome measures as well as the effect size were included in the table of evidence for easy comparison of findings between studies. The complete table of evidence for the seven studies is presented in Appendix E.

**Summary of Study Characteristics**

**Nature of study.** All the seven studies were written in English and were conducted using RCT design. Five of them were single-centered studies (Abuelkheir et al., 2014; Gupta et al., 2013; Halperin, McGrath, Smith, & Houston, 2000; Halperin, Halperin, McGrath, Smith, & Houston, 2002; Taddio, Nulman, Goldbach, Ipp, & Koren, 1994) while the remaining studies were conducted in multiple sites. The years of publication for the studies spread across
21 years, with the earliest published in 1993 and the most recent one in 2014.

In three of the studies, the EMLA patches, placebo and funding were supplied by the pharmaceutical company of EMLA (Cassidy et al., 2001; Halperin et al., 2000; Halperin et al., 2002) while studies conducted by Taddio et al. (1994) and Uhari (1993) also received partial support from it. The study conducted by Abuelkheir et al. (2014) was funded by the Research Group Project Grant from a local university, whereas the study by Gupta et al. (2013) did not receive any funding at all.

**Subject characteristics.** Healthy children undergoing routine immunization who fulfilled the inclusion and exclusion criteria were included in the studies and were randomly assigned to either the intervention group (IG) or the control group (CG). Sample sizes in the seven studies ranged from 90 to 216, involving a total of 1,043 subjects. The mean age of the subjects ranged from 0.8 month old to 4.7 years old.

In four of the studies, subjects were recruited from clinic settings (Abuelkheir et al., 2014; Gupta et al., 2013; Taddio et al., 1994; Uhari, 1993). The studies conducted by Halperin et al. (2000) and Halperin et al. (2002) recruited their subjects from an ambulatory setting, whereas the study of Cassidy et al. (2001) sampled its subjects in private office settings.
Characteristics of IG. For all studies, the intervention used was application of EMLA to the vaccination site prior to immunization procedure. Four of them used EMLA cream as intervention (Abuelkheir et al., 2014; Gupta et al., 2013; Taddio et al., 1994; Uhari, 1993), while in the remaining studies, EMLA was in the form of single unit dose patch. For the studies that used EMLA cream, the areas of cream application were all covered with occlusive dressing.

The dosage of EMLA varied among studies. Four studies used 1 gram of EMLA (Cassidy et al., 2001; Gupta et al., 2013; Halperin et al., 2000; Halperin et al., 2002), while Taddio et al. (1994) used 2.5 grams in their study and the study of Abuelkheir et al. (2014) used 0.5 gram for each vaccination site. The dosage of EMLA was not specified in the study of Uhari (1993). None of the studies provided justifications for the dosage used.

EMLA was removed no longer than 10 minutes before the immunization procedure in four studies (Cassidy et al., 2001; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994), while data for the time of removal were not available in the remaining studies. The mean duration for EMLA to stay on the immunization site before its removal ranged from 56.52 minutes to 83 minutes.

Characteristics of CG. In all studies, there was no difference between the IG and the CG except for the substitution of EMLA by the placebo. Six of the
studies reported using an inert oil that could not be visually differentiated from EMLA as the placebo, among which Abuelkheir et al. (2014) reported using the Bepanthen cream, Gupta et al. (2013) using the Vaseline cream and Taddio et al. (1994) using coconut oil as the placebo.

**Outcome measures.** Crying time and scoring from pain assessment tools were used as outcome indicators in the selected studies. Three of the studies solely relied on the pain assessment scores as outcome measures (Cassidy et al., 2001; Halperin et al., 2002; Uhari, 1993) while the remaining studies used crying time together with pain assessment scores to measure the outcome.

There were variations on the types of pain assessment tools used among the studies. Modified Behavioral Pain Scale (MBPS) was used in four of the studies (Abuelkheir et al., 2014; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994) while visual analogue scale (VAS) was used in three of the studies (Abuelkheir et al., 2014; Cassidy et al., 2001; Taddio et al., 1994). Cassidy et al. (2001) also used the Face Pain Scale (FPS), Children’s Hospital of Eastern Ontario Pain Scale (CHEOPS) and Child Facial Coding System (CFCS) to assess pain, whereas Gupta et al. (2013) used the Modified Neonatal Facial Coding Score (MFCS) and Uhari (1993) used a visual scale on ruler to indicate the degree of pain. Except the FPS was self-rated by children, the rest of the pain assessment
tools were rated by study personnel, nurses or parents.

**Effect size.** The effect sizes of the outcomes were presented as the difference between IG and CG with $p < 0.05$ indicating a significant difference.

**Quality Assessment**

The SIGN Methodology Checklist for Controlled Trials was used to assess the internal validity and overall quality of the studies (Appendix F).

**Appropriate and clearly focused question.** All the studies were able to address an appropriate and clearly focused question of evaluating the effectiveness of pre-vaccination EMLA application in reducing pain among children during immunization procedures.

**Randomization.** Randomization methods were mentioned explicitly in five of the studies, in which computer-generated lists of random numbers were used for subject allocation (Abuelkheir et al., 2014; Gupta et al., 2013; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994).

**Allocation concealment.** Methods of allocation concealment were mentioned in four of the studies. Two studies used computerized allocation systems for concealment (Abuelkheir et al., 2014; Halperin et al., 2002), while Gupta et al. (2013) used serially-numbered opaque and sealed envelopes and Halperin et al. (2000) used centralized allocation by a study statistician.
uninvolved with the study to achieve allocation concealment.

**Blinding.** Blinding to the intervention under study could be achieved in all the studies. All studies were double-blinded with the type of intervention given unknown to both the study personnel and subjects.

**Comparable intervention and comparison groups.** In all studies, IGs and CGs were similar in characteristics before the implementation of the intervention.

**Treatment is the only difference.** In all studies, IGs and CGs were treated equally, with the only difference being the use of EMLA in the IGs and the use of placebo in the CGs.

**Standard, valid and reliable outcome measures.** Outcome measures were clearly described in all studies. Except for the study conducted by Uhari (1993), all studies used standard, validated and reliable assessment tools to measure the outcomes. In Uhari’s study, the assessment tool used was not validated and the outcomes were measured based on the nurses’ and parents’ subjective judgment.

**Drop-out rate.** None of the subjects withdrawn in two of the studies (Abuelkheir et al., 2014; Gupta et al., 2013). For the remaining studies, the drop-out rates ranged from 1.3% to 12.5%.

**Intention-to-treat analysis (ITT).** For studies with drop-outs, ITT were used in the studies conducted by Cassidy et al. (2001) and Uhari (1993). In the
remaining studies, modified ITT were used with explanations for excluding the subjects from the analyses clearly stated in the text (Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994).

**Comparable results from all sites.** The studies of Cassidy et al. (2001) and Uhari (1993) were conducted in multiple sites without any site-specific data given. The remaining studies were all conducted in single sites.

**Overall assessment.** The overall effects of the studies were due to the intervention alone with all results applicable to the target group of this review paper. Risks of bias were kept to the minimal in three of the studies (Abuelkheir et al., 2014; Gupta et al., 2013; Halperin et al., 2002), with the remaining studies showing acceptable reduction of bias.

Four studies included sample size calculations to determine their statistical powers (Gupta et al., 2013; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994). Except that the sample size was not met by the CG in the study of Taddio et al. (1994), all the calculated sample sizes were adequately met by both arms in the remaining studies.

Level of evidence was assigned to each of the studies according to the criteria listed in Appendix B. As a result, two studies were rated 1++ (Abuelkheir et al., 2014; Gupta et al., 2013), three studies were rated 1+ (Halperin et al., 2000;
Summary and Synthesis

Summary of Study Results

All studies evaluated the effectiveness of pre-vaccination EMLA application in reducing pain among children during routine immunization, with all of them affirming its effectiveness as immunization pain relief by demonstrating either a statistically significant reduction in total crying time or a significantly lower pain assessment score in the IGs when compared with the CGs.

Diversity of Results

Duration of crying. Three studies demonstrated that pre-vaccination EMLA application could lead to statistically significant reduction of total crying time in the IGs with effect sizes ranging from -0.12 to -0.43 ($p < 0.05$) (Abuelkheir et al., 2014; Gupta et al., 2013; Taddio et al., 1994).

Although the study conducted by Halperin et al. (2000) also reported a shorter duration of crying in the IG, its effect size was statistically insignificant. This inconsistent result might be due to its relatively short observation time during the data collection process. In their study, Halperin et al. (2000) recorded baby’s crying for up to 2 minutes only while the remaining studies collected data on
baby’s crying behavior for at least 3 minutes or above. Since it may take time for children to manifest changes in pain sensation through crying, an observation time of 2 minutes might be too short to capture the change and the genuine effect of EMLA might not be adequately detected in Halperin et al.’s study.

**MBPS scores.** MBPS is an assessment tool for measurement of behavioral pain. With an overall score ranging from 0 to 10, it examines the degree of pain by assigning ratings to an individual’s facial expression, crying and body movement (Taddio, Nulman, Koren, Stevens, & Koren, 1995).

Among the four studies which used MBPS as outcome measures, Abuelkheir et al. (2014) and Taddio et al. (1994) found that the post-vaccination MBPS scores were significantly lower in the IGs (effect sizes from -0.13 to -0.19) with significantly less deviation from the baseline scores (effect sizes from -0.41 to -0.5) when compared to the CGs, suggesting children who received EMLA were experiencing less pain during the immunization procedures.

Although Halperin et al. (2000) also reported a lower MBPS score with less deviation from the baseline in the IG, the results were not statistically significant. This discrepancy may be due to the relatively small sample size (82 in IG and 83 in CG) recruited, such that results derived were too small-scale to be statistically significant. On the other hand, although the sample size in the study of Taddio et
al. (1994) was the smallest among the four studies, the mean duration for EMLA application was the longest (83 minutes), which enabled EMLA to exhibit a statistically significant effect in their study.

The study conducted by Halperin et al. (2002) also reported a lower MBPS score with less deviation from baseline in the IGs, but the results were statistically insignificant for the three subgroups with children below six months of age, whereas result for the six month old subgroup was statistically significant. The small sample size ranging from 22 to 28 in these subgroups may again be accounted for the inconsistent results within the same study.

**VAS scores.** VAS is a horizontal 10 centimeters line depicting the degree of pain from “no pain” to “worst possible pain”. It is commonly used as an observational rating scale for evaluating the degree of pain in children (Taddio et al., 2009b).

Consistent results were found in the three studies using VAS as outcome measure. All of them reported significantly lower VAS scores in their IGs, with the IGs having 32% to 46% reduction in the post-vaccination VAS scores when compared with the CGs. In the studies conducted by Abuelkheir et al. (2014) and Taddio et al. (1994), the reduction in VAS scores also correlated to that of the MBPS scores, further affirming the pain-relieving effect of EMLA.
**Scores in other pain assessment tools.** For studies using pain assessment tools other than MBPS and VAS, all of them reported a statistically significant reduction in pain scores for the IGs when compared with the CGs, with effect sizes ranging from -0.2 to -0.53 depending on the types of assessment tools used, except for Cassidy et al.’s study.

In the study conducted by Cassidy et al. (2001), use of CHEOPS indicated a statistically significant reduction in pain scores in the IG while the CFCS demonstrated statistically insignificant group differences between the IG and CG immediately after immunization. This contradicting result may be due to the differences in the scoring criteria used in the two instruments. CHEOPS assigned ratings by examining 6 categories of behavior ranging from crying to leg movements, whereas CFCS rated the degree of pain based on thirteen facial actions ranging from brow lowering to horizontal mouth stretching (Cassidy et al., 2001). Since changes in children’s facial expressions might not be distinctive enough to be detectable by the observer, observing changes in facial actions alone using CFCS might fail to capture important indicators of pain leading to insignificant results, whereas CHEOPS could reflect the genuine effect of EMLA by examining a broader range of behaviors other than facial expressions.
Data Synthesis

Methodologies of pre-vaccination EMLA application for the seven studies were synthesized below to serve as a basis for the formulation of an EBP guideline in the MCHC.

**Target group.** Evidence from the studies demonstrated that pre-vaccination EMLA application could significantly reduce pain and crying during routine immunization among children below six years of age.

**Dosage and formulation.** EMLA with a dosage of 1 gram, 2.5 grams or 0.5 gram for each vaccination site all showed promising effect in reducing pain and crying among children during immunization procedures, with both cream and single unit dose patch demonstrating equal effectiveness. Since application of EMLA in cream form required an additional procedure of covering the area with an occlusive dressing, the use of single unit dose patch appeared to be the better option when implementing the innovation under the MCHC setting as the application procedure is simplified to economize the time consumed (Nilsson et al., 1994).

**Duration.** Evidence suggested that application of EMLA on vaccination site for at least 60 minutes could reduce pain and crying in children undergoing immunization. Removal of EMLA patch no longer than 10 minutes before
vaccination could also promote its pain reduction effect.

**Implication for Practice**

Overall, application of EMLA at least 60 minutes before immunization could reduce pain and crying among children below six years of age. As demonstrated by Abuelkheir et al. (2014), Gupta et al. (2013) and Uhari (1993), pre-vaccination EMLA application could be implemented in immunization clinic settings with promising results. It is recommended that the use of EMLA could be incorporated into the MCHC setting and an EBP guideline for effective pain management should be formulated to facilitate translation of knowledge into practice, such that the deleterious effects of pain could be alleviated, adherence to immunization schedule could be maintained and health of the community could be safeguarded.
Chapter 3  Implementation Potential

After affirming the need for immunization pain control in Chapter 1 and critically appraising the effectiveness of the innovation in reducing immunization-induced pain in Chapter 2, implementation potential of the innovation will be assessed in this chapter. Using the criteria developed by Polit and Beck (2012) as basis for evaluation, transferability and feasibility of the innovation will be examined, cost-benefit analysis will also be conducted to determine whether pre-vaccination EMLA application could be a practicable option for immunization pain relief among children in the MCHCs.

Target Setting

Currently, there are 31 MCHCs in HK providing integrated services of developmental surveillance, parenting education and immunization to HK children (FHS, 2014b). As immunization is one of the main service scopes in the MCHCs, the innovation could be implemented in one of the MCHCs in the HK region to demonstrate its practicability before generalizing it to other MCHCs.

Target Population

Under current immunization programme, children at or below eighteen months of age are advised to visit MCHCs for routine immunizations while children with incomplete immunization could also return to the MCHCs before
six years old for catch-up vaccinations. Hence children below six years of age visiting the designated MCHC for immunizations will be included as the target group of the innovation.

Transferability of Findings

Incorporation of Innovation into the Proposed Setting

MCHCs are primary healthcare centres providing immunization programmes for children in HK (FHS, 2014a). Corresponding to the service scope of MCHCs, the review studies selected for critical appraisal were conducted in well-baby immunization clinics (Gupta et al., 2013; Uhari, 1993), pediatric outpatient clinics (Abuelkheir et al., 2014; Taddio et al., 1994), ambulatory clinics (Halperin et al., 2000; Halperin et al., 2002), as well as in private office settings (Cassidy et al., 2001). With all of them sharing the same characteristic with MCHCs in providing immunization service to children at the community level, the innovation could fit into the MCHC setting and would be able to demonstrate its efficacy accordingly.

Similarity of Target Populations

Target populations in the review studies ranged from infants below three months of age (Gupta et al., 2013) to children aged between four to six years old (Cassidy et al., 2001). Since the research populations could fully cover the age range of the target population in the designated MCHC, the innovation is highly
transferable to be implemented in the MCHC setting.

Philosophy of Care

While the principle underlying the innovation is to minimize immunization-induced pain and to alleviate its deleterious effects on children, the philosophy of care in MCHCs is to promote the health of HK children by “developing evidence-based strategies and programmes to meet the changing needs of the communities” (FHS, 2013). With both seeking to promote the well-being of children through the use of EBP, the underlying principle of the innovation is clearly in line with the prevailing philosophy of MCHCs and is therefore appropriate to be implemented in the designated MCHC.

Benefit Sufficient Number of Clients

According to the statistics from Child Health Service System (2014), annually there are approximately 16,500 children attending the designated MCHC for child health services, among which 90% of them would receive immunizations in the MCHC. It is expected that each month around 1,235 children visiting the MCHC for immunization could be benefited from the innovation. With its capability of serving large number of clients within a short period of time, transferability of the innovation could further be justified.
Time Frame for Implementation

It is expected that the innovation, from its preparation, implementation to evaluation, will take approximately twelve months to complete.

At first, an innovation committee consists of representatives from medical, nursing and pharmacy disciplines will be set up for proposal preparation and guideline development over a one-month period. It will take another three months for the administrative level of DH to grant approval for the proposal. After that, centre-wide staff training and preparation of equipment will be launched afterwards and is expected to take two months to complete. Pilot test will also be carried out in the designated MCHC over a one-month period for formative evaluation and refinement of the guideline, followed by formal implementation of the innovation in the designated MCHC over a two-month period. Finally, another three months will be spent for data analysis and summative evaluation.

As the innovation does not require much time for its implementation and evaluation, it is appropriate to be implemented in the MCHC. A Gantt chart is attached in Appendix G for better presentation of the implementation time frame.

With research findings sharing similar setting and population characteristics, and with the innovation upholding similar philosophy of care as well as benefiting sufficient number of clients within a short range of time, the innovation could be
highly transferable to be incorporated into the MCHC setting.

**Feasibility**

**Organizational Climate & Administrative Support**

As stated in the mission statement of FHS, the organization and the MCHCs directly under its governance always advocate for the use of EBP (FHS, 2013). Over the past five years, MCHCs have demonstrated their determination in performing EBP by promoting hands-off technique during breastfeeding coaching as well as eliminating the step of aspiration during delivery of vaccines.

Apart from this, the administrative level of FHS is also keen on creating an atmosphere conducive to innovations in the MCHCs by organizing the “Sharing of Good Practice Scheme” on an annual basis to encourage nursing staffs to exchange innovative ways of service delivery between MCHCs. Peer review meetings were also conducted in the MCHCs on a monthly basis such that nurses could have an opportunity to make evidence-based recommendations in improving the quality of care in MCHCs.

With such a supportive environment advocating for the use of EBP in the MCHCs, it is anticipated that the innovation could receive much support from the organization if the innovation could be communicated to the administrative level effectively during regular senior staff meetings within the FHS unit.
Interference to Current Function

As nurses at the interview stations will be required to apply the EMLA patch onto the injection sites during routine interviews with clients, the innovation is expected to cause certain degree of interference to current service provision in the designated MCHC. The duration of routine interview may also be slightly prolonged as additional time will be required for nurses to explain the purpose of the innovation to parents and to seek for their consent, which may eventually affect the efficiency of service delivery in the MCHC.

Despite this, these problems could be tackled by providing education leaflets stating the purpose and mechanism of EMLA to clients during routine interviews so that efficiency of interview could be improved. Moreover, the long-term benefits of the innovation such as improving adherence to routine immunization schedule to prevent repeated visits and the resultant decrease in caseload could also be emphasized so that consensus on implementing the innovation could be reached among nursing staff.

Consensus & Friction among Staff

While the innovation is expected to be well-accepted by the medical officers and junior nurses whose university training involves EBP as the major emphasis in their curriculums, resistance may occur among senior nurses on the other hand.
Having been trained and worked in the clinical setting throughout their career, some senior nurses in the MCHC may have developed a conventional way of nursing care delivery based on the experience they have accumulated over the years. Being less familiar with the merits of EBP and with many of them already accustomed to the current practice, senior nurses may be reluctant to implement the innovation. Besides, the extra step of EMLA patch application may increase the workload of interviewing nurses to some extent, thus opposition from nurses at the interview stations may also occur. As a result, consensus on implementing the innovation may be difficult to arrive.

The above obstacles could be tackled by strengthening the EBP basis of nursing staff in the MCHC. Research evidence on the undesirable effects of immunization-induced pain and the efficacy of pre-vaccination EMLA application should be communicated to nursing staff during the monthly peer review meetings to promote staff’s acceptance to the innovation so as to liaise for their support and cooperation during the implementation process.

**Availability of Skills**

As the innovation only requires simple skills of applying the EMLA patch onto the injection site, a one-hour training workshop demonstrating the use of EMLA patch could be arranged in the designated MCHC for nursing staff to
acquire such skills. Members of the innovation committee will also be available in the designated MCHC to provide skill support when implementing the innovation. Moreover, guidelines with photos demonstrating the application method could also be made available at the interview stations for reference by interviewing nurses to ensure the feasibility of the innovation.

**Availability of Equipment**

EMLA patches, education leaflets and illustrated guidelines are the only equipment needed. EMLA patches could be made available from the pharmacy and the education leaflets and guidelines could be prepared by the Health Information Section (HIS) of FHS. By keeping equipment requirement to the minimum, implementation of the innovation is highly practicable in the MCHC.

**Availability of Evaluation Tools**

Two sets of pain assessment tools will be required to collect data on pain levels during the evaluation process. As the pain assessment tools could be prepared and supplied by HIS, the feasibility of the innovation remains high.

With organizational support, equipment and evaluation tools to be readily available, it is highly feasible for the innovation to be implemented in the designated MCHC if consensus among nurses could be reached and interference to daily function could be kept to a minimum.
Potential Risk of the Innovation

With six of the review studies reported mild skin pallor at the site of EMLA application, the innovation is associated with slight risk of minor skin reaction (Abuelkheir et al., 2014; Cassidy et al., 2001; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994; Uhari, 1993). However, the side effects were only transient as most of them could resolve soon after removal of EMLA.

Potential Benefits of the Innovation

With the proposed innovation, children could become less agitated during the immunization process. Immunization safety could thus be ensured and the risks of immunization failure related to slipping out of needles could be reduced, which in turn could bring about the non-material benefits of reduced stress among immunization nurses as well as increasing staff morale among nursing staffs.

The innovation could also help to alleviate the stress experienced by parents such that they would be more compliant in adhering to the recommended immunization schedule. As parents are more willing to let their children receive multiple vaccines in a single visit instead of spreading them into separate visits, the long-term benefits of reduction in caseload and reduction in the overall workload of staff could be achieved in the MCHC.
**Risks of Maintaining Current Practice**

Currently, no pain management guideline is available in MCHCs to minimize immunization pain for children. If absence of pain relief remains to be the current practice, immunization-induced pain would continue to exhibit its harmful effects on children and lead to development of needle phobia among children as well as avoidance of medical procedures in adulthood, resulting in greater risks of delayed diagnosis and treatment in future (Hamilton, 1995; Pate et al., 1996).

Apart from this, non-adherence to immunization schedule associated with absence of pain control may also put the health of the community at risk as it may affect the immunization coverage and threaten the integrity of herd immunity in HK, resulting in resurgence of communicable diseases in the community (Taddio et al., 2009a).

**Material Costs of the Innovation**

Supply of EMLA patches will be the major source of material cost for the innovation. Other expenditures include printing of education leaflets, guidelines and evaluation forms.

With the retail price of EMLA patch being approximately Hong Kong dollar (HKD) $35 per patch, the total material costs of the innovation will be HKD $36,818 for every 1,000 clients (Pharmacy Checker, 2014) (Appendix H).


**Non-material Costs of the Innovation**

Non-material costs mainly derived from the time consumed on staff training as well as from client education and EMLA patch application during the routine interviews. Apart from attending the one-hour training workshop, nursing staff are expected to spend an additional five minutes on client education and EMLA patch application, while an additional three minutes will also be required for evaluation of the innovation.

With the average salary for registered nurse in DH to be approximately HKD $177 per hour, the total non-material cost of the innovation will be HKD $25,724 for every 1,000 clients (Civil Service Bureau, 2013) (Appendix H).

**Costs of Not Implementing the Innovation**

By observation, around 35% of parents prefer to spread their children’s immunizations into separate visits to minimize immunization pain, putting great burden to the MCHC for the additional manpower and time it consumed in covering up the increased caseload. With each repeated visits, an extra 20 minutes will be spent for conducting routine interview and an extra 5 minutes will be required to complete the immunization procedure. It is estimated that every 1,000 children visiting the MCHC would result in 350 extra visits, such that a non-material cost of HKD $25,812.5 will be generated (Appendix I).
When presenting in monetary terms, for every 1,000 clients visiting the MCHC, a total of HKD $62,542 will be spent in carrying out the innovation to avoid 350 repeated visits costing HKD $25,812.5 in expenditure, resulting in a net cost of HKD $36,729.5 for implementing the innovation in the designated MCHC. Although the innovation may result in a slight increase in the total expenditure of immunization programme, it is considered worthwhile to be implemented in the MCHC for the long-term benefits it could bring about for the children and the community in HK.
Chapter 4  Developing an EBP Guideline

In the guideline, the title as well as the aim and objectives are clearly stated to facilitate better communication among nursing staff. Intended users and target group are also clearly defined to allow proper utilization of the guideline. Recommendations are also clearly listed to guide pain control measures in the MCHC.

Recommendations made are based on the seven review studies using the Levels of Evidence and the Grades of Recommendations suggested by SIGN, with Levels of Evidence denoting the quality of the evidence obtained while Grades of Recommendations is used to determine the strength of supporting evidence in which the recommendations are based on (SIGN, 2011). The criteria for assigning the Levels of Evidence and Grades of Recommendations are listed in Appendix B and Appendix J respectively.

As a result, a total of six recommendations are included in the EBP guideline.

The complete version of the EBP guideline is available in Appendix K.
Chapter 5  Implementation Plan

In previous chapters, implementation potential of pre-vaccination EMLA as immunization pain relief in the MCHC has been affirmed and an EBP guideline on immunization pain control has also been developed to guide the practice change. In this chapter, a communication plan will be formulated to initiate, to guide and to sustain the change in the designated MCHC. A pilot study plan will also be established to test the feasibility of the innovation in the local setting.

Communication Plan

Identifying Stakeholders

Stakeholders are individuals who can affect the practice change (Agency for Healthcare Research and Quality, 2014). They must be identified and addressed to as their support could facilitate practice change in the local setting. Administrative level of DH, the medical officer (MO) in-charge and nursing officer (NO) in-charge of the designated MCHC, frontline nurses, children and their parents visiting the MCHC, as well as the pharmacy unit are the key stakeholders for the innovation.

Support from the administrative level is crucial as it takes a decisive role in granting approval and allocating funding for the innovation. Staffs in the designated MCHC are also important stakeholders as the MO and NO in-charge
are leaders of the MCHC who supervise the overall operation of the innovation while frontline nurses are the actual users of the EBP guideline. Children and their parents are major stakeholders as they are the actual recipients of the innovation, while the pharmacy unit is also an important stakeholder as it oversees the supply of EMLA patch whose availability directly affects the success of the EBP guideline.

Initiating Change

Communication flow will be in an initial “bottom-up” approach to aggregate frontline support, followed by the adoption of a “top-down” model during the implementation phase to ensure better control and adherence (Bigda-Peyton, 2010).

As the first step, proposer of the innovation, that is the author of this paper, will disclose the undesirable effects of immunization-induced pain to clinic staffs during informal discussions to raise their awareness on the need for pain control. Evidence affirming the effectiveness of EMLA patch in reducing pain will then be shared during peer review meetings to mobilize staff support.

An innovation committee composed of two register nurses (RNs) including the proposer of the innovation, MO and NO in-charge of the MCHC, as well as the Chief Pharmacist from the pharmacy unit will then be set up to lead the
change. A proposal detailing the need for pain control with an evidence-based report affirming the effectiveness of the innovation and a detailed budget plan for its implementation will be drawn up by the RNs in the committee over a one-month period. The proposal will then be presented to members within the committee to seek for consensus and will be proposed to the administrative level during senior staff meetings by the MO and NO in-charge of the committee to solicit support and approval from the higher level. Granting of approval is expected to take three months and the decision to implement the innovation will then be disseminated to clinic staffs during weekly clinic meeting by the innovation committee.

**Guiding Change**

Implementation of innovation will be guided by the innovation committee. Evidence affirming the effectiveness of the innovation should continue to be shared among clinic staffs during peer review meetings to strengthen their EBP basis. Long-term benefits of the innovation in decreasing the caseload should also be stressed to mitigate resistance from nurses in changing their current practice. A one-hour training workshop including thorough explanation on the EBP guideline and skill demonstration on EMLA patch application will also be arranged by RNs from the innovation committee to ensure competence of nurses in delivering the
innovation. Illustrated guidelines will also be made available at the interview stations to serve as quick reference for nurses.

Posters introducing the launch of the innovation will be posted in the waiting hall and education leaflets stating the purpose of EMLA patch will also be distributed to parents so that they could be made well-informed of the practice change.

Decision to implement the innovation will also be communicated to the pharmacy unit by the Chief Pharmacist from the innovation committee so that stock-keeping of EMLA patch could be carried out efficiently. It is expected that staff training and preparation of equipment could be achieved within a two-month period.

**Sustaining Change**

Throughout the implementation period, close communication between the NO in-charge and the Chief Pharmacist will be maintained to ensure availability of EMLA patch stock. To ensure proper delivery of the innovation, RNs from the innovation committee will be readily available in providing support to their colleagues. Nursing audits will also be carried out during first month of implementation by the NO in-charge to ensure nurses’ adherence to the EBP guideline by assessing their skills in delivering the innovation using a
standardized checklist. Feedbacks from nurses will be collected and reviewed during clinic meetings so that modifications on the EBP guideline could be made to enhance its compatibility with clinic routine. A detailed timeline on the communication plan is attached in Appendix L for quick reference.

Pilot Study Plan

Pilot study is trial-running a project in a smaller scale so that potential barriers could be identified and modifications could be made before its full-scale implementation (Hockenberry, Brown, & Melnyk, 2011). After seeking ethical approval from the administrative level, it will be conducted in the designated MCHC to test the feasibility of the innovation and to assess the capability of the evaluation instruments in measuring the outcomes.

Participant Criteria

To correspond with the EBP guideline, participants of the pilot study should be children below six years of age visiting the MCHC for immunization. Due to its preliminary nature, only 30 participants will be recruited after obtaining verbal consent from their parents and the whole study is expected to take two service sessions to complete.

Materials Required

EMLA patch will be made readily available by the pharmacy unit before the
launch of study. Education leaflets and illustrated guidelines will also be prepared so that their usability could be evaluated. For outcome measurements, two sets of pain assessment tools together with a data collection form for collecting demographic data will be used. A questionnaire will be available for nurses to collect their comments on the overall logistics of the implementation process and their self-reflected competence in delivering the innovation. Another set of questionnaire will be provided to parents, or the companion of the participant in case parents were absent, to collect their views on the performance of clinic staff, the clarity of education leaflets and to assess their overall satisfaction level on the innovation. Details of the evaluation tools mentioned above will be discussed in Chapter 6.

**Process**

Before the launch of pilot study, training workshop will be arranged for nurses and materials required will be prepared by the innovation committee over a two-month period. The study will then be conducted in two service sessions in which nurses and parents will be asked to complete a questionnaire to express their views on the innovation. Feedbacks collected will be reviewed in weekly clinic meetings to determine if modification is required. Data analysis will be carried out at the end of the study and is expected to take three weeks to complete.
The formative evaluation report will then be sent to the administrative level to justify the feasibility of the innovation. Results of the pilot study will also be disseminated to clinic staffs to acknowledge their contributions and to solicit further support for the EBP guideline.
Chapter 6 Evaluation Plan

In this chapter, evaluation plan will be set up to assess the effectiveness of the innovation. Outcome measures, timing to take measurements and sample size will be specified to guide the evaluation process, while method for data analysis and the basis for evaluation will also be stipulated to determine the efficacy of the innovation in the designated MCHC.

Outcome Identification

Client Outcomes

Reduction in pain response will be evaluated to assess the clinical benefits of the innovation. It could be achieved by assigning pain scores to participants using MBPS. MBPS is a validated pain assessment tool that examines the severity of pain by assigning ratings to an individual’s facial expression, crying and body movements with an overall score ranging from 0 to 10 (Taddio et al., 1995) (Appendix M). MBPS score will be collected by an assessor, who will be one of the RNs from the innovation committee, prior to immunization as baseline and within 15 seconds after the vaccination to detect deviation from baseline. The mean MBPS score difference will be compared with those from the review studies in Chapter 2 and the reduction in MBPS score deviation will be used as the primary outcome of the innovation, with a small deviation from baseline.
indicating a reduction in pain response.

Perceived level of pain will also be evaluated as the secondary outcome using VAS. VAS is a validated observational rating scale for assessing degree of pain using a ten-centimeter horizontal line with 0 indicating “no pain” whereas 10 representing “worst possible pain” (Taddio et al., 2009b) (Appendix N). Rating will be assigned to participants immediately after vaccination by the assessor and will be compared with those obtained from existing literature to detect reduction in the mean VAS rating.

To facilitate the evaluation process, both MBPS scores and VAS rating will be recorded on a data collection form (Appendix O).

**Healthcare Provider Outcomes**

Compliance level of nurses will be evaluated by satisfaction questionnaire. A questionnaire consists of 6 statements alongside a five-level Likert scale ranging from “strongly disagree” to “strongly agree” will be prepared for nurses to collect data on their satisfaction level and self-reflected competence in adopting the EBP guideline (Appendix P).

Another set of questionnaire with similar format will be available for parents to evaluate their overall satisfaction level towards the innovation (Appendix Q).
System Outcome

To measure system effectiveness, level of utilization will be assessed. Total number of eligible clients and the actual number of participants receiving the innovation will be recorded so that an overall utilization rate could be generated at the end of the implementation period. Parents’ satisfaction level collected from the questionnaire in Appendix Q will also be evaluated as another indicator for system effectiveness.

Timing and Frequency of Measurement

For client outcomes, MBPS scores will be collected at two time points whereas VAS rating will be assigned once only. An initial MBPS score will be given to participants immediately before the immunization. Since manifestations of pain occur instantly after immunization and vary within seconds, second set of MBPS score and the VAS rating will be generated within 15 seconds after the immunization to ensure accuracy of ratings (Cassidy et al., 2001; Taddio et al., 1994).

For healthcare provider outcomes, data on parents’ overall satisfaction level could be collected after the immunization procedure while nurses will be asked to complete the questionnaire at the end of the implementation period.

For system outcome, total number of eligible clients and the actual number
of participants receiving the innovation will be recorded daily and the overall utilization rate will be calculated at the end of the implementation period.

**Nature and Number of Clients**

**Eligibility Criteria**

To correspond with the target groups in the review studies, the EBP guideline as well as the pilot study, children aged below six years of age visiting the MCHC for vaccination will be recruited as participants. Interviewing nurses will be responsible to screen for their eligibility and obtain verbal consent from parents before delivering the innovation.

**Sample Size**

The primary outcome measure will be used as basis for sample size estimation. From the review studies, MBPS score deviation reduced by 26% to 50% when pre-vaccination EMLA was applied (Abuelkheir et al., 2014; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994). It is therefore considered that an effect size of 0.26 could prove the effectiveness of the innovation.

Assuming an effect size of 0.26 with a standard deviation of 1.5, given the power to be 0.8 and the confidence level to be 0.05, the estimated sample size will be 263 as calculated from an online statistical application using the one sample t-test method (Lenth, 2009). Considering the issues of dropouts and refusals, the
resultant sample size becomes 300 after a 10% attrition rate is taken into account.

As eligible clients are readily available, participants will be recruited using convenient sampling and recruitment is expected to take two months to complete.

**Data Analysis**

The evaluation objective is to identify a reduction in post-vaccination pain response in children receiving the innovation. Data collected will be analyzed using the Statistical Package for Social Science (version 22) for Windows.

For client outcomes, statistical analysis will be carried out using one-sample t test to detect differences in MBPS scores before and after the immunization. Mean MBPS score deviation as well as mean VAS rating will also be generated and compared to existing data in the review studies to identify any reduction in pain levels among the participants.

For healthcare provider outcomes and system outcome, satisfaction level of nurses and parents as well as the utilization rate of the innovation will be calculated and summarized using descriptive statistics (Trochim, 2006).

**Basis for Evaluation**

Concerning client outcomes, past literature revealed that pre-vaccination EMLA application could reduce post-vaccination MBPS score deviation by 26% to 50%. Studies from Abuelkheir et al. (2014), Cassidy et al. (2011) and Taddio et
al. (1994) also confirmed a 32% to 46% decrease in VAS rating after EMLA application. With reference from these studies and taking a slightly conservative estimation, it is considered that a 30% reduction in the mean MBPS score deviation with a 35% decrease in the VAS rating could prove the effectiveness of the innovation in the local setting.

For healthcare provider outcomes, the innovation is considered effective if over 70% of nurses and parents reported “strongly agree” or “agree” for all items in the satisfaction questionnaires. For system outcome, an overall utilization rate of 80% will be sufficient to prove the effectiveness of the innovation in the local setting.

**Conclusion**

Existing literature has affirmed the need for immunization pain control while evidence from the review studies also revealed the effectiveness of pre-vaccination EMLA application in minimizing pain response among vaccinated children. To promote the innovation in the MCHC, an EBP guideline must be formulated to guide the practice change, a communication plan should be set up to engage support from stakeholders, a pilot test should be carried out to test its feasibility and an evaluation plan with outcome measures clearly stated should be set up to assess its effectiveness in the local setting. It is expected that
pre-vaccination EMLA patch application could reduce the pain response in vaccinated children and is worthwhile to be generalized to other MCHCs in DH.
## Appendices

### Appendix A – Hong Kong Childhood Immunization Programme

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>Immunization to be Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn</td>
<td>BCG&lt;sup&gt;i&lt;/sup&gt; Vaccine</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B Vaccine - First dose</td>
</tr>
<tr>
<td>1 month</td>
<td>Hepatitis B Vaccine - Second dose</td>
</tr>
<tr>
<td>2 months</td>
<td>DTaP-IPV&lt;sup&gt;ii&lt;/sup&gt; Vaccine - First Dose</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal Vaccine - First Dose</td>
</tr>
<tr>
<td>4 months</td>
<td>DTaP-IPV Vaccine - Second Dose</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal Vaccine - Second Dose</td>
</tr>
<tr>
<td>6 months</td>
<td>DTaP-IPV Vaccine - Third Dose</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal Vaccine - Third Dose</td>
</tr>
<tr>
<td></td>
<td>BCG = Bacille Calmette-Guérin</td>
</tr>
<tr>
<td>1 year</td>
<td>MMR&lt;sup&gt;iii&lt;/sup&gt; Vaccine - First Dose</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal Vaccine - Booster Dose</td>
</tr>
<tr>
<td></td>
<td>Varicella Vaccine - First Dose</td>
</tr>
<tr>
<td>18 months</td>
<td>DTaP-IPV Vaccine - Booster Dose</td>
</tr>
</tbody>
</table>

<sup>i</sup> BCG = Bacille Calmette-Guérin  
<sup>ii</sup> DTaP-IPV = Diphtheria, Tetanus, acellular Pertussis and Inactivated Poliovirus  
<sup>iii</sup> MMR = Measles, Mumps & Rubella  

(FHS, 2014a)
### Appendix B – Levels of Evidence

<table>
<thead>
<tr>
<th>Levels of Evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort studies</td>
</tr>
<tr>
<td></td>
<td>High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

(SIGN, 2011)
### Appendix C – Search Strategy and Result

<table>
<thead>
<tr>
<th>Performing Keyword Search</th>
<th>Electronic Databases</th>
<th>Manual Search</th>
<th>Total</th>
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<tr>
<td>Date Range for Performing Search</td>
<td>From 5 May 2014 to 31 July 2014</td>
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<tr>
<td>Performing Keyword Search</td>
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<tr>
<td>(1) “children” or “infant” or “childhood”</td>
<td>362,224</td>
<td>2,359,741</td>
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<tr>
<td>(2) “eutectic mixture of local anesthetics” or “EMLA” or “lidocaine and prilocaine”</td>
<td>311</td>
<td>1,777</td>
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</tr>
<tr>
<td>(3) “immunization” or “vaccination” or “injection”</td>
<td>42,746</td>
<td>814,069</td>
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<tr>
<td>(4) “pain”</td>
<td>161,972</td>
<td>580,585</td>
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<tr>
<td>(5) Combination of (1) and (2) and (3) and (4)</td>
<td>3</td>
<td>90</td>
<td>949</td>
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<td>After Removing Duplicated Studies</td>
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<td>15</td>
<td>793</td>
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<td>After Screening for Titles and Abstracts</td>
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<td>9</td>
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<td>After Reading Full Text</td>
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<tr>
<td>After Screening Reference Lists of Eligible Studies</td>
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<td>0</td>
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<tr>
<td><strong>Grand Total</strong></td>
<td><strong>7</strong></td>
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</tr>
</tbody>
</table>
Appendix D – PRISMA Flow Diagram Depicting Flow of Systematic Search

Records identified through database searching (n = 949)

Additional records identified through other sources (n = 0)

Records after duplicates removed (n = 793)

Records screened (n = 793)

Records excluded (n = 778)

Full-text articles assessed for eligibility (n = 15)

Full-text articles excluded (n = 8) due to not adhering to eligibility criteria

Studies included in qualitative synthesis (n = 7)

(Moher et al., 2010)
## Appendix E – Table of Evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study Design &amp; Evidence Level</th>
<th>Source of Funding</th>
<th>Subject Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome Measures</th>
<th>Effect Size (IG - CG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuelkheir et al., 2014</td>
<td>Design Double-blind RCT Evidence Level 1++</td>
<td>Research Group Project Grant by University in Saudi Arabia</td>
<td>Children attending well-baby pediatric clinic for routine vaccination (Total no. = 216)</td>
<td>EMLA cream to vaccination site Composition 0.5g of EMLA cream for each site Adhesion Method Covered with occlusive dressing Removal Time Wiped off before injection Mean Duration for Application 56.52 min n = 107</td>
<td>Placebo cream to vaccination site Composition 0.5g of inert oil (Bepanthen cream) visually identical to EMLA for each site Adhesion Method Covered with occlusive dressing Removal Time Wiped off before injection Mean Duration for Application 57.64 min n = 109</td>
<td>1. MBPS (range 0-10) to measure: (a) degree of pain within 10 sec after vaccination (b) pain score difference from baseline 2. VAS (range 0-10) to measure degree of pain: (a) At beginning of vaccination (b) After completion of vaccination 3. Total crying time</td>
<td>1. MBPS Score (a) -19.13% (p &lt; 0.001) (b) -41.02% (p &lt; 0.001) 2. VAS (a) -50.62% (p &lt; 0.001) (b) -32.3% (p = 0.001) 3. Total Crying Time -42.73% (p &lt; 0.001)</td>
</tr>
<tr>
<td>Citation</td>
<td>Study Design &amp; Evidence Level</td>
<td>Source of Funding</td>
<td>Subject Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Effect Size (IG - CG)</td>
</tr>
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<tr>
<td>Cassidy et al., 2001</td>
<td>Design Double-blind RCT</td>
<td>EMLA patch, placebo and funding by pharmaceutical company of EMLA</td>
<td>Children undergoing DPTP² injection in private office settings (Total no. = 161)</td>
<td>EMLA patch to vaccination site</td>
<td>Placebo patch to vaccination site</td>
<td>Primary Outcome</td>
<td>Using All-Patients Treated Approach</td>
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<tr>
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<td></td>
<td>Composition 1g of EMLA cream</td>
<td>Composition 1g of inert oil visually identical to EMLA</td>
<td>(1) Children’s self-reported pain using FPS (range 0-6) within 15s of vaccination</td>
<td>During Vaccination</td>
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<tr>
<td></td>
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<td></td>
<td>Removal Time Removed &lt;10mins before vaccination</td>
<td>Removal Time Removed &lt;10mins before vaccination</td>
<td>(2a) -42.54%</td>
<td>(2a) -42.54%</td>
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<tr>
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<td></td>
<td></td>
<td>Duration for Application 60-120 mins n = 83</td>
<td>Duration for Application 60-120 mins n = 78</td>
<td>(2b) -43.53%</td>
<td>(2b) -43.53%</td>
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<tr>
<td></td>
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<td></td>
<td>Mean Age 4.7 years old</td>
<td>Mean Age 4.7 years old</td>
<td>(3) -6.25%</td>
<td>(3) -6.25%</td>
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<td></td>
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<td>(4) -24.44%</td>
<td>(4) -24.44%</td>
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<td>After Vaccination</td>
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<td>(3) -6.52%</td>
<td>(3) -6.52%</td>
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<tr>
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<td>(4) -20.24% (NS)</td>
<td>(4) -20.24% (NS)</td>
</tr>
</tbody>
</table>
| Citation       | Study Design & Evidence Level | Source of Funding | Subject Characteristics                                                                 | Intervention                          | Comparison                                | Outcome Measures                      | Effect Size  
(IG - CG) |
|----------------|------------------------------|-------------------|-----------------------------------------------------------------------------------------|----------------------------------------|------------------------------------------|----------------------------------------|-------------------------------|
| Gupta et al., 2013 | Design RCT                  | N/A               | Infants brought to immunization clinic for routine DPT vaccine (Total no. = 90)         | EMLA cream to vaccination site         | Placebo cream to vaccination site       | Primary Outcome                       | (1) -30.71%  
(p < 0.05) |
|                |                              |                   |                                                                                       | Composition 1g of EMLA cream           | Composition 1g of Vaseline cream        | Secondary Outcomes                    | (2a) 0 (NS)  
(2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   |                                                                                       | Adhesion Method                        | Adhesion Method                        | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   |                                                                                       | Covered with occlusive dressing (Tegaderm) | Covered with occlusive dressing (Tegaderm) | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   |                                                                                       | Mean Duration for Patch Application ~60mins | Mean Duration for Patch Application ~60mins | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   |                                                                                       | n = 30                                  | n = 30                                   | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | Inclusion Criteria                                                                      |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - Healthy term infants < 3 months                                                     |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - On breastfeeding                                                                     |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - For first DPT vaccine                                                                |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - Accompanied by their mothers                                                        |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | Exclusion Criteria                                                                     |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - History of hospital admission for > 48hrs                                           |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - History of perinatal asphyxia                                                       |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - Small for gestational age                                                            |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - Preterm babies                                                                      |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - Neurological abnormalities                                                            |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | - History of previous surgery                                                         |                                        |                                          | (2b) -19.58%  
(p < 0.05)  
(2c) -52.54%  
(p < 0.05) |
|                |                              |                   | Mean Age                                                                               | IG: 2.2 months       | CG: 2.2 months                           |                                        |  
60 |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Study Design &amp; Evidence Level</th>
<th>Source of Funding</th>
<th>Subject Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome Measures</th>
<th>Effect Size (IG - CG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halperin et al., 2000</td>
<td>Design Double-blind RCT</td>
<td>EMLA patch, placebo and funding by pharmaceutical company of EMLA</td>
<td>Infants brought to family physicians for routine MMR&lt;sup&gt;iv&lt;/sup&gt; in an ambulatory setting (Total no. = 160)</td>
<td>EMLA patch to vaccination site Composition 1g of EMLA cream</td>
<td>Placebo patch to vaccination site Composition 1g of inert oil visually identical to EMLA</td>
<td>1. Using MBPS (range 0-10) to obtain: (a) Post-vaccination pain score; (b) Pain score difference from baseline</td>
<td>1. MBPS Score (a) -7.04% (NS) (p = 0.043)</td>
</tr>
<tr>
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<td>Inclusion Criteria</td>
<td>Mean Duration for Application 65.4 mins Removal Time Removed &lt; 10 min before vaccination n = 80</td>
<td>Mean Duration for Application 63.7 mins Removal Time Removed &lt; 10 min before vaccination n = 80</td>
<td>2. Mean duration of cry</td>
<td>2. Mean Duration of Cry -3.33% (NS)</td>
</tr>
<tr>
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<td>Exclusion Criteria</td>
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<td>Mean Age</td>
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<td>IG: 12.4 months</td>
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<td></td>
<td>CG: 12.3 months</td>
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<tr>
<td>Citation</td>
<td>Study Design &amp; Evidence Level</td>
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<td>Comparison</td>
<td>Outcome Measures</td>
<td>Effect Size (IG - CG)</td>
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<tr>
<td>Halperin et al., 2002</td>
<td>Design Double-blind RCT</td>
<td>EMLA patch, placebo and funding by pharmaceutical company of EMLA</td>
<td>Infants undergoing DTaP-IPV-Hib and Hepatitis B vaccinations in an ambulatory setting (Total no. = 165)</td>
<td>• EMLA patch to vaccination site • Left in place for 60 to 180 min Composition 1g of EMLA cream Dosage • &lt;6m: 1 patch for all injection sites • 6m: 2 patches with 1 for each site Mean Duration for Application 62-65mins Removal Time Removed &lt; 10 min before vaccination n = 82</td>
<td>• Placebo patch to vaccination site • Left in place for 60 to 180 min Composition 1g of inert oil visually identical to EMLA Dosage • &lt;6m: 1 patch for all injection sites • 6m: 2 patches with 1 for each site Mean Duration for Application 62-65mins Removal Time Removed &lt; 10 min before vaccination n = 83</td>
<td>Using MBPS (range 0-10) to obtain: (1) Post-vaccination pain score; (2) Pain score difference from baseline</td>
<td>0–2 month subgroup (1) -1.05% (NS) (2) -7.87% (NS) 2 month subgroup (1) 1.31% (NS) (2) -51.35% (NS) 4 month subgroup (1) -6.63% (NS) (2) -27.76% (NS) 6 month subgroup (1) -8.16% (p = 0.005) (2) -37.57% (p = 0.004)</td>
</tr>
<tr>
<td>Citation</td>
<td>Study Design &amp; Evidence Level</td>
<td>Source of Funding</td>
<td>Subject Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Effect Size (IG - CG)</td>
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<tr>
<td>Taddio et al., 1994</td>
<td>Design</td>
<td>Double-blind RCT</td>
<td>Supported in part by pharmaceutical company of EMLA</td>
<td>Infants in pediatric outpatient clinic (Total no. = 96)</td>
<td>EMLA cream to vaccination site by parents ~60mins before appointment</td>
<td>Placebo cream to vaccination site by parents ~60mins before appointment</td>
<td>(1) Assess degree of pain using MBPS (range 0-10) to measure: (a) Post-vaccination score within 15s of vaccination (b) Pain score difference from baseline</td>
</tr>
<tr>
<td></td>
<td>Evidence Level 1+</td>
<td></td>
<td>Inclusion Criteria</td>
<td>Composition ~2.5g of EMLA cream</td>
<td>Composition ~2.5g of coconut oil visually and cosmetically identical to EMLA</td>
<td>(1a) -12.5%  (p = 0.001) (1b) -50%  (p = 0.001) (2) -45.83%  (p = 0.002) (3) -11.86%  (p = 0.027)</td>
<td></td>
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<td></td>
<td>Exclusion Criteria</td>
<td>Adhesion Method Covered with occlusive dressing (Tegaderm)</td>
<td>Adhesion Method Covered with occlusive dressing (Tegaderm)</td>
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<tr>
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<td></td>
<td>Mean Age 5m</td>
<td>Mean Duration for Application 83 min</td>
<td>Mean Duration for Application 83 min</td>
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<tr>
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<td></td>
<td></td>
<td>Removal Time Removed within several minutes before injection n = 49</td>
<td>Removal Time Removed within several minutes before injection n = 47</td>
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<tr>
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<td></td>
<td></td>
<td>(2) 10cm VAS within 15s of vaccination to measure degree of pain</td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(3) Total crying time</td>
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</tr>
<tr>
<td>Citation</td>
<td>Study Design &amp; Evidence Level</td>
<td>Source of Funding</td>
<td>Subject Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Effect Size (IG - CG)</td>
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<tr>
<td>Uhari, 1993</td>
<td>Design Double-blind RCT Evidence Level 1-</td>
<td>Supported in part by pharmaceutical company of EMLA</td>
<td>Infants attending clinics for vaccination (Total no. = 155) Inclusion Criteria • Attending clinics between February 1991 and June 1992</td>
<td>EMLA cream to vaccination site for &gt;1hr before vaccination Adhesion Method Covered with occlusive dressing (Tegaderm) Mean Duration for Application 69.7 min n = 79</td>
<td>Placebo cream to vaccination site for &gt;1hr before vaccination Adhesion Method Covered with occlusive dressing (Tegaderm) Mean Duration for Application 65.6 min n = 76</td>
<td>Rating by nurses and parents using visual scale on ruler (range 0-10) to evaluate degree of: (1) Pain (2) Crying</td>
<td>Nurses’ Evaluation (1) -34.21% (p &lt; 0.003) (2) -30% (p &lt; 0.003) Parents’ Evaluation (1) -39.58% (p &lt; 0.001) (2) -32.08% (p &lt; 0.003)</td>
</tr>
</tbody>
</table>

i: G6PD = Glucose-6-Phosphate Dehydrogenase
ii: DPTP = Diphtheria, Pertussis, Tetanus and Polio
iii: DPT = Diphtheria, Pertussis, Tetanus
iv: MMR = Measles-Mumps-Rubella
v: DTaP-IPV-Hib = Diphtheria-Tetanus-acellular Pertussis-Inactivated Poliovirus-Haemophilus Influenzae type b conjugate
## Appendix F – Quality Assessment Using SIGN Methodology Checklist for Controlled Trials

### Section 1: Internal Validity

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<tr>
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<tbody>
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<td>Clearly Focused Question</td>
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<td>✓</td>
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<tr>
<td>Allocation Concealment</td>
<td>✓</td>
<td>Can’t Say</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Can’t Say</td>
<td>Can’t Say</td>
</tr>
<tr>
<td>Blinding</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Comparable Groups</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Treatment is the Only Difference</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Valid and Reliable Outcome Measures</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Drop-Out Rate</td>
<td>0</td>
<td>Overall: 5.6%</td>
<td>0</td>
<td>IG: 0</td>
<td>Overall: 3.6%</td>
<td>Overall: 12.5%</td>
<td>IG: 5.1%</td>
</tr>
<tr>
<td>Intention to Treat Analysis</td>
<td>N/A</td>
<td>✓</td>
<td>N/A</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Comparable Results from All Sites</td>
<td>N/A</td>
<td>Can’t Say</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Can’t Say</td>
</tr>
<tr>
<td>Section 2: Overall Assessment</td>
<td>Abuelkheir et al., 2014</td>
<td>Cassidy et al., 2001</td>
<td>Gupta et al., 2013</td>
<td>Halperin et al., 2000</td>
<td>Halperin et al., 2002</td>
<td>Taddio et al., 1994</td>
<td>Uhari, 1993</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------------------</td>
<td>----------------------</td>
<td>-------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Risk of Bias Minimized</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Overall Effect due to Intervention Alone</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Result Applicable to Target Group</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Notes</td>
<td>No sample size calculation</td>
<td>No sample size calculation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No sample size calculation</td>
</tr>
<tr>
<td>Level of Evidence</td>
<td>1++</td>
<td>1-</td>
<td>1++</td>
<td>1+</td>
<td>1+</td>
<td>1+</td>
<td>1-</td>
</tr>
</tbody>
</table>
### Appendix G – Gantt Chart Illustrating the Time Schedule for the Implementation Process of the Proposed Innovation

<table>
<thead>
<tr>
<th>Task</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of Proposal &amp; Guideline by Working Group</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
</tr>
<tr>
<td>Approval of Proposal by the Administrative Level of DH</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
</tr>
<tr>
<td>Staff Training &amp; Preparation of Equipment</td>
<td></td>
</tr>
<tr>
<td>Pilot Testing</td>
<td></td>
</tr>
<tr>
<td>Formal Implementation of the Proposed Innovation</td>
<td>8 9 10 11 12</td>
</tr>
<tr>
<td>Data Analysis &amp; Evaluation</td>
<td>8 9 10 11 12</td>
</tr>
</tbody>
</table>
Appendix H – Material and Non-material Costs of Implementing the Innovation

### Material Cost per 1,000 Clients

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMLA Patch</td>
<td>$35/patch x 1,000</td>
<td>$35,000</td>
</tr>
<tr>
<td>Printing &amp; Photocopy of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education Leaflet (1 Page)</td>
<td>$0.3/page x 1,000</td>
<td>$300</td>
</tr>
<tr>
<td>Guideline for Nurses (5 Pages)</td>
<td>$0.3/page x 5 x 12 sets</td>
<td>$18</td>
</tr>
<tr>
<td>Evaluation Forms (5 Pages)</td>
<td>$0.3/page x 5 x 1,000</td>
<td>$1,500</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$36,818</strong></td>
</tr>
</tbody>
</table>

### Non-material Cost per 1,000 Clients

<table>
<thead>
<tr>
<th>Manpower and Time Consumed</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manpower Release for Attending Training Workshop (1 hour)</td>
<td>$177/hour&lt;sup&gt;i&lt;/sup&gt; x 12 nurses</td>
<td>$2,124</td>
</tr>
<tr>
<td>Additional Time for Client Education and EMLA Application (5 minutes)</td>
<td>$2.95/minute&lt;sup&gt;ii&lt;/sup&gt; x 5 minutes x 1,000</td>
<td>$14,750</td>
</tr>
<tr>
<td>Additional Time for Evaluation (3 minutes)</td>
<td>$2.95/minute&lt;sup&gt;ii&lt;/sup&gt; x 3 minutes x 1,000</td>
<td>$8,850</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$25,724</strong></td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td><strong>$62,542</strong></td>
</tr>
</tbody>
</table>

---

<sup>i.</sup> The mean monthly salary of registered nurses in DH at Master Pay Scale point 20 is $31,200 per month. Having to work 4 weeks per month and 44 hours per week, the hourly salary for registered nurses in MCHC would be $31,200/4/44 = $177 per hour (Civil Service Bureau, 2013).

<sup>ii.</sup> With the hourly salary of registered nurses in MCHC to be $177 per hour, wage for each minute would be $177/60 = $2.95 per minute.
## Appendix I – Non-material Costs of Not Implementing the Innovation

<table>
<thead>
<tr>
<th>Manpower and Time Consumed</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Time for Nurse Interview (20 minutes)</td>
<td>$2.95/minute x 20 minutes x 350</td>
<td>$20,650</td>
</tr>
<tr>
<td>Additional Time for Completing Immunization Procedure (5 minutes)</td>
<td>$2.95/minute x 5 minutes x 350</td>
<td>$5,162.5</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td></td>
<td><strong>$25,812.5</strong></td>
</tr>
</tbody>
</table>

---

i. It is estimated that for every 1,000 clients, 35% of them will spread the immunizations into two separate visits. Hence 1,000 x 35% = 350 repeated visits will be generated.
### Appendix J – Grades of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
</table>
| A     | At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population  
Or  
A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |
| B     | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results  
Or  
Extrapolated evidence from studies rated as 1++ or 1+ |
| C     | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results  
Or  
Extrapolated evidence from studies rated as 2++ |
| D     | Evidence level 3 or 4  
Or  
Extrapolated evidence from studies rated as 2+ |

(SIGN, 2011)
Appendix K – EBP Guideline on Pre-vaccination EMLA Application

Title

“An evidence-based practice guideline on pre-vaccination application of EMLA patch for children below six years of age in reducing immunization-induced pain in the MCHC”

Aim

- To alleviate immunization-induced pain and distress in children undergoing immunization procedures in the MCHC

Objectives

- To summarize research evidence for immunization pain relief among children below six years of age
- To formulate recommendations on immunization pain relief based on the evidence available
- To standardize immunization pain relief practice by promoting pre-vaccination application of EMLA patch in the MCHC

Intended Users

The guideline is intended for use by all nursing staff responsible for delivering vaccinations to children in the designated MCHC. Registered nurses or enrolled nurses who have received training on immunization skills and are
assigned to perform immunization procedures will be the target users of the guideline.

**Intended Target Group**

Children below six years of age visiting the MCHC for immunization will be the target group for pre-vaccination EMLA patch application.

**Recommendations**

**Recommendation 1**

Single dose circle-shaped EMLA patch saturated with 1 gram of EMLA emulsion rather than EMLA cream should be used to streamline the application procedure by omitting the step of covering the cream with an occlusive dressing.

[Grade of Recommendation: A]

**Available Evidence:**

a. The development of a patch containing a single dose has simplified the application of EMLA. (Halperin et al., 2000) (1+)

b. Compared with the cream, the EMLA patch is potentially an easier, more precise way to administer the drug in the outpatient setting. (Cassidy et al., 2001) (1-)

**Recommendation 2**

EMLA patch should be applied onto the injection site by nurses at the interview.
stations at the beginning of the nurse interview to allow more time for onset of action.

[Grade of Recommendation: A]

Available Evidence:

a. Although the delayed onset of action of EMLA was cited by healthcare providers as one of the major barriers against the routine use of this pain-relieving strategy for immunization in the office setting, the development of a protocol for EMLA application by the nurses on the child’s arrival helped to overcome this obstacle. (Abuelkheir et al., 2014) (1++)

b. Study of Uhari (1993) recommended that EMLA could be applied in advance to allow time for the anesthesia to take effect after its application. (1-)

Recommendation 3

Degree of patch adhesion should be assessed after its application to the injection site to ensure adequate release of EMLA for better pain relief effect.

[Grade of Recommendation: B]

Available Evidence:

a. Patch adhesion correlated negatively with pain during the needle phase; less patch adhesion, probably reflecting less drug delivery, was related to greater behavioral pain scores in the needle phase. (Cassidy et al., 2001) (1-)
**Recommendation 4**

EMLA patch should be applied onto the injection site for at least 60 minutes to achieve pain relief effect.

[Grade of Recommendation: A]

Available Evidence:

a. Findings from the review studies supported that application of EMLA patch onto the injection sites for at least 60 minutes could result in significant reduction in pain scores in children undergoing immunization procedures.

(Cassidy et al., 2001; Gupta et al., 2013; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994; Uhari, 1993) (1--; 1++; 1+; 1+; 1+; 1-)

**Recommendation 5**

EMLA patch should not be removed for more than 10 minutes before the immunization procedures to ensure its efficacy.

[Grade of Recommendation: A]

Available Evidence:

a. This is the common element described in the interventions from the review studies which contributed to the significant reductions in pain during immunization procedures. (Cassidy et al., 2001; Halperin et al., 2000; Halperin et al., 2002; Taddio et al., 1994) (1--; 1+; 1+; 1+)
**Recommendation 6**

MBPS as well as VAS should be used to evaluate the level of pain among children undergoing immunization procedures.

[Grade of Recommendation: A]

**Available Evidence:**

a. Both the MBPS score recorded by the observer and the VAS score recorded by the nurse administering the vaccines correlated well to support the effectiveness of EMLA in pain relief. (Abuelkheir et al., 2014) (1++)

b. The 10 cm VAS has been found to be a highly sensitive measure of pain, with a uniform distribution and good correlation with descriptive scales. (Cassidy et al., 2001) (1-)

c. Test-retest validity of the MBPS was assessed with the reliability coefficients all indicating excellent reliability of the observations. (Halperin et al., 2000; Halperin et al., 2002) (1+; 1+)

d. The MBPS scores obtained from video analysis were significantly correlated with VAS pain scores obtained from direct observation, suggesting that both scales measured similar responses. (Taddio et al., 1994) (1+)
# Appendix L – Timeline for Communication Plan

<table>
<thead>
<tr>
<th>Task</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of Proposal by Innovation Committee</td>
<td>1</td>
</tr>
<tr>
<td>Seeking Approval from Administrative Level</td>
<td>2 - 4</td>
</tr>
<tr>
<td>Preparation of Materials and Staff Training</td>
<td>4 - 6</td>
</tr>
<tr>
<td>Nursing Audits by NO In-charge</td>
<td>6 - 8</td>
</tr>
<tr>
<td>Skill Support from RNs of Innovation Committee</td>
<td>8</td>
</tr>
</tbody>
</table>
## Appendix M – Modified Behavioral Pain Scale

<table>
<thead>
<tr>
<th>Observed Behavior</th>
<th>Score</th>
<th>Pre-vaccination Score</th>
<th>Post-vaccination Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facial Expression</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definite positive expression</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutral expression</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly negative expression e.g. grimace</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definite negative expression e.g. furrowed brows, eyes closed tightly</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laughing or giggling</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not crying</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moaning, quiet vocalizing, gentle or whimpering cry</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full lunged cry or sobbing</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full lunged cry, more than baseline cry</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body Movements</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual movements/activity, or resting/relaxed</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial movement or attempt to avoid pain by withdrawing the limb where puncture is done</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agitation with complex movements involving the head, torso, or the other limbs, or rigidity</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Taddio et al., 1995)
Appendix N – Perceived Level of Pain Using Visual Analog Scale

Infant No:___________________

Please mark a cross on the straight line below to indicate the perceived level of pain of the vaccinated child within 15s after the completion of immunization procedure.

No pain ←------------------------→ Worst Possible Pain
Appendix O – Data Collection Form on Immunization Pain Scores

Infant No: ____________________

Date: ____________________

Age: ____________________

Types of Vaccination Received

- Hepatitis B
- DTaP-IPV
- Pneumococcal
- Measles, Mumps and Rubella
- Varicella

Pain Scores

<table>
<thead>
<tr>
<th>Before Vaccination</th>
<th>Within 15s after vaccination completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBPS</td>
<td>MBPS</td>
</tr>
</tbody>
</table>

Score

| Score | | |
|-------|---|---|---|
|       |   |   |   |
### Appendix P – Satisfaction Questionnaire for Nursing Staff

Please put a tick in the appropriate boxes below to indicate your views on the following statements:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The EBP guideline is user-friendly and easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>There is adequate training provided concerning the implementation of the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Equipment is adequate and readily available during the implementation period of the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Workload is affordable even after the launch of the proposed innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>With the EBP guideline readily available and the training provided, I am competent in delivering the innovation to the participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Overall, I am satisfied with the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional comment:

____________________________________________________________________________________
____________________________________________________________________________________

80
Appendix Q – Satisfaction Questionnaire for Parents

Please put a tick in the appropriate boxes below to indicate your views on the following statements:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Nursing staff could provide clear explanation and clarify my concerns on the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>The education leaflet contains adequate information on the innovation and is easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Nursing staff are well-trained in delivering the innovation to my child</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>The innovation is beneficial to my child and could make my child less distressful during the immunization procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Overall, I am satisfied with the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional comment:
____________________________________________________________________________________________________________________
____________________________________________________________________________________________________________________
____________________________________________________________________________________________________________________
References


*Topics in Pain Management, 23*(7), 1-7.


Becoming Pincushions from Immunizations?. *Archives of Pediatrics & Adolescent Medicine, 149*(8), 845-849.

