Abstract of thesis entitled

“An evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture"

Submitted by

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Background: Venipuncture is one of the most common source of pain and ranked one of the three most painful procedures by children in hospitals. Studies had shown that there are various adverse effect of unmanaged pain which had increased attention in management of pain that WHO had developed the guideline about managing persisting pain in hospitalized children, however, procedural pain including pain caused by venipuncture was excluded. Furthermore, it was found that children are at high risk of having insufficient pain management in acute setting due to the lack of evidence-based policies in optimizing pain management in children, and the under-utilization of pharmaceutical method due to time-constraint and the fear of adverse effects of medication. Therefore, investigation into
non-pharmaceutical method had been done to reduce the pain level of children during venipuncture. A device "BUZZY" which is the combination of vibration and cooling effect was proven to be effective in reducing pain during venipuncture.

**Objective:** This translational study aim to develop an evidence-based protocol in using BUZZY to reduce pain in children aged 4-18 years old during venipuncture.

**Method:** A systematic search of 3 electronic databases, which are PubMed, Mosby's Nursing Consultant and PsycINFO, was conducted with outcome measures as pain level reduced using BUZZY during venipuncture for pediatric patients. The selected studies were then appraised and summarized with the best evidence synthesized to develop an evidence-based protocol having the transferability, feasibility and cost-benefit ratio been considered.

**Result:** With the inclusion and exclusion criteria set, four studies were included in the quantitative analysis (meta-analysis) and evaluated using the SIGN checklist and all of them were of high quality of evidence. It is evidentially proven the proposed protocol in using BUZZY to reduce pain in children aged 4-18 years old during venipuncture is highly transferable, feasible and cost-effective. With
all the evidence found, 4 recommendations were synthesized and developed.

**Conclusion:** The proposed evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture is effective and should be developed.
An evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture

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

I declare that the dissertation thereof represents my own work, except where due acknowledgement is made, and that 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......................................................................................

Cheung Ngo Sze
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An evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture

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1. Introduction

1.1. Background

The definition of pain was described as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in term of such damage” suggested by the International Association for the Study of Pain (IASP) (Bonica J.J, 1979). Venipuncture which is a needle-procedure, including vascular access and setting up of intravenous cannulation, was reported to be one of the most common source of pain (Linhares et al., 2012), and ranked within the top three most painful procedures by children in hospitals (Ortiz, M.I., Lopez-Zarco, M. & Arreola-Bautista, E.J., 2012). It is a procedure done for getting access to the veins for blood taking or setting up vascular cannulation.

The commonly used methods in reducing pain caused by needle-procedure can be classified into pharmaceutical, which is the use of topical analgesia (Kim, Choi, & Kwak,
For topical analgesic cream, such as Eutetic Mixture of Local Anaesthetics (EMLA), which is a mixture of lidocaine 2.5% and prilocaine 2.5% or LMX which contains 4% Lidocaine, they will be applied to the skin where the venipuncture will be, for minutes to hours in advance. The lidocaine creams prevent pain by releasing lidocaine into the epidermal and dermal layer of skins, yet, it was suggested by the manufacturer that they should be applied to the skin for at least 60mins to reach analgesic effect. Also, they had to be avoided to be used in patient with G6PD and special precaution for patients using antiarrhythmic medicine as interaction may occur. Moreover, side-effect might occur ranging from mild reactions on the skin such as edema, vaso-constriction and erythemia to severe complications such as
toxicity in central-nervous system and cardiovascular system (Tran & Koo, 2014).

For the use of vapocoolant, a volatile refrigerant liquid ethyl chloride will be sprayed before venipuncture to the designated area to freeze the skin in some clinical setting. Its mechanism of action is by producing freezing feeling at the skin to reduce the sensitivity of peripheral nerve endings and results in analgesic effect. However, it was reported to be ineffective when compared to placebo in reducing pain in children during venipuncture and vascular cannulation (Hogan, Shah as & Taddio, 2014).

Both the lidocaine cream and vapocoolant are single-use analgesia which are costly and might need to be applied to the skin for a period of time before needle-procedure to show the analgesic effect.

Apart from the above methods, a device named “BUZZY” was also available to reduce pain during venipuncture. It is a device combined vibration and cooling effect by attaching a
reusable ice-pad to the bee-like vibrating device. This device cost USD$ 39.95 each with batteries and a reusable ice-pad which can vibrate for at least 20 hours, approximately for 380 attempts of venous access (Baxter, Cohen, McElvery, Lawson & Baeyer, 2011). According to the Gate Control Theory, the central nervous system will modulate the pain signal transmitted from the peripheral nervous system in the dorsal horn of the spinal cord by a gating system (Melzack & Wall, 1965), which will be blocked by the fast vibrating motion (Kakigi & Shibasaki, 1992), and prolonged cooling (Nahra & Plaghki, 2005). This device is not required to be applied for a period of time before procedure for the therapeutic effect. It should be placed 5cm above the area for needle-procedure just before the procedure and kept vibrating throughout the whole procedure.

1.2. Affirming the need

Management of pain is one of the major concerns of the WHO in recent years that pain level was considered as one of the vital signs as pain would cause short-term and long-term
adverse effect to patients with no relationship with their age, gender, race, ethnicity and social-economic status. The adverse effects are different in patients who experienced different kind of pain. The acute pain caused by medical procedurals including venipuncture, lumbar puncture was categorized as procedural pain in the study by Mertin, Sawatzky, diahl-Jones, & Lee (2007) and its harmful effects could be manifested in various forms including physically, emotionally, behaviorally and psychologically (Mertin, Sawatzky, Diehl-Jones, & Lee, 2007). Physiologically, tachycardia, increase in blood pressure and myocardial oxygen utilization might occurred due to acute pain; also, cortisol and glucagon release as the respond to stress due to acute pain might lead to hyperglycemia (Dunwoody, et al, 2008). Behaviorally, pediatric patients in different age group would have different expression in pain which includes exhibition of regressive behavior or physical resistance for toddlers, being uncooperative and in need of restrainers for preschoolers, experience nightmares about being in pain for school-age children; and for all, they might experience disturbance in sleep (Pawar, & Garten, 2008). Apart
from the immediate physiological and behavioral response of children to pain, having experienced under-treated pain, with their negative memory, they will be expecting and rating a greater level of pain in their subsequent experience in painful procedures when compared to those who had their pain well-treated previously (Noel, Chamber, McGath, Klein & Stewart, 2012). Therefore, it is undeniable that procedural pain in children has to be well acknowledged and managed accordingly, whenever possible, as the fundamental of human rights to prevent them from falling into the vicious cycle (American Academy of Pediatrics, 2001; Brennan, Carr, & Cousins, 2007).

Although there was increased attention in management of pain that WHO had developed the guideline about managing persisting pain in hospitalized children but procedural pain such as pain from needle-procedure were excluded in this guideline (World Health Organization [WHO], Geneva, 2012). Apart from that, it was reported that the management of procedural pain in pediatric emergency units varies among
physicians and nurses without standard protocol or guidelines by the survey done in Canada and Alberta (Ali, Chambers, Johnson, Craig, Newton, Vandermeer, & Curtis, 2014; Ali, Chambers, Johnson, Newton, Vandermeer, Williamson, & Curtis, 2014), which is also the situation in my clinical setting.

In my clinical setting, for children aged less than 4 years old, 24% sucrose solution would be administered orally for the pain relief during medical procedures including venipuncture. However, there is no standard protocol or guideline in the method in reducing pain during medical procedure such as venipuncture. To my clinical experience, around 90% of the patients experienced at least one attempt of venipuncture for setting up intravenous access or taking blood during their admission period in my clinical setting. For patients older than 4 years old, EMLA cream is the only option for pain relief during venipuncture in my clinical setting. Although EMLA cream is a “top-up item”, medication that was classified as commonly used and allowed to be stocked in the clinical setting for emergency use and immediate access without the
need of retrieving from the pharmacy, in my clinical setting, it was only prescribed to those patients who are medically unfit for agitating, such as croup patients, according to the doctors’ preferences. Furthermore, it was found that children are at high risk of having insufficient pain management in acute setting due to the lack of evidence-based policies in optimizing pain management in children, and the under-utilization of pharmaceutical method due to time-constraint and the fear of overdosing (Ali, Chambers, Johnson, Craig, et al., 2014; and Ali, Chambers, Johnson, Newton, et al., 2014). As mentioned in the previous section, other than pharmaceutical method, such as use of topical analgesia, which needed doctors’ prescription and time for action after application, BUZZY is another option in reducing pain during venipuncture that no medication needed to be administrated throughout the procedure. As a result, it can overcome the barriers such as fear of overdosing and time constraint. Therefore, it is inevitable to develop an evidence-based practice of using BUZZY to reduce pain in children during venipuncture.
With the clinical issue identified above, the research question and PICO would be formulated as below

Is it effective to reduce pain in children aged 4-18 years old, who are being admitted to the hospital during venipuncture with the use of BUZZY?

- **P:** Children aged 4-18 years old being admitted to the hospital with the needs of venipuncture
- **I:** use of BUZZY throughout the procedure
- **C:** no intervention
- **O:** reduce in pain

1.3. Objectives and significance

The objectives of this study are as below:

1.3.1. to identify relevant literatures according to the research question stated above, and
1.3.2. to conduct a systematic review to appraise and evaluate the selected literatures critically, and

1.3.3. to summarize and synthesize the evidence from the systematic review, and

1.3.4. to develop an evidence-based protocol in using BUZZY to reduce pain in children aged 4-18 years old during venipuncture, and

1.3.5. to develop a plan to implement and evaluate the evidence-based protocol stated above

As discussed above, venipuncture is a commonly seen needle-procedure in the pediatric emergency unit which is the most common cause of pain in children being hospitalized. Also, the harmful effects of procedural pain could be manifested in various forms and will affect the patients in different aspect including cognitive, physical, emotional and psychological. Yet, guidelines in reducing pain during venipuncture was not available nowadays with barriers in
promoting the use of topical analgesic, which is the most common ways being used. Moreover, the cost of using the BUZZY was calculated as USD$0.1 for each attempt (Canbulat, N., Ayban, F., Inal, S., 2015). Therefore, a systematic review and evidence-based guideline in reducing pain during venipuncture using the BUZZY should be developed with no doubt.
2. Critical Appraisal

With the needs of addressing and managing the pain caused by venipuncture using the device Buzzy illustrated in the previous section, relevant literatures were searched and critiqued systematically. Searching and appraisal strategies used, results of the literatures, summary and synthesis will be described in this section.

2.1. Search and Appraisal Strategies

Inclusion/Exclusion Criteria

Inclusion and exclusion criteria were identified before performing searching. For the type of studies, primary studies of randomized trials or quasi-randomized controlled trials were included. Concerning the contents, literatures with target participants of pediatric patients aged more than 3 years old; with the intervention of using the combination of cold and vibration, or using Buzzy as the pain relief method during venipuncture; and measuring the reduction in pain with the use of the intervention would be included. However,
for those literatures having target participants as patients with cognitive impairment or outpatient would be excluded.

**Search Strategies**

With the inclusion and exclusion criteria identified above, a systematic search of 3 electronic databases, which are PubMed, Mosby's Nursing Consultant and PsycINFO, was conducted since July 2015 until Oct 2015. The search was limit to the literature published within 10 years to make sure the information is up-to-date. No limitation was made to the language as to recruit as many information as possible and to minimize the bias. The keywords and strategy used in the search in the electronic databases were as below:

Manual search was also done by using these keywords. The reference lists of the selected articles were also screened manually for relevant information.

**Appraisal Strategies**

All the selected articles searched were appraised individually using the Scottish Intercollegiate Guidelines Network (SIGN) methodology Checklist 2: Randomized controlled trials appraisal tool which was established since 1993 and met the criteria of Appraisal of Guidelines for Research and Evaluation in Europe II (AGREE II) in identifying guidelines with good quality (appendix I).

2.2. Results

**Search Result**

198 articles were found in the 3 database, PubMed, Mosby's Nursing Consultant and PsycINFO, and 4 other articles were found from other sources including screening reference list of relevant literatures using the above
keywords and strategy (appendix ii). After removing the duplicated articles, 32 literatures were left. With the screening of the titles and abstracts of all 32 articles, 19 of them were excluded as they were irrelevant to our topic.

Among the 13 articles being left behind, the full texts of them were assessed, in which nine of them were being excluded for the following reason. There is only the abstract published without detailed content of the trial for the study by Baxter (2009), while the article by Bowen & Dilezal (2014) had only briefly mentioned the technique of using BUZZY to reduce pain in pediatric patients during needle stick procedures without evaluating its effectiveness. Apart from that, five of them were having different target group as our research question which are children with cognitive impairment; outpatients; in need of vaccination; and adults (Baxter, Leong & Mathew, 2009; Canbulat, Ş.N., Inal & Sevim, 2015; Luthy, Beckstrand, Pulsipher, et al., 2013; Schreiber, Cozzi, Rutigliano, 2015; Whelan, Kunselman, Thomas, Moore & Tamburro, 2014) as our target population is children with
normal cognitive ability aged 4-12 years old being admitted to the hospital who are in need of venipuncture.

Moreover, the article by Baxter A. & Lawson M (2014) is measuring a different outcome, instead of the efficacy in reducing pain; it evaluated the differences in blood results of the same patients with blood taken with and without the use of Buzzy. For the one by Bowen & Dolezal (2014) is using a different intervention which was the combination of the use of J-tip, a specific type of catheter for venipuncture and Buzzy, in which, the effect of using Buzzy alone was not singled out.

As a result, the remaining four articles were being included in quantitative analysis (meta-analysis) and evaluated using the SIGN checklist (appendix III).

Table of Evidence

| Study Design |  
|---|---|
A table of evidence was developed to extract the data from the articles (appendix IV). All the articles included in the meta-analysis are well designed randomized controlled trials which belong to level I according to the hierarchy of evidence described in Melnyk & Fineout-Overholt (2005) (appendix v).

Concealment method

The concealment methods were explained in details in two of the articles which were having their participants unaware of the group assignment. One of them used sequential patient number assignment which was concealed in opaque envelops (Baxter, Cohen, McEvlery, Lawson & von Baeyer, 2011) while another one used computer-generated table for group assignment (Canbulat, Ayban & Inal, 2015). However, the concealment methods were not mentioned in the other two articles (Inal & Kelleci, 2012; Moadad, Kozman, Shanine, Ohanian & Badr, 2015).

In all the studies included, subjects and investigators were not blinded about the treatment allocation, as this is
not applicable to this methodology that the device could be seen, heard or felt by the subjects and the known of the presence of the device is part of the method in reducing pain as distraction. Although double-blinded or single-blinded studies were not applicable, subjects were blinded to which group they were assigned to, therefore, risk of allocation bias and the subjects bias were limited.

Baseline Characteristics

All the baseline characteristics of the subjects in all studies were recorded in detail and showed no significance difference (p>0.05). However, the use of buzzy was not the only pain relieving measures introduced to the intervention group in the study by Baxter, et al. (2015). Among the intervention group in this study, apart from receiving BUZZY, half of them received LMX as LMX is standard care to be given by the nurses to those patient before confirming to have the need of venipuncture if they anticipated the need of venipuncture in the clinical setting of this study; and 9 out of 41 subjects received vapocoolant apart from the use of
BUZZY as the investigator was not present during venipuncture and the nurses were only instructed to do their practice as usual. Although BUZZY was not the only intervention applied to the subjects in the intervention group, half of the subjects in the control group also received LMX; therefore, there is no significance difference between intervention group and control group. Moreover, by eye-balling comparison, only 9 subjects received vapocoolant together with BUZZY would not have significant effect on the result. Therefore, the only significant difference among intervention groups and control groups in all the studies was the use or no use of the BUZZY only.

**Outcome Measures**

The primary outcome of the studies were clearly stated as reducing the pain and anxiety during venipuncture in three of the studies (Baxter, Cohien, McElvery, Lawson & von Baeyer, 2011; Canbulat, Ayban & Inbal, 2015; Inal & Kelleci, 2012) and reducing pain alone in the study by Moadad, Kozman, Shahine, Ohanian & Badr (2015). Wong Baker's Face
Scale (WBFS) was used in measuring pain level in the study by Canbulat, Ayban & Inbal (2015) and Moadad, Kozman, Shahine, Ohanian & Badr (2015) while Face Pain Scale - Revised (FPS-R) was adopted in the study by Baxter, Cohien, McElvery, Lawson & von Baeyer (2011) and Inal & Kelleci (2012). For the assessment of anxiety, Children's Fear Scale (CFS), Children's Anxiety and Pain Scale (CAP) and Observational Scale of Behavioral Distress (OSBD) were used by Canbulat, Ayban & Inbal (2015), Inal & Kelleci (2012) and Baxter, Cohien, McElvery, Lawson & von Baeyer (2011) respectively. All the measuring tools used in the studies, which are WBFS, FPS-R, CAP, CFS, OSBD, were all validated with high reliability (de Castro Goncalves, 2014; Jay, Ozolins, Elliott, & Caldwell, 1983; Mcmurtry, Noel, Chambers & Mcgrath, 2011 Tomlinson, von Baeyer, Stinson, & Sung, 2010).

**Dropout rate**

There is no dropout in all the studies that all the subjects recruited in the studies completed the whole intervention.
Appraisal Result

With the above aspect evaluated, the studies were rated as 1++ for the one by Canbulat, Ayban & Inbal (2015) and Inal & Kelleci (2012); 1+ for the one by Moadad, Kozman, Shahine, Ohanian & Badr (2015) and Baxter, Cohien, McElvery, Lawson & von Baeyer (2011). In conclusion, all the studies included were of high quality of evidence and their results could be adopted in the synthesis progress.

2.3. Summary and Synthesis

Participants characteristics

The subjects would be excluded from the recruitment in the 4 studies if there was an lesion at the proposed area Buzzy would be placed, if there was injury to the nerve which affect the extremity previously, if they were hemodynamically unstable, or if they are patient of sickle cell disease or Raynaud disease who had hypersensitivity to coldness (Baxter, Cohen, McElvery, Lawson & von Baeyer,

The age of the subjects being recruited in these studies ranging from 4 years old to 18 years old in which the age group of the subject is 7-12 in the study by Canbulat, Ayban & Inal (2015); 6-12 in the study by Inal & Kelleci (2012); 4-18 in the study by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011); and 4-12 in the study by Moadad, Kozman, Shahine, Ohanian & Badr (2015). Although there are some differences in the age group of the subject being recruited, all the subjects included are aged 4 or above and the mean ages are similar which is around 8-9.

Sample Size

Except the study by Canbulat, Ayban & Inal (2015), all the other three studies had calculated the required sample sized required to detect a significant difference in the outcome measurement with a power of 0.8 in the study by Inal & Kelleci (2012) and Moadad, Kozman, Shahine, Ohanian
& Badr (2015) and 0.95 in the study by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011); and the acceptable type I error size of 0.05 in all studies.

The total sample sized was stated clearly in all studies. Although there were 56 subjects recruited in the study by Moadad, Kozman, Shahine, Ohanian & Badr (2015) which was more than the required sample size calculated, 50 subjects, only 48 of them were analyzed as there were missing data in 2 samples and 6 of the recruited subjects didn’t receive a successful venipuncture on the first attempt. Meanwhile, the sample sizes of the study by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011), Inal & Kelleci (2012) were 83 and 120 which were larger than the required sample sized calculated. For the study by Canbulat, Ayban & Inal (2005) the sample size was 176.

**Intervention**

Apart from the target group, the interventions among all studies were similar. In the study by Cabulat, Ayban & Inal
(2015) and Inal & Kelleci (2012), Buzzy was applied to about 5cm above the area where the venipuncture will be located, whereas in the study by Moadad, Kozman, Shahine, Ohanian & Badr (2015), it was located at 5-10cm proximal to the proposed drip site, and at the pedestal nearest to the venipuncture site in the study by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011). Parents and the subjects were given the opportunity to administer Buzzy during the procedure after education and training provided on the use of Buzzy which limited to 3 minutes before procedure in the study by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011) and Moadad, Kozman, Shahine, Ohanian & Badr (2015), whereas the application was done by the researcher nurse in the study by Inal & Kelleci (2012) and no explanation on who applied Buzzy in the study by Canbulat, Ayban & Inal (2015).

Besides the method of application of Buzzy, there are some other different interventions being carried out in these studies. Among these four studies, the subjects in two studies
also received other forms of analgesia before the procedure. Some of the subjects in the study by Moadad, Kozman, Shahine, Ohania & Badr (2015) had taken oral analgesics due to reasons other than venipuncture which had been clearly illustrated in the article, but there is no significant difference in the number of subject who had oral analgesia before the procedure between intervention and control groups; moreover; all the analgesia were taken at least 4 hours before the procedure that the analgesic effect during procedure was questionable. Besides, in the study by Baxter, Chen, McElvery, Lawson & von Baeyer (2011), some of the subjects also received topical analgesic cream, as it would be applied to the designated area decided by the nurse if they anticipated the chance of venipuncture, yet, the number of subjects received in each group (46.3% in intervention group and 50% in control group) showed no significant differences between the intervention and control group.

Measuring tools
For the assessment tools, two of the studies used WBFS in measuring the pain level (Cannbulat, Ayban & Inal, 2015; Moadad, Kozmann, Shahne, Ohanian & Badr, 2015) and two of the studies adopted FPS-R (Baxter, Cohen, McElevery, Lawson & von Baeyer, 2011; Inal & Kelleci, 2012). The WBFS was a scale with 6 hand-drawn faces shown horizontally with a smiling face indicating “no hurt” that score 0 on the left to a crying face indicating “Hurts Worst” that score 5 on the right; whereas the FPS-R showing 6 faces horizontally with a neutral facial expression of “no pain” on left to the “most pain possible” on the right. FPS-R was a validated measuring tool with extensive support on its reliability for assess pain level for children of 4-12 years old while WBFPS also is a validate tools for measuring pain level, thus, it was found to be more preferred by children of all ages, parents and health care providers when comparing with other pain scale (Luffy & Grove, 2005; Tomlinson, von Baeyer, Stinson & Sung, 2010).

The assessment of pain was reported by the clients only in the study by Canbulat, Ayban & Inal (2015) while the study
by Baxter, Cohen, McElvery, Lawson & von Baeyer (2011) included the pain level reported by parents besides self-report pain level; whereas Inal & Kelleci (2012) and Moadad, Kozman, Shahine, Ohanian & Badr (2015) also evaluated the pain level reported by observe nurse, parents and clients.

**Results of the Studies**

All the studies included showed coherent result that self-reported and nurses-reported pain were significantly reduced ($p<0.05$) in the intervention group when compared to the control group (Canbulat, Ayban & Inal, 2015; Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011; Inal & Kelleci, 2012; Moadad, Kozman, Shahine, Ohanian & Badr, 2015). However, in the study by Moadad, Kozman, Shahine, Ohanian & Badr (2015), the reduction in pain rated by parents were insignificant ($p=0.114$) which was contradicting with the results in the two other studies ($p=0.005$ & $p=0.001$) (Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011; Inal & Kelleci, 2012), while no parents-reported pain level was measured in the study by Canbulat, Ayban & Inal (2015). Although the
results were not coherent among all the studies concerning
the pain level reported by parents, self-reported pain had
been described as the “gold standard” of pain assessment
(Schiaveato & Criag, 2010). Though for pediatric patients, this
standard had been controversy over years, with debates over
years, it was concluded that self-report remained the gold
standard in pain assessment in pediatric which might be
needed to be judged by trained and experienced health care
professionals along with other signs and symptoms shown if
necessary in order to provide an accurate judgment and thus,
providing appropriate management (Twycross, Voepel-Lewis,
Vincent, Franck & von Baeyer, 2015). Hence, even though
insignificant reduction in pain level was reported by the
parents in one of the studies (Moadad, Kozman, Shahine,
Ohanian & Badr, 2015), only the report by the clients along
with the report by nurses was evidential enough to be taken
into consideration.

Moreover, Moadad, Kozman, Shahine, Ohanian & Badr
(2015) had not only analyzed the result as a whole group,
they had done the analysis separately according to their characteristics, including age group, gender and Body Mass Index (BMI). Even though insignificant reduction in pain level was shown for the subjects aged 8-12 (p=0.062), male (p=0.073), without previous hospitalization (p=0.071) and with analgesics (p=0.214) and the difference in reduction in pain level did not vary with the BMI, after classifying the subjects into subgroups as above, the sample size of each group was largely reduced to around 20 and to only 13 for group with analgesic. As mentioned above, sample size required to detect a significant difference in the outcome measurement calculated in the study was 50, therefore, having the sample sizes reduced to around 20, the reduction in the pain level in each subgroup were not significant enough to be detected, thus, these results were not taken into consideration.

**Synthesis of evidence**

In conclusion to the information discussed above, the use of Buzzy is evidentially proven to be effective in reducing
pain in children aged 4-18 years old, who is in need of
venipuncture and is not critically ill, does not have wound at
the skin where Buzzy had to be placed, did not have any
injury to the nervous system affecting the designated
extremities and does not have sickle cell disease or disease
which show hypersensitivity to coldness, when compared to
the usual practice that no clear guideline available. Thence, a
protocol should be developed. With the synthesis from the
above review, the use of Buzzy should the only method to be
instilled in the protocol with instruction explained explicitly to
all health care staff to ensure the consistency and
compliance. Moreover, Buzzy should be instructed to be
placed 5cm above the proposed area for venipuncture with at
most 3 minutes of education and training being provided to
the parents and children on its use prior to the procedure,
and the application of Buzzy should be performed by parents
or subjects. WBFPS should be used in assessing the level of
pain as it is adopted in most of the pediatric emergency unit
in Hong Kong and it was shown to be more preferred by
children. Thus, pain assessment should be done by evaluating
the level of pain reported by the children and the observing nurses during procedure.
3. Implementation Potential and Clinical Guideline

With the literatures reviewed and evidence synthesised above, in order to develop an evidence-based guideline, the implementation potential has to be evaluated including the transferability and feasibility.

3.1. Transferability

The target setting of the study is a the Pediatric Intensive Care Unit (PICU) which was embedded in a ward mixed with the Neonatal Intensive Care Unit (NICU) and the Special Care Baby Unit (SCBU), in which the target group would be the patients being admitted into the PICU who are in need of venipuncture. The patients being admitted to the PICU ranging from baby of 3 months old with body weight more than 3.5kg to children up to 17 years old. The official number of pediatric bed stat is 8, however, due to high turnover rate, number of pediatric patients being admitting annually is around 300 in 2015. According to my clinical experience, around 50% of the admission of this unit is
booked cases of post-operation patients who are at high risk of deterioration; or needs of inotropic support or intubation and required intensive care support. Another source of admission include referral from other unit from the local or other hospital such as general pediatric unit, pediatric oncology, cardiology, etc., which make up of around 45% of admission. The remaining 5% of admission is from Accident and Emergency Department (AED) of local and other hospital for emergency pediatric support such as trauma cases, burn cases. Venipuncture for blood taking and setting up intravenous access was done at least once to every admission in average in the target setting. Currently, there was no intervention in measuring and managing pain experienced by pediatric patients aged above 3 years old in the PICU during venipuncture. For those aged less than 3 years old, 24% sucrose solution would be given orally to relieve their pain during painful procedures including venipuncture.

In the literature reviewed, all the 4 studies were conducted in developed country with western culture,
whereas, our target hospital is one of the university teaching hospital which adopted the western medicine. Moreover, all of the studies were taken place in hospital with high diversity of pediatric cases including the emergency department (Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011), pediatric unit and children's cancer center (Moadad, Kozman, Sahine, Ohanian & Badr, 2015), Pediatric Surgical Department (Canbulat, Ayban & Inal, 2015), and phlebotomy station of pediatric clinic (Inal & Kelleci, 2012), which matches the source of admission of our target setting. In addition, the target population of the reviewed studies is similar to that of our target population that the age group of subjects are 7-12 years old (Canbulat, Ayban & Inal, 2015), 4-12 years old (Moadad, Kozman & Shanine, 2015), 6-12 years old (Inal & Kelleci, 2012), 4-18 years old (Baxter, Cohen, Celery, Lawson & von Baeyer, 2011). Therefore, the innovation of the studies can be applied to the target setting and population.

Another important element of transferability is the philosophy of care between the innovation and the target
setting. In the target setting, the philosophy of care is to provide comprehensive and quality care with empathy and expertise. Priority of pain management in the intensive care unit was easily being neglected as most of the attention always focused on the emergency life-saving treatment. However, in recent few years, pain management was regarded as an important management in the target unit that promotion of the use of 24% sucrose solution orally for pain relieve for patients 3 years old or younger had been taken place and continuous pain assessment by nurses had been highly promoted. The aim of the proposed intervention is to decrease the pain of the pediatric patients during venipuncture which fits into the philosophy of care of the target unit.

Venipuncture is a common procedure in the target setting, as all the patients being admitted were in need of IV access for blood taking, or giving intravenous fluid or medication infusion, or in case of any sudden deterioration and need of resuscitation. In my experience, although around
80% of the patients were having IV access on admission, 90% of the admitted patients experienced at least one venipuncture during the stay in the target unit. By estimation, there are around 300 patients being benefited by this intervention annually.

In the reviewed studies, 1 of them provided at most 3 minutes of training on the use of BUZZY to the subjects and their parents prior to venipuncture and applied BUZZY immediately before the start of venipuncture, while the rest of the 3 studies merely applied BUZZY right before the start of venipuncture. In our target setting, parents were not allowed to stay with the patients during procedure, therefore, BUZZY will be applied by the health care provider with the chance to hold by the patients without the need of training before each venipuncture.

Moreover, the evaluation of pain was done immediately after the procedure in all the studies.
3.2. Feasibility

In the target setting, venipuncture of pediatric patients, unless assessed and permitted by Medical Officer (MO) to be done by Houseman Officer (HO), was performed by the MO or more senior medical staff as every site for venipuncture was very precious in pediatric patients that some of the venous access site have to be reserved for Percutaneous Intravenous Central Catheter (PICC) insertion. This procedure is usually done with the help of nurses to stabilize sooth and calm the patients. Therefore, support of using the proposed intervention had to be obtained from both parties.

In view of the succeed in setting up the protocols and guidelines by nurses to enhance patients’ comfort and nursing care in the target setting currently, such as the administration of 24% sucrose solution during invasive procedures as pain relieve for patients who are 3 years old or younger, nurses autonomy and freedom in developing new guidelines along with administrative support from the Chief of Service (COS), Departmental Operation Manager (DOM),
Director of department, Nursing Consultant (NC) and Ward Manager (WM) were demonstrated. Moreover, a support group led by the NC in the target setting is present in promoting evidence-based practice through teaching and helping nursing staff in appraising and analyzing research studies; and help in developing evidence-based protocol. In addition, subsidies were given to nursing staff in local and overseas training and encouraging the development of evidence-based protocol in the target unit.

In addition, in the target unit, a new or updated device is introduced to the ward every 2 months in average with high acceptance for trial and feedback. In view of that, high acceptance of new devices and ideas were demonstrated in the ward. Therefore, the proposed intervention is feasible to be carried out in the target unit organizationally.

Another in-negligible aspect of feasibility is the from the users' point of view. For the reason that BUZZY is a brand new device and idea in the target ward, training and education on the benefits, uses and precaution had to be
given to all nursing and medical staff. As BUZZY is a simple device with only 2 parts had to be assembled and 1 button for on-off, around 15-min training time would be needed. In the target setting, a 15-min talk is scheduled during the handover time between morning shift and evening shift which was conducted by nurses in turns to update or share new ideas or protocols. The introduction and training of using BUZZY to nurses can be launched during that period of time. In addition, as nurses are usually present during venipuncture by doctors, the application of BUZZY could be performed by the assisting nurse to replace the application of tourniquet without introducing interference to the current nursing practice and no extra manpower was needed during the intervention phase. Therefore, the intervention should be feasible to be performed in the target unit to this extent.

For doctors, even though this device was introduced as a pilot in 2014; and the doctors of the pediatric department in the target hospital were rotated from times to times between different pediatric wards that some of the PICU doctors might had experiences in using BUZZY, there are still part of the
PICU doctors have not heard of it. Consequently, barriers might be present for some of the doctors might be have the thought that using this device might lower down the successful rate in venipuncture as this is not their usual practice. Also, extra training time had to be squeezed out from their heavy workload and tight working schedule. In short, resistant to change is one of the potential barriers.

For the evaluation, assessment on the level of pain experience by the patients has to be done immediately after the procedure using validated pain measuring tool. In the target setting, Wong Baker Pain Scale (WBPS) is the pain assessment tool adopted and commonly used. All the nursing staff was familiar with and well-trained to use it. However, extra time will be needed for evaluating and recording the pain score during venipuncture which might lead to opposing sound from nursing staff.

Apart from evaluating the effectiveness of reducing pain in children during venipuncture, collecting opinions from doctors and nurses are also very important in the evaluation.
phase. Therefore, extra time had to be consumed for users to complete and respond to the survey about the comments on usage which might also be one of the potential barriers in promoting this intervention.

Another potential barrier is concerning the availability of the device in the target unit. As the concerning device was not available in the target unit, previous arrangement in obtaining the device for training and promotion had to be done. This device is invented and originated from a company located in Atlanta and there is only one distributor in Hong Kong, yet, there is no trading history between the distributor and the target unit. Therefore, this would be another potential barrier in getting access to the materials needed.

With the above feasibility issues discussed, in order to carry out the proposed intervention, resolving plans had to be developed which will be further discussed in the next chapter.
3.3. Cost-benefit ratio

In proposing a new intervention, other than transferability and feasibility, its risks and benefits should be explicitly reviewed. There is no risks and side-effect of using BUZZY in patient aged 4 or above reported in the reviewed study or from the manufacturer, yet, discomfort might be experienced by the patients or cold panniculitis might be caused due to the direct and prolong contact of ice-pad with their skin (Polcari and Stein, 2010). Although there is potential risk in using BUZZY as there might be a direct contact of ice-pack to the skin, prevention could be done by closely monitoring any discomfort experienced during the intervention and discontinuing of the device abruptly if discomfort was noted. On the other hand, with proper use of the device under close observation, pain was reported to be reduced in the reviewed studies (Canbulat, Ayban & Inal, 2015; Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011; Inal & Kelleci, 2012; Moadad, Kozman, Shahine, Ohanian & Badr, 2015). In contrary, if pain was not well managed during
venipuncture, not only the patients will suffer from pain, various negative impacts might also be resulted including increased distress in the next venipuncture or even develop needle-phobia (Leahy, Kennedy, Hesselgrave, et al, 2008; Thurgate and Heppell, 2005) which might increase the difficulty in having them cooperate during the upcoming intervention and might decreased their willingness in blood donation when they grow up (Olatunji, Etzel, Ciesielski, 2010). Therefore, it is obvious that the benefits of using BUZZY outweighed its risks as the risk is preventable with proper nursing care.

The cost of carrying out the intervention was calculated with the estimation of 300 admissions per year in the target unit. With the statistic from the target unit, the average venipuncture per case is 1. Therefore, the estimation of venipuncture in a year was estimated to be 300. With reference with the study by Baxter, Cohen, McElvery, Lawson and von Baeyer in 2011, each device can be used for at least 20 hours which was estimated to be able to serve for 308
attempts. Along with the power needed for demonstration and training, 2 more AAA batteries which was provided as top-up items from the hospital authorities would be needed in a year. The device as a package with 1 vibration device (the BUZZY), 4 reusable ice-pad (wings), 1 Silicone Comfort Strap which can be replaced by the existing tourniquet in long rung, 2 AAA Batteries (preinstalled in unit) and 1 Instruction Manual costs USD69.9 (around HKD 550). Other than the cost of the device, maintenance cost would be the cost for cleaning utensils which were already available in the target unit and the warranty cost which is included along with the purchase for 12 months. Therefore, with all the manpower and material cost calculated in the budget plan (Appendix VI), the total annual cost for the intervention is HKD 2050.

3.4. Evidence-based Practice Guideline

The evidence-based practice guideline (Appendix VII) was developed to summarize and synthesize the clinical evidence from the reviewed articles; to formulate a clinical practice instruction with standardized method in using BUZZY
to reduce pain level of patient aged 4-17 years old that are in
need of venipuncture. The target users of this guideline are
all the nursing and medical staff working in the PICU who is
responsible in taking care of patients during venipuncture or
performing venipuncture respectively. Four
recommendations were made on the evidences from the
reviewed articles and graded according to the Grade of
Recommendation (SIGN, 2004) with reference to the level of
evidence of the reviewed articles.
4. Implementation Plan

After discussing the implementation potential and the clinical guideline on using the BUZZY to reduce pain in pediatric patients during venipuncture, an implementation plan should be developed including the communication plan, pilot study plan and evaluation plan.

4.1 Communication Plan

The communication plan will start with the identification of stakeholders as it is a crucial step in implementing a new evidence based practice. It helps in addressing the purpose of the change and reducing confusion, hence facilitating the implementation of the practice (Schmidt & Brown, 2012). In the administration level, approval has to be obtained from the Cluster General Manager in Nursing (CGMN) who is responsible in approving guidelines and funding.

For the managerial level, the stakeholders are the Chiefs of Service (COS) and the Director of the Pediatrics and Adolescents Medicine Department, Department Operation
Manager (DOM), Ward Manager (WM), Nursing Consultant (NC), Advance Practice Nurse (APN). As this guideline does not only include nursing practice, it may also influence the practice of the pediatricians; approval should also be obtained from the COS. Also, support from the director is important as he is responsible for updating the guidelines and provides training for pediatricians. Moreover, WM and NC are the key stakeholders as they are in charge of all the resources and management of the ward activities. Apart from the above, APNs are also part of the key stakeholders in managerial level as they are responsible for providing training, updating new practices and arranging resources.

Medical Officers (MO), House Officers (HO), APN, Registered Nurses (RN), Health Care Assistance (HCA) and Technical Care Assistance (TCA) are the stakeholders in operational level. In the target setting, MO and HO are responsible for performing venipuncture with the help of RN or APN. HCA and TCA are responsible for storing and cleaning of medical utilities.
Effective communication is important in promoting and implementing a new guideline as it can avoid misunderstanding and misconception. With the identification of stakeholders, specific communication plan could be developed to meet their needs.

A core committee will be formed by staff that share similar thoughts and interested in promoting the change. Having the involvement of APN and RN, point of view from the managerial and operational level could be taken into consideration. Therefore, apart from the proposer, recruitment of two APNs and five RNs, which is the usual component of a committee in developing evidence-based guidelines in our clinical setting as to cover the shift duties, will be done to form the core committee. After forming the core committee, internal meetings among committee members will be held to work out the implementation plan. A detailed introduction will be done by the proposer in the meeting; literature reviews and limitation of the current practice as well as the benefit of the proposed plan will be
discussed. With a thorough understanding of the proposed idea, possible resistance will be discussed and anticipated in the meetings. After synthesis of ideas among members, strategies of change will be developed. Implementation schedule and budget plan will then be worked out with the practical guidelines, recommendations and training plan.

With plan for change developed, meetings with different stakeholders will be arranged individually to propose the change and discuss on their concerns to gain support and approval. Information sheets with details of proposed guideline, literature review and implementation plan will be prepared for individual meetings. For the meeting with the NC and the Director, limitation of the current practice and benefit of the proposed guideline will be stressed supported with literature reviews. Also, detailed practical guidelines will be discussed to recognize their concerns and beliefs. With their comments and recommendations, appropriate modification to the guideline and plans could be made as they are expertise in developing protocols and guidelines.
With the polished guidelines and plans in hand, meeting will be arranged with WM. As manpower and resources would be the main concern of WM, besides the proposed guideline, implementation and budget plan, no extra manpower for the implementations and the reusability of the equipment with 12-month warranty using the existing cleaning utensil supplied by the hospital authority would also be clearly illustrated.

With the support from WM, meetings with DOM, COS and CGMN will be arranged. For human resources and budget plan would be their main concern, detailed information on manpower arrangement and budget plan will be explained along with the illustration of cost-benefit ratio to obtain support and approval.

After obtaining approval and support, introduction and training has to be arranged for all frontline staff involved. For the committee members, training will be provided with the demonstration from sales representative of the manufacturer in order to provide accurate and correct usage of the BUZZY. After the completion of this training session, all committee
members will be the trainers of the device. Having all the
committee members being the qualified trainers, introduction
of the guideline, with information sheet, and quick references;
and demonstration of the use of the BUZZY will be presented
by them in turns during the “15-mins talk”, which was set
within the overlapping hand-over time between morning and
evening shift, for a week. Apart from introducing the proposed
intervention, trainers will also be the resource persons who
are responsible in assisting and giving advice on the
intervention.

Sustaining the change is as essential as initiating the
change. In order to sustain the change, concerns and
comments from users are very important. Therefore, feedback
from nurses will be gathered by the use of an evaluation form
to be filled in and random interview with the users after using
the device concerning the intervention alone and the
facilitation of the intervention.
4.2 Pilot Study Plan

After one month of recruitment of core committee members and one month for meetings and resources preparation, a pilot study will be carried out for 3 months to explore the feasibility of the implementation of the proposed intervention. Besides, we can also evaluate the acceptability of the staff and obstacles faced, so that modification could be made before full implementation accordingly.

The pilot study will only be carried out during A/ P shift as the manpower during N shift is limited. The inclusion criteria of the pilot study will be same as the one in the proposed innovation so as to maintain the consistency and avoid misunderstanding. Patients in the PICU who needed to receive venipuncture will be recruited into the pilot study by convenient sampling. A quick reference guideline on the inclusion criteria, usage of the device, pain score and a usage log for recording brief information of the sample will be put together with the device at the tray prepared for venipuncture. A reference folder will also be prepared by the
core committee including the detailed information about the proposed intervention, literatures, guideline on the usage of the device, pain score and, survey for nurses and doctors.

Upon the end of the pilot study, evaluation of the outcome would be done by the core committee member in the following aspects: compliance, satisfaction and feedback from users. Staff compliance will be evaluated by cross-checking the pain score and usage log and the patients who meet the criteria among the period of pilot study. Also, random spot check will also be done by the core committee members. Apart from compliance, staff satisfaction and feedback are also very important in the pilot study as this can help improving and modifying the guideline. Collection of opinions would be done by inviting all the users including doctors and nurses to complete a survey which will be in a format of Likert 5-point scale with questions covering workload, resources, difficult overcame and open ended question collecting feedback.
With all the feedback from nurses and doctors, the feasibility of the proposed innovation could be assessed. Also, with all those valuable opinion collected within the 3 months pilot study, revision and modification of guidelines will be done by the committee members in the following month before putting into full implementation. Having the renewed guideline, full implementation will be carried out for 5 months, in which, the proposed innovation will be in full practice during all the shifts, and, evaluation will be done after this period of time.

4.3 Evaluation Plan

Evaluation is an important part of implementing an evidence-based practice as it can identify the improvement and accountability of promoting the innovation and increase support in the new intervention (Mateo & Kirchhoff, 2009). Therefore, after implementation of the proposed intervention for 5 months, evaluation will be taken place for 1 month. An outcome-based evaluation would be taken place, therefore, an evaluation plan would be developed with the identification and
measurement of outcomes, design of the study, calculation of sample size, data analysis, and basis for implementation identified.

**Identification and measurement of outcome**

The outcome of the intervention was identified in the aspect of patients’ outcome and healthcare providers’ outcome. The patients’ outcome which is the primary objective of the innovation is to reduce the pain level of paediatric in-patients during venipuncture. Wong Baker’s Face Pain Score (WBPS) with score 0-5 would be used for measuring the pain level of the patients experienced during venipuncture as it is a validated measuring tool for patients older than 3 years old. Also, this measuring tool was easy to use by observing the facial expression by nurses or choosing the appropriate face from the WBPS by the clients and it is used extensively in the clinical setting. The pain score would be completed by the nurses through observation or asking the subjects, and documented in the daily progress note immediately after the procedure.
For the healthcare providers’ outcome, satisfaction, acceptability and compliance would be assessed throughout the implementation period and evaluated by the end of the 5 months implementation. A survey (Appendix IIX) with the use of Likert Scale concerning the workload, difficulty, acceptance; and open-ended questions for collecting comments and suggestions would be distributed and to be completed by all the staff after using the device. Compliance will be assessed by random check that the committee member will observe the process if venepuncture was done in their shift of duties, and comparing the number of eligible patients with the number of patients received the proposed intervention.

**Design**

All the eligible subjects would be assigned to the intervention group and the control group without the proposed intervention taken place alternatively as it is impossible and unethical to perform the venepuncture twice to assess the pain difference in the same subjects with and without the use of the proposed intervention. Therefore, independent t-test will be
used to compare the pain score of two groups of subjects to evaluate the reduction in pain during venipuncture with the use of the proposed innovation.

**Sample size**

Sample size is calculated by the use of the G*Power program with reference to the study by Moadad, N., et al. (2015) as the eligible criteria of the study including the age group, 4-18 years old, was exactly the same as that of the proposed innovation and the measuring tool used in the study was also the WBFS. In the study, the SD was 2.22-2.62 for the pain score measured by the nurses and the reduction of pain score was from 4.9 to 3.04 which was reduced by 37.2%. With reference to the study by Moadad, et al., (2015), effect size calculated was $d$: 0.766. With the power of 80% and the acceptable type I error as 0.05, the total sample size needed is 76 patients. The dropout rate would be expected to be 0% as intervention would be a one-time procedure. In my experience, there are about 300 eligible subjects in the clinical setting in a year; therefore, 5 months are sufficient enough for the full implementation.
Data analysis

The pain score of the two groups will be analysed using SPSS. In order to identify the reduction in pain experienced by the patients during venipuncture, independent t-test will be used to determine if the pain score among the intervention group is lower.

Satisfaction and acceptance will be evaluated by calculating the score of the 5-point Likert Scale survey completed by the staff. Moreover, all qualitative data including the comments and suggestions from staff would be summarised into a written report.

4.4 Basis for Implementation

For the patients’ outcome, the reduction of the pain score in the intervention group will be compared to the control group. With reference to the study by Moadad, et al. (2016), in which the reduction of pain among the intervention and control group was 37.2%, having 30% reduction in pain score reported in
the intervention group comparing to control group would be considered as effective.

For the health care providers’ outcome, acceptance from health care providers is aimed to be received. As this is a totally new innovation in the target setting, resistance in promotion and implementation was expected. Therefore, with the average score calculated in the survey completed by the users higher than 50%, the innovation would be regarded as feasible with acceptance from health care providers.

With the above two outcomes achieved, the implementation would be fully implemented in the target setting.

5. Conclusion

Venepuncture is a commonly seen procedure (Linhares et al., 2012) which was among the top three most painful procedures by children in hospitals (Ortiz, Lopez-Zarco & Arreola-Bautista, 2012). Also, the adverse effects of unmanaged or undertreated pain from
procedures was found to be multi-dimensional including physical, behavioural and emotional (Dunwoody, et al., 2008; Pawar & Garten, 2008; Leahy, Kennedy, Hesselgrave, et al., 2008; Noel, Chamber, McGath, Klein & Stewart, 2012; Thurgate and Heppell, 2005). Therefore, the pain brought by venepuncture should be well addressed and managed in children.

From the literature review, all the studies had showed the effectiveness in reducing pain level of pediatric patients using BUZZY during venipuncture. Moreover, with the evaluation of the transferability, feasibility and cost-benefit ratio, the new practice was believed to be applicable in the target setting.

In summary, an evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture should be developed.
### Section 1: Internal validity

**In a well conducted randomised controlled trial (RCT) study...**

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<th>Notes</th>
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<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
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</table>
|   | Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.  
  **Yes** - if elements of the research question are present in the text.  
  (Note that this does not have to be exactly in the PICO format, but all the elements must be present).  
  **No** - if there is no clear question in the text. This would normally result in rejection of the paper. |
| 1.2 | The assignment of subjects to treatment groups is randomised |
|   | Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.  
  **Yes** - if a good randomisation method is used such as computer generated off-site allocation. If a poor randomisation method is used such as a coin-flip then mark as ‘yes’, but mention in notes that the randomisation method was poor.  
  **No** - if alternate allocation used or deterministic methods such as day of the week, birth date, day of arrival at the clinic etc.  
  **Can’t say** – if randomisation is mentioned but method not specified. This must be mentioned in the notes field and will downgrade the study. |
<p>| 1.3 | An adequate concealment method is used. | Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. <strong>Yes</strong> if centralised allocation, computerised allocation systems, sequential use of numbered/coded identical containers or sequential, numbered, sealed, opaque envelopes. <strong>No</strong> if method of concealment used is regarded as poor, or relatively easy to subvert (such as investigators being able to access the sequence or use of non-identical containers or unsealed envelopes). Mark as ‘no’ if no concealment method is reported. <strong>Can’t say</strong> if concealment is mentioned but not described. This must be mentioned in the notes field and will downgrade the study. |
| 1.4 | The design keeps subjects and investigators ‘blind’ about treatment allocation | <strong>Yes</strong> - It is important to assess who was actually blinded not what the authors call it. <strong>No</strong> - if the study could have been blinded, but was not. <strong>Can’t say</strong> – if the presence of blinding is not clear. The notes field should record the type of blinding used and any issues that this could have had on the results. |
| 1.5 | The treatment and control groups are similar at the start of the trial. | The study should report any important differences in the composition of the study groups with regard to characteristics that could affect response to the intervention being investigated eg sex, age, stage of disease, social background, ethnic origin, co-morbid conditions. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded. <strong>Yes</strong> - if the patient groups look reasonably similar. <strong>No</strong> - if the patient groups have important differences in factors that may influence the outcomes. <strong>Can’t say</strong> – if the patient groups have not been adequately described |
| 1.6 | The only difference between groups is the treatment under investigation. | If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. Yes - if there appears to be no important differences between treatment groups other than the treatment being studied No - if there appears to be an important difference between the two groups. Can’t say – if there is no description of groups |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated it should be rejected. If the study bases its main conclusions on secondary outcomes make a clear note of it in section 2.4 and clearly report the results from the primary outcome. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study. Yes – if there are clearly described outcome measures. No - if measures are entirely subjective and based on human judgement with no validation. Can’t say – if measures are unclear |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the dropout rate may be expected to be higher in studies conducted over a long period of time. A higher dropout rate will normally lead to downgrading, rather than rejection of a study. |</p>
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<th>1.9</th>
<th>All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</th>
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In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analyzed according to the group to which they were originally allocated irrespective of the treatment they actually received. Intention-to-treat (ITT) analysis aims to include all participants randomised into a trial irrespective of what happened subsequently. As the term is often used incorrectly, judgement should be based on the details provided.

**Yes** – if the method used to deal with missing patient data is explained.

**No** - Analysis of participants according to the actual interventions received, irrespective of their randomised allocation; analysis based only on participants who completed the trial and complied with (or received some of) their allocated intervention (per-protocol analysis); analysis based only on participants for whom outcome data were obtained (available case analysis).

**Can’t say** - if there is insufficient information to make an assessment

**Not applicable** - If the trial’s objective is purely explanatory (to determine efficacy rather than effectiveness, that is the extent to which a treatment achieves its intended effect under ideal circumstances) and adequate justification is given for using an ‘as treated’ or ‘per protocol’ analysis.
1.10 Where the study is carried out at more than one site, results are comparable for all sites.

In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

**Yes** - if there is no marked difference in the site data reported or if there is no difference in the centres that can be determined

**No** - if there is one or more sites that have markedly worse or better data than the others. Or if the sites have different characteristics such as community treatment against hospital in-patient treatment.

**Can’t say** - if no site specific data is given

**Not applicable** - if there is only one site.

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

#### 2.1 How well was the study done to minimise bias?

Code as follows

- High quality (++)
- Acceptable (+)
- Low quality (-)
- Unacceptable – reject

Studies which have poor randomisation or treatment allocation concealment are likely to be low quality.

#### 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, how certain are you that the overall effect is due to the study intervention?

This requires clinical input and must be addressed by the clinicians on the group.

#### 2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

#### 2.4 Notes. Summarise the authors’ conclusions. Do the results reported in the paper support the conclusions? Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.
Appendix II: PRISMA Flow Diagram

PRISMA 2009 Flow Diagram

Identification

Records identified through database searching

Additional records identified through other sources

Records after duplicates removed (n = 32)

Records screened (n = 13)

Records excluded (n = 19)

Full-text articles assessed for eligibility (n = 4)

Full-text articles excluded, with reasons (n = 9)

Studies included in qualitative synthesis (n = 0)

Studies included in quantitative synthesis (meta-analysis) (n = 4)
### Appendix III: Literatures evaluated using SIGN checklist

#### Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification (Include author, title, year of publication, journal title, pages)</th>
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</table>

**Guideline topic:**

**Key Question No:**

**Reviewer:**

**Before** completing this checklist, consider:

Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:**

1. Paper not relevant to key question □ 2. Other reason □ (please specify):

**Section 1: Internal validity**

*In a well conducted RCT study…* | Does this study do it? |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes v Can’t say □ No □</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. Randomisation on a basis of a computer-generated table of random number.</td>
<td>Yes v Can’t say □ No □</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used. Concealment method was not mentioned.</td>
<td>Yes □ Can’t say v □ No □</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes □ Can’t say v □ No v</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes v Can’t say □ No □</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes v Can’t say □ No □</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way. Pain: Faces Pain Scale- revised Anxiety:Children’s Anxiety and Pain Scale (CAPS)</td>
<td>Yes v Can’t say □ No □</td>
</tr>
</tbody>
</table>
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? 0

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). Yes ☐ No ☐ Can’t say ☐ Does not apply v

1.10 Where the study is carried out at more than one site, results are comparable for all sites. Yes ☐ No ☐ Can’t say ☐ Does not apply v

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias? Code as follows: Double-blind was not applicable to this methodology but the researcher was not involved in the evaluation of pain and anxiety level. Instead parents, subject and another nurse were involved to evaluate the score The observer nurse, parents and subject are blinded to each other’s rating. High quality (++), Acceptable (+), Low quality (-), Unacceptable – reject 0 v

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? Yes. As all the valuables other than the intervention were not significantly different and the reports by parents, observer and subject aligned the same way and showed significant reduction in pain and anxiety level (p<0.05).

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline? Yes.

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. The use of BUZZY which induced the use of vibration and cold stimulation is effective to reduce pain and anxiety level for children aged 6-12 years old during setting up of peripheral IV access when comparing to no intervention being taken.

SIGN Methodology Checklist 2: Controlled Trials


Guideline topic: Key Question No: Reviewer:
Before completing this checklist, consider:

Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):  

<table>
<thead>
<tr>
<th>Section 1: <strong>Internal validity</strong></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In a well conducted RCT study…</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes v Can’t say □</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. Randomisation done by flipping a coin (heads=control, tails=experimental)</td>
<td>Yes v Can’t say □</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used. No information on concealment mentioned.</td>
<td>Yes □ Can’t say v</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes □ Can’t say □ No v</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes v Can’t say □</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes v Can’t say □</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way. Pain: Wong Baker Faces Pain Rating Scale (WBFPS)</td>
<td>Yes v Can’t say □</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>0</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes □ Can’t say □ Does not apply v</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes □ Can’t say □ Does not apply v</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

2.1 *How well was the study done to minimise bias?*  
Code as follows:  
Although double-blind was not applied as the investigators could

| High quality (++) □ |
| Acceptable (+) v |
| Low quality (-) □ |
| Unacceptable – reject 0 □ |
not be totally blinded out for the device had to be applied throughout the procedure, the pain level was not only evaluated by the investigators but also reported by the subject and parents.

| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes. The demographic data didn’t show significant differences in two group of subjects. Also different factors had been evaluated for their relationship with pain level that only BUZZY or no BUZZY showed significant differences. Also, although the pain level reported by the parents didn’t show significant different (p=0.114) between two group, the self-reported and by the nurse showed significant difference (p=0.011, 0.014). Literature showed that the level of correlation of parent’s evaluation of pain level with subjects might varies with the age of the subjects. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | The authors had concluded that the application of buzzy was effective in reducing pain in children in peripheral IV insertion and it was recommended to be put into usual practice. |
## Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification (Include author, title, year of publication, journal title, pages)</th>
</tr>
</thead>
</table>

### Guideline topic: Key Question Reviewer: No:

**Before** completing this checklist, consider:

Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question 2. Other reason (please specify):

### Section 1: Internal validity

**In a well conducted RCT study...**

| 1.1 | The study addresses an appropriate and clearly focused question. | Yes v Can't say □ No □ |
| 1.2 | The assignment of subjects to treatment groups is randomised. Randomised using a computer generated table of random number into 2 equal groups | Yes v Can't say □ No □ |
| 1.3 | An adequate concealment method is used. | Yes v Can't say □ No □ |
| 1.4 | The design keeps subjects and investigators 'blind' about treatment allocation. Subjects were being blinded but the investigators cannot be blinded as the device exists with vibration sound could be heard throughout the procedure. | Yes v Can't say □ No □ |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes v Can't say □ No □ |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes v Can't say □ No □ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. Pain: Wong Baker Face Scale & Visual Analog Scale Anxiety: Children’s Fear Scale | Yes v Can't say □ No □ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0 |
### 1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes □</td>
<td>No □</td>
<td>Can’t say □</td>
</tr>
<tr>
<td>✗</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

#### 2.1 How well was the study done to minimise bias?

- Code as follows:
  - Although double-blind was not applied as the investigators could not be totally blinded out for the device had to be applied throughout the procedure, the pain level was not only evaluated by the investigators but also reported by the subject and parents. Also, for the anxiety level, it was evaluated by another team who were not present during the procedure by reviewing the video tape.

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<td>Low quality (-)</td>
</tr>
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<td>No □</td>
<td>Can’t say □</td>
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<td>✗</td>
<td></td>
<td></td>
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</tbody>
</table>

- Unacceptable – reject 0 □

#### 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

- Yes. The demographic data didn’t show significant differences in two group of subjects. Pre-procedural anxiety level was evaluated and showed no significant difference. (p>0.05)

#### 2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

- Yes.

#### 2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The application of external cold with vibration stimulation was effective in relieving pain and anxiety in children during setting up peripheral IV access when compare to no intervention being administered.
Methodology Checklist 2: Controlled Trials

Study identification  (*Include author, title, year of publication, journal title, pages*)

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<tr>
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</tr>
</tbody>
</table>
### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

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</tbody>
</table>

- High quality (++)
- Acceptable (+)
- Low quality (-)
- Unacceptable – reject

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#### 2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The application of external cold with vibration stimulation was effective in relieving pain and anxiety in children during setting up peripheral IV access when compare to no intervention being administered.
## Appendix IV: Table of Evidence

<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
<th>Sample characteristics (intervention/ control)</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
</table>
Mean age : 8.25/8.61 (p=0.136)  
BMI: 25.41/26.94 (p=0.192)  
Female: 12.5%/14.8% (p=0.82)  
Preprocedural anxiety  
Self-report: 2.03/ 2.11 (p=0.716)  
Parent report: 2.11/ 2.17 (p=0.776)  
Observer report: 2.18/ 2.24 (p=0.768) | External cold and vibration stimulation via Buzzy applied around 5cm above the application area just before the procedure until the peripheral Iv cannulation done (n=88) | No intervention (n=88) | Pain (self-reported)  
1.1 WBFS² (0-10)  
1.2 VAS³ (0-100)  
1.3 Immediately after Anxiety  
2.1 Children’s Fear Scale (CFS) (0-4)  
2.2 Pre-procedure & immediately after Anxiety  
2.3 By parents & observer | Pain  
1.1 WBFC: -2.95 (t=-6.498, p=0.000)  
1.2 VAS: -2.43 (t=-6.065, p=0.000)  |
Mean age: 9.2/9.41 (p=0.55)  
Female(%):31/26 (p=0.36)  
BMI: 17.04/16.76 (p=0.65)  
Preprocedural anxiety CAP⁴  
5.1 Parents report: 2.2/2.16 (p=0.87) | External cold and vibration stimulation via Buzzy applied around 5cm above the application area just before the procedure until the | No intervention (n=60) | Pain: FPS-R⁵  
1.1 By observer nurse, self and parents  
1.2 Pre-procedural & procedural | Pain  
1.1 Self: -3.78 (p=0.001)  
1.2 Parent: -3.7 (p=0.001)  
1.3 Observer: -3.7 (p=0.001)  |

---

1. BMI: Body Mass Index  
2. WBFS: Wong Baker’s Face  
3. VAS: Visual Analog Scale  
4. Children’s Anxiety and Pain Scale: Children’s Anxiety and Pain Scale (Only the part for anxiety assessment was used)  
5. FPS-R: Face Pain Scale – Revised
5.2 Observer report: 2.15/2.05 (p=0.67) 
6. Previous venipuncture: 
6.1 1-3: 46/43 (p=0.53) 
6.2 4-10: 14/17

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>peripheral iv cannulation done (n=60)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>Observer report: 2.15/2.05 (p=0.67)</td>
</tr>
<tr>
<td>6</td>
<td>Previous venipuncture:</td>
</tr>
<tr>
<td>6.1</td>
<td>1-3: 46/43 (p=0.53)</td>
</tr>
<tr>
<td>6.2</td>
<td>4-10: 14/17</td>
</tr>
</tbody>
</table>


1. Age: 4-18 y.o. 
2. Mean age: 10.10/9.91 
3. Female: 41.5/55 
4. Preprocedural anxiety: 
   4.1 self reported: 2/3 (p=0.286) 
   4.2 parents reported: 3/3 (p=0.608) 
5. LMX47 used (%): 46.3/50 
6. Vapocoolant used\(^8\) (%): 40/90

Parents/ clients receive training and practice of the device for max of 3mins
Nurse or the enroller will apply the evice with ice with a strap at the location of the tourniquet. 
(n=41) LMX4 was used for 20 clients (50%)

Nurses were given no direction other than using of their normal practice in which 38 of them received vapocoolant and 2 did not. 
(n=40) LMX was used for 19 clients (46%)


1. Age: 4-12 y.o. 
2. Mean age: 8.48/8.95 (t/ \(\chi^2\)=0.26) 
3. Female(%): 48/52.2 (t/ \(\chi^2\)=0.48) 
4. Previous hospitalisation: 60/52.17 (2 t/ \(\chi^2\)=0.2)

Parents and children holding the device with ice pack attached underneath at 5-10cm proximal to the dorsum of the

No Buzzy. (n=23)

1. Pain: FPS-R\(^9\) 
   1.1 Self-report 
   1.2 Parents report 
2. OSBD\(^10\) by 2 trained students through video tape 

Parents and children holding the device with ice pack attached underneath at 5-10cm proximal to the dorsum of the

No Buzzy. (n=23)

1.1 Self-report 
1.1.1 age 4-8 (n=22) 
1.1.2 age 8-12 (n=26) 
1.1.3 Male (n=24) 
1.1.4 Female (n=24) 
1.1.5 BMI\(^12\)B<23 (n=27) 

1. Pain 
   1.1 -2.07( p=0.011) 
   1.1.1 -2.23 (p=.0007) 
   1.1.2 -1.43 (p=0.062)

---

\(\chi^2\): Chi-squared test

\(^7\) LMX4: a topical anesthetic cream, 4% Liposomal Lidocane; Ferndale Labs, Ferndale, Mich

\(^8\) Vapocoolant used among those who did not receive LMX4 in advance.

\(^9\) FPS-R: Face Pain Scale – Revised

\(^10\) OSBD: Observational scale of behavioral distress

\(^11\) WBFS: Wong Baker’s Face

\(^12\) BMI: Body Mass Index
| IV insertion. Journal of Pediatric Nursing /RCT(1+) | 5. On analgesics: 20/34.7 (t/χ²=0.53) | proposed drip site immediately before procedure. (n=25) | 1.1.6 BMI > 23 (n=21)  
1.1.7 On analgesics (n=13)  
1.1.8 No analgesics (n=35)  
1.2 By observing nurse  
1.3 By parents | 1.1.3 -1.92 (p=0.073)  
1.1.4 -3.33 (p=0.001)  
1.1.5 -1.33 (p=0.081)  
1.1.6 -0.93 (p=0.5)  
1.1.7 -1.37 (p=0.214)  
1.1.8 -2.49 (p=0.021)  
1.2 -1.86 (p=0.014)  
1.3 -1.45 (p=0.114) |
**Appendix V: Rating System for the Hierarchy of Evidence (Melnyk & Fineout-Overholt, 2005)**

<table>
<thead>
<tr>
<th>Level</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence from at least one well-designed RCT</td>
</tr>
<tr>
<td>II</td>
<td>Evidence from well-designed controlled trials WITHOUT randomization</td>
</tr>
<tr>
<td>III</td>
<td>Evidence from well-designed case-control and cohort studies</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence from systematic reviews of descriptive and qualitative studies</td>
</tr>
<tr>
<td>V</td>
<td>Evidence from a single descriptive or qualitative study</td>
</tr>
<tr>
<td>VI</td>
<td>Evidence from the opinion of authorities and/or reports of expert committees</td>
</tr>
</tbody>
</table>
Appendix VI: Budget Plan

### Preparation Cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Unit Price (HKD)</th>
<th>Unit required</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Registered Nurse (Organization)</td>
<td>181/hour</td>
<td>5 hours</td>
<td>905</td>
</tr>
<tr>
<td>2. Venue (Introduction to doctors)</td>
<td>Seminar room in target unit (Free)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Doctors (15mins training time)</td>
<td>Within working hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Nurses (15mins training time)</td>
<td>During 15-mins talk</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td><strong>905</strong></td>
</tr>
</tbody>
</table>

### Running Cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Unit Price (HKD)</th>
<th>Unit required*</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. BUZZY device package:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(12-month warranty)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Buzzy® Mini Healthcare</td>
<td>550</td>
<td>2</td>
<td>1100</td>
</tr>
<tr>
<td>4 Universal Healthcare Wings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ice-pad)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Silicone Comfort Strap</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 AAA Batteries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(preinstalled in unit)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Instruction Manual</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td><strong>1600</strong></td>
</tr>
<tr>
<td>2. AAA Batteries</td>
<td>Top-up items from hospital</td>
<td></td>
<td><strong>1100</strong></td>
</tr>
<tr>
<td>3. Evaluation Survey for nurses and doctors</td>
<td>0.5</td>
<td>1000</td>
<td>500</td>
</tr>
<tr>
<td>4. Freezer for ice-pad</td>
<td>Available in target setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Blood taking utensils</td>
<td>Available in target setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Cleaning Utensils</td>
<td>Top-up items from hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal:</strong></td>
<td></td>
<td></td>
<td><strong>1600</strong></td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td></td>
<td></td>
<td><strong>2505</strong></td>
</tr>
</tbody>
</table>

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*Unit required was calculated by the estimation of 300 admission/year and 1 venipuncture needed for each cases which make up to 300 venipuncture/year.
Appendix VII: Evidence-based Practice Guidelines

Title:

An evidence-based protocol of using BUZZY in reducing pain level of pediatric patients during venipuncture

Background:

In view of the adverse effect of unmanaged or under-treated pain from procedures including venipuncture reported from previous studies that physically, increase in blood pressure, tachycardia and hyperglycemia might happen (Dunwoody, et al, 2008); behaviorally, regressive behaviors or physical resistance and uncooperative might be presented (Pawar, & Garten, 2008), which might increase the difficulty in venipuncture; increase in distress, resistance and pain level during next venipuncture might be expected and rated and might develop needle-phobia in the future (Leahy, Kennedy, Hesselgrave, et al, 2008; Noel, Chamber, McGath, Klein & Stewart, 2012; Thurgate and Heppell, 2005).

In addition, in PICU, there is around 300 admission a year and each admission require 1 venipuncture in average. Although needle-procedure was found to be the most common source of
pain in hospitalized children (Kennedy, Hesselgrave, Gurwitch, Barkey, & Miller, 2008) and was ranked as the second worst experience in the hospital (Wong, Baker, 1988), there is no existing protocol in accessing, managing or reducing needle pain in PICU. Therefore, it is important to set up an evidence-based practice protocol in reducing pain in children during venipuncture.

**Objectives:**

1. to summarize and synthesize the clinical evidence in using BUZZY to reduce pain level of children during venipuncture

2. to formulate an clinical practice instructions in using BUZZY to reduce pain in during venipuncture on the best evidence available

3. to standardize the method in reducing pain level of children during venipuncture in PICU

**Target users:**

This guideline is intended to support nurses of all level who take care of patients during venipuncture and all doctors including
House Officer and Medical officers who are responsible in performing venipuncture in reducing pain level of pediatric patients during venipuncture in PICU.

**Target group:**

Patients aged 4-17 years old who are admitted to the PICU with the need of venipuncture including for venous blood taking with needle puncture and setting up IV access.

**Evidence based recommendation:**

1. **Eligible criteria:**

1.1. Patients should be aged at least 4 years old and less than 18 years old (Grade A)

   **Evidence:**

   The use of BUZZY was effective in reducing pain level of pediatric patients aged 7-12 years old (Canbulat, Ayban & Inal, 2015 [1++]), aged 6-12 years old (Inal & Kelleci, 2012 [1++]), aged 4-18 years old (Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011 [1+])
and aged 4-12 years old respectively (Moadad, Kozman, Shahine, Chanian & Badr, 2015 [1+]).

1.2. Patients who had analgesic within 6 hours of time before the venipuncture should be excluded. (Grade A)

Evidence:

Patients who had analgesics received within 4 hours of time showed insignificant reduction in pain level with the use of BUZZY when compared to the control (p=0.214) (Moadad, Kozman, Shahine, Chanian & Badr, 2015 [1+]). Patients with analgesic received within 6 hours of time before venipuncture were excluded from the studies and results were consistent to be significantly effective in reducing pain with the use of BUZZY when compared to the control group. (Canbulat, Ayban & Inal, 2015 [1], Inal & Kelleci, 2012 [1++]).

2. Application of BUZZY

2.1. BUZZY should be applied to the area 5cm proximal to the proposed site for venipuncture (Grade A)

Evidence:
External cold and vibration stimulation using BUZZY was applied around 5cm above the venipuncture and the result was should to be effective to reduce pain during venipuncture (Canbulat, Ayban & Inal, 2015 [1++], Inal & Kelleci, 2012 [1++]), whereas the device was applied with the same technique at 5-10cm proximal to the proposed venipuncture site and significant reduction of pain during venipuncture was also shown (Moadad, Kozman, Shahine, Ohanian & Badr, 2015 [1+]).

2.2. Application of BUZZY with vibration on should be started immediately before procedure until the venipuncture was successful or failed and needed to be repositioned. (Grade A)

Evidence

External cold and vibration stimulation was started just before the start of the procedure until it was done or repositioned and the result was should to be effective to reduce pain during venipuncture (Baxter, Cohen, McElvery, Lawson & von Baeyer, 2011 [1+], Canbulat, Ayban & Inal, 2015 [1++], Inal & Kelleci, 2012 [1++]),
Inal & Kelleci, 2012 [1++], Moadad, Kozman, Shahine, Ohanian & Badr, 2015 [1+]}. 
Quick Reference guide:

4-18 year-old patient in need of venipuncture who fits into the inclusion and exclusion criteria

Analgesic given within 6 hours?

No

Yes

Excluded

Assemble the BUZZY with its freezing wings (ice-pad)

Apply to 5cm proximal to the proposed venipuncture site and turn the vibration on immediately before venipuncture

Assess the pain level during venipuncture using Wong Baker Pain Scale

Ice-pad still cold?

Yes

No

Successful venipuncture?

Yes

Record the pain level and fill in the nursing survey

Re-locate the proposed venipuncture site
References:


Appendix IIx: Survey for evaluation

Survey on the evidence-based protocol of using BUZZY in reducing pain level of paediatric patients during venipuncture

Please circle the appropriate score for the following sentence.

<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. The protocol is clearly and easily understandable.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. The device is easy to use.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. The pain score is easy to use.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. The quick reference is clear and useful.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. The workload of the new implementation is appropriate.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. You support the new innovation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Other comments/suggestions:

________________________________________________________________________

________________________________________________________________________

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References


venipuncture pain in a pediatric emergency department.

Pediatric Emergency Care 2015, 27 (12), 1151-1156.


Ramsook, C., Kozinetz, C.A. & Moro-Sutherland, D. (2001). Efficacy of ethyl chloride as a local anesthetic for
venipuncture and intravenous cannula insertion in a pediatric emergency department. Pediatr Emerg Care, 17(5), 341-343.


