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## Don't Be Such a Buzzy®Kill: Reducing Pain During Vaccinations in College-Age Students

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# VALPO

**DON'T BE SUCH A BUZZY®KILL: REDUCING PAIN DURING VACCINATIONS IN  
COLLEGE-AGE STUDENTS**

by

**KATHERINE LONG BSN, RN, DNP STUDENT**

**EVIDENCE-BASED PRACTICE PROJECT REPORT**

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

**DOCTOR OF NURSING PRACTICE**

2021

*Katherine Long*

Student

05/05/2021

Date

Advisor

05/05/2021

Date



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## **DEDICATION**

I would like to dedicate this project to my family and thank them for their patience and support throughout the duration of the DNP program. Without their encouragement, love, and continuous prayers with and for me this would not have been possible. Thank you for pushing me toward goals I did not think I could achieve, for giving me shoulders to lean on when I needed them, and always pointing me toward Jesus in my struggles.

I would also like to dedicate this project to my classmates, for whom I have immense respect and have had the privilege of walking alongside while we tirelessly worked toward obtaining a doctoral degree.

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## ABSTRACT

Immunizations play a fundamental role in reducing the occurrence of preventable diseases in the population. Injections related to immunization are the most frequent pain-producing medical procedure implemented worldwide and account for nearly 12 billion injections annually (CDC, 2019; Taddio et al., 2015). These procedures are often perceived as simple but can have a variety of complications including pain. This evidence-based practice project addressed the following PICOT question: In college-aged students receiving immunizations (P), does the Buzzy® device (I) when compared to non-intervention standard of care (C) effectively reduce injection site pain (O) over a 12-week time period (T)? The Buzzy® device, which uses a combination of vibration and cryotherapy, was used to reduce injection site pain. This project took place at a Midwest university health center in northern Indiana, and the sample included 38 college-aged students who met the eligibility criteria and consented to participate. The primary outcome in this project was self-reported pain level. Data were collected using a visual pain scale and associated questionnaire; pre-intervention and post-intervention self-reported pain levels were compared using a paired *t*-test to determine efficacy. The outcomes of this project indicated a statistically significant reduction in injection site pain with use of the Buzzy® device during intramuscular injections. Additionally, the staff at the project site have verbalized intent for continued use of the Buzzy® in the future for needle-based procedures.

*Key words:* immunization, intramuscular injection, needle, pain, analgesia





## CHAPTER 1

### INTRODUCTION

#### Background

Immunizations play a vital role in diminishing the occurrence of preventable diseases in the general population across the globe. Because of vaccines, diseases that could have a detrimental impact on individual life have been significantly diminished in occurrence, with diseases like diphtheria and polio nearly eliminated (CDC, 2018). Injections related to vaccination are the most frequent pain-producing medical procedures performed worldwide. Among pediatric and adult patients alike, vaccinations account for nearly 12 billion injections annually (CDC, 2019; Taddio et al., 2015).

Intramuscular (IM) injections are often assumed to be simple procedures but can have complications. One of the most common complications associated with these injections is pain. There is a large degree of variation in the amount of pain experienced by individuals receiving an immunization. Common factors that affect pain associated with IM injections include anxiety, previous poor experiences, patient position, medication volume and viscosity, chemical composition of the drug, available solution of the drug, rate of delivery, injection technique, and anatomic location of the injection site (Sahin & Eser, 2018).

Studies have been performed using numerous interventions to assist with injection site pain associated with IM injections. These intervention includes z-track technique, local cold application, manual pressure on injection site, slow injection, and topical lidocaine or other anesthetic cream. Overall, there has been supportive data for all of these interventions, but there is no single integrated intervention to optimize pain relief universally (Öztürk, Baykara, Karadag, & Eyikara, 2017; Sahin & Eser, 2018; Taddio et al., 2015). Many times, patients are fearful of injections because they perceive it will be a painful procedure. The patient then anticipates pain, has anxiety, and this can exacerbate or negatively influence the perception of

pain experienced during the procedure. In fact, it has been reported that up to 30.6% of patients experience fear of injections (Sahin & Eser, 2018). With data showing this is an issue that occurs across a variety of ages, situations, and healthcare settings, an intervention is needed to aid in minimizing injection site pain and the associated fear.

### **Data from the Literature Supporting Need for the Project**

The Centers for Disease Control and Prevention (CDC) recommends routine immunization as best practice to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, and adults (CDC, 2019). Many individuals are exposed to needle-based procedures throughout their lifetime, often beginning in childhood with immunizations. As previously stated, up to 30.6% of patients experience fear of injections and pain related to a number of factors which can negatively impact individual health and prevent future vaccination compliance (Sahin & Eser, 2018).

There are several methods of pain management for needle-based procedures including pharmacological and nonpharmacological. Pharmacological methods of pain control include local topical anesthetics such as 5% lidocaine-prilocaine cream, 4% tetracaine gel, 4% lidocaine cream, and needle-free powder lidocaine and iontophoresis. These have not been universally accepted because of their cost and the duration of time required to take effect (a minimum of 15 minutes with a maximum of 60 minutes). Medications also have a higher risk of adverse reactions which can complicate completion of the injection procedure. In addition to this, many alternative interventions are not time-efficient or cost-effective, and require staff training; this does not lend to busy healthcare settings, making the translation to consistent practice unlikely (Canbulat et al., 2015).

It is recommended that interventions for IM injections pain relief should be as noninvasive as possible and have the ability to be administered rapidly to improve pain control (Yilmaz et al., 2019). Some nonpharmacological interventions meeting these criteria include distraction techniques such as watching television and blowing bubbles (pediatrics) and music

distraction. Also included as nonpharmacological are physical techniques such as manual pressure and the use of a ShotBlocker® device to apply pressure at the injection site. While these have supportive data and shown the ability to improve the level of pain individuals experienced, no single integrated distraction technique has shown the ability to consistently optimize pain relief (Sivri Bilgen & Balci, 2019; Taddio et al., 2015; Yilmaz et al., 2019).

Within recent years, the Buzzy® device has come to the forefront of research as a means of convenient, effective pain relief. The bee-shaped device combines tactile stimulation with topical cryotherapeutic analgesia via ice-pack wings. The device acts as a nonpharmacological method of pain relief based on the Gate Control Theory (Ballard et al., 2019; Canbulat et al., 2015; Sahin & Eser, 2018; Sivri Bilgen & Balci, 2019). The combination of distracting vibration along with prolonged cold exposure at the injection site blocks nerve impulses while disrupting the patient's focus during the painful procedure. This device has several advantages including ease of use, a short duration of time to see desired effects, and the ability to easily clean and reuse the device making it more cost-effective (Bergomi et al., 2018). The statistical evidence backing the efficacy of this device has been consistent across the literature, with several sources that declare its efficacy in a variety of populations (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Sahin & Eser, 2018; Sivri Bilgen & Balci, 2019).

#### **Data from the Clinical Agency Supporting Need for the Project**

The facility where this evidence-based practice (EBP) project was conducted is a health center at a private university in northern Indiana serving the faculty and student population. This clinic is not part of a larger organization. The health center staff consists of a director, a physician, three nurse practitioners, a registered nurse, a medical assistant, and a receptionist. The director of the health center, a doctoral educated nurse practitioner (NP), approved the project and served as site facilitator. All other staff agreed to participate with the medical assistant and registered nurse agreeing to use the Buzzy® device accordingly.

The care provided at this facility ranges in age and complexity. It offers easy access for domestic and international college-aged students so they remain healthy and able to pursue their education. Patients' age ranges vary with the vast majority being 18 years of age and higher. The comprehensive services offered are similar to that of any other family practice clinic and provides access to specialties via referral. As of fall semester 2020, campus has mandated both the meningococcal B and influenza vaccines for the student body. A method of pain relief with IM injections is present within this facility which will vaccinate nearly 4,000 students and staff members (Site Facilitator, personal communication, July 3, 2020).

The student body that this health center serves is 68.9% White, 10.1% Hispanic or Latino, 5.3% Black, 6.5% non-domestic international students, 2.3% Asian, 0.1% American Indian, 0.1% Native Hawaiian or other Pacific Islander, and the remaining 7.7% identifying as more than one ethnicity or one that was not listed. As of fall 2019, only 7.3% of students were registered as part-time; the remaining 92.7% were registered as full-time students (University in Northern Indiana, 2019).

The town where this EBP project was located is in the northern part of Indiana and has a population of 35,501 people. The poverty rate is 13.6% and the median household income is \$52,507 annually. The race and ethnicity statistics are as follows: 86.4% White, 3.06% Black or African American, 2.48% Asian, 0.83% two or more races, 0.25% American Indian or Alaska Native, 0.17% Native Hawaiian or other Pacific Islander, and 0.47% other (Data USA, 2017).

### **Purpose of the Evidence-Based Practice Project**

The purpose of this EBP project was to reduce the amount of pain experienced with IM injections in college-aged students. The literature supports a need for holistic care approaches for individuals with needle fear through physical and psychological components during needle-based procedures such as immunizations. By using an evidence-based intervention for this EBP project, the incorporation of a systemic search of the literature, and assimilation of critically appraised research this allows to work towards goal achievement of vaccination injection site

pain reduction. Reaching this goal provides for not only IM injection pain relief, but improving the individual's overall experience and future adherence to healthcare.

### **PICOT Question**

This evidence-based practice project will address the following PICOT question: In college-aged students receiving immunizations (P), does the Buzzy® device (I) when compared to non-intervention standard of care (C) effectively reduce injection site pain (O) over a 12-week time period (T)?

### **Significance of the EBP Project**

The fear of needles or in severe cases, needle phobia, typically begins at a young age and can carry through to adulthood. Fear of needles contributes to a variety of notable, harmful consequences such as vaccination noncompliance and avoidance of health care. Additionally, needle fear is a known contributor to vaccination hesitance, making the alleviation of injection site pain a public health issue that can have a significant impact (McMurtry et al., 2015). The Buzzy® device has been shown to have statistically significant results in diminishing injection site pain in both children and adults (Sahin & Eser, 2018; Canbulat, Ayhan, & Inal, 2015; Tadio et al., 2015). By using a nonpharmacological intervention based on the Gate Control Theory, pain can be diminished without the associated risks of using another chemical substance and considers the practicality of time efficiency (Canbulat, Ayhan, & Inal, 2015). Assuaging injection site pain in adults and children can aid in the promotion of future vaccination compliance and have a meaningful, positive impact on individual's perception of health care. Lastly, it has important indications for public health as a whole by facilitating the empowerment of individuals to receive recommended routine vaccinations and further global efforts to diminish preventable diseases.

## CHAPTER 2

### EBP MODEL AND REVIEW OF LITERATURE

#### Evidence-based Practice Model

A variety of evidence-based practice models were reviewed and analyzed to determine the best fit for application to this project. After a thorough evaluation, the Johns Hopkins Nursing Evidence-Based Practice Model (JHNEBPM) was selected as a guide for project development and implementation. This model was created specifically to transition EBP into the clinical setting for clinical, educational, and operational practice (Melnyk & Fineout-Overholt, 2019).

#### Overview of EBP Model

The JHNEBPM model was initiated in 2002 after a gap was recognized in the standard of nursing practice by the organizational leadership at Johns Hopkins Hospital (JHH). The deficiency was in the translation of research to practice. A team was formulated with the endeavor of accelerating the conversion of best practice research principles for nurses to practice in both the clinical setting and at bedside (Melnyk & Fineout-Overholt, 2019).

By including nurses as key stakeholders in the development and piloting of this model, it ensured that the model would be formulated with nursing feedback and evaluation. The construction of the JHNEBPM allowed for a clear delineation of the EBP process, with mentored steps and tools to accompany each phase of the process. When using the model, a person starts by formulating an inquiry related to best practice about a clinical problem. The next step is initiating the practice question, evidence, and translation (PET) process. The PET process is the core of the JHNEBPM, with 19 steps outlined among the three phases. The steps begin with the recruitment process of an interprofessional team and progress through dissemination of findings (Melnyk & Fineout-Overholt, 2019).

The first phase, practice question, prioritizes the recruitment of an interprofessional team and the refinement and defining of the clinical problem and EBP question. Key stakeholders are

identified, responsibility of project leadership is determined, and a schedule of team meetings is completed. During the evidence phase, an internal and external search for evidence is performed. Appraisal of the evidence is achieved to determine its level and quality. The evidence is then summarized and a synthesis of the findings, quality, and strength is generated. Next, recommendations for changes in practice are developed based on the body of literature and evidence synthesis. During the final phase, translation, recommendations are analyzed to determine fit, feasibility, and appropriateness. Once this occurs, the project leader can create an action plan, secure support and resources for implementation, implement the action plan, appropriately evaluate outcomes, report findings and outcomes to stakeholders, identify next steps, and disseminate the findings (Dang & Dearholt, 2017).

### **Application of EBP Model to DNP Project**

This model is particularly useful as it acknowledges internal and external factors and how they influence the process of problem-solving and clinical decision making, which incorporates participation from a variety of key stakeholders (Dang & Dearholt, 2017). This is an essential part of any EBP project, especially with the setting for this EBP project being performed at a university. The considerations in this setting include the impact of external factors on schools, academic calendars, and a higher level of inquiry from parents and other associated stakeholders.

The 19-step process outlined in the JHNEBPM across three phases was used for the planning, development, implementation, and translation of the Buzzy® device into practice. In the first phase, a practice question was raised regarding the best practice for reducing injection site pain in college-age students receiving IM injections. Key stakeholders at the practice included a physician, three NPs, a registered nurse, and a medical assistant. Other key stakeholders included participants and their families. Evidence regarding the efficacy and usefulness of the Buzzy® device was discussed with stakeholders and identified as being helpful for college-age students being seen in the health center for IM injections. The Buzzy®



device was selected for implementation because it met the needs outlined by the initial gap in practice and addressed the practice question with supported evidence from the literature.

### **Strengths and Limitations of EBP Model for DNP Project**

When assessing the usefulness and applicability of the JHNEBPM, a number of strengths and weaknesses were identified. A strength of the model is its creation for nurses to translate research into best practice in the clinical setting. By using it as a guide for an EBP project in a doctoral level nursing program, a certain level of continuity can be achieved. Both the end goal of the project and the model are the same because they identify and implement best practice in a way that applies to nurses, clinicians, and other medical professionals. In addition to this, the model integrates multiple noteworthy facets into this translation such as education, current practice, research, and practicality. This allows for the model to provide a best practice recommendation which is approachable and versatile guiding a change in practice. Also, it provides support for the implemented practice to be practical and sustainable for long-term inpatient and outpatient settings.

An added strength of the JHNEBPM is its recognition of the value of non-research data. A well-rounded, comprehensive look at the literature can be achieved and less tangible variables can be considered because this model excludes scales to assess expert opinion and valuable qualitative data (Melnik & Fineout-Overholt, 2019). Finally, the JHNEBPM is structured in a way that allows the researcher or project leader to introduce new questions throughout the project. The structure allows for new EBP processes to be initiated without interrupting the cycle of inquiry, evidence-gathering, and dissemination. This type of open system contributes to the development of best practice by encouraging the pursuit of relevant and influential information without disrupting the ultimate ambition of best practice.

Limitations of the JHNEBPM are present, and one of them can be extracted from its strengths. Even though the model clearly delineates steps of the EBP process, the 19 steps associated with the three phases make it detailed and can appear complex. For a novice project

leader, these steps are extremely helpful in guiding an effective project, but to an expert the 19 steps may be deemed excessive or constricting to the EBP process.

## Literature Search

### Sources Examined for Relevant Evidence

The literature review for this project initiated in the Joanna Briggs Institute (JBI) and Cochrane Library databases. These were selected initially because they tend to offer high level and quality evidence guiding best practice for setting new standards of care. Relevancy for this literature search was determined via inclusion and exclusion criteria which included strategies to decrease injection site pain with needle-based procedures and excluded pain relief with needle-based procedures where the primary cause of pain was not at the injection site (i.e. lumbar puncture). Additionally, nonpharmacological methods were preferred not required, and the method had to transfer to the adolescent or young adult population in the primary care setting.

JBI was the first database searched for quality systematic reviews, using key terms *immunization AND pain*. The limiters used in this database for the search included evidence published within the last five years. This search yielded 32 results, of which five were relevant but were evidence summaries or protocols and were ultimately excluded. Another search was performed using the terms *intramuscular injection AND pain*. This search yielded 25 results, of which eight were relevant. These included evidence summaries and protocols, along with one systematic review. Citation chasing resulted in three useful articles also found in Medline with Full Text. Ultimately, the systematic review was excluded because the reported confidence in the evidence was low.

The next database searched was Cochrane Library. Initial key terms searched included *"intramuscular injection\*" AND pain\**. Limiters included publication between January 2015 and June 2020 and English language. With these key terms, there were 22 results, and none were relevant. To make a more accurate search, key terms were modified to *immunization OR needle AND pain\* OR analgesia*. The limiters of publication between January 2015 and June 2020

were used, along with English language. There were 125 results, of which eight were relevant. Ultimately, these were excluded because seven applied to specific pediatric populations such as newborns or children undergoing specific treatment and involved interventions not transferable to the adolescent and young adult population. The eighth result was excluded because the recommended intervention could not be practically applied to the primary care setting. An additional search was performed in Cochrane using the key terms *needle AND pain*. This search yielded 86 results, four of which were relevant to pain relief with IM injections but were excluded as the interventions assessed were not relevant to the project's population.

After Cochrane Library was thoroughly explored, the Trip database was searched. This database is known to be useful in finding established clinical practice guidelines from various reputable organizations in medicine. The key search terms used for the best search were "*intramuscular injection\**" AND *pain\**. The limiters used in this database included evidence published within the last five years and USA guidelines. From this search, there were 21 results, of which none were relevant based on the aforementioned criteria.

The literature search continued in Medline with Full Text. Best search key words included "*intramuscular injection\**" OR "*IM injection\**" AND *pain\** AND *adult\** OR *adolescen\**. Limiters used in the search included evidence published within the last five years, English language, and Scholarly (Peer Reviewed) Journals. This search yielded 157 results, 21 of which were relevant and three duplicates which were found through citation chasing in JBI. An additional search was performed with the same previous key terms and limiters, plus "*needle insertion.*" This search yielded 175 results, but none of the new pieces of evidence were found to be relevant.

After a comprehensive search of Medline with Full Text, a search was performed in CINAHL. The initial search included key terms "*intramuscular injection*" OR "*IM injection*" AND *pain* OR "*pain reduc\**" OR "*pain relief*" OR "*pain manag\**" AND *adult\** with limiters including evidence published in the last five years, English language, and Scholarly (Peer Reviewed)

Journals. The search came up with 53 results, but was refined to include key terms and truncation symbols “*intramuscular injection\**” OR “*IM Injection\**” AND *pain\** AND *adult\** OR *adolescen\** with the same limiters previously mentioned. This search yielded 76 results, 14 of which were relevant and five of which were duplicates of articles found within Medline with Full Text.

Once the majority of articles were found, references were reviewed to ensure saturation had been achieved and all sources had been exhausted. Through citation chasing, three articles were found which were included within this project. One was through an article found in Medline with Full text, and the other two were found via ValpoScholar in another evidence-based practice project titled *What's all the Buzzy® about? Using Cryotherapy and Vibration for Pain During Vaccinations in Children*. After going through the references to ensure saturation, two more articles were found and included. Additionally, a hand search was done on the Buzzy® website, which gives access to a variety of articles with supporting evidence for this device. The studies that met the inclusion and exclusion criteria had already been found in other databases. The summary of selected data for this project can be referenced in Table 2.1.

### **Levels of Evidence**

The evidence leveling and appraisal tools selected for this project were the Johns Hopkins Nursing Evidence-Based Practice (JNHEBP) research appraisal tools. These tools provide the user the ability to both level the evidence and determine the quality with established criteria to minimize error due to subjectivity. For example, when appraising randomized controlled trials (RCTs) or systematic reviews, there are three questions asked of the appraiser. If the answer to all three questions is “yes,” then the article is determined to be level I, or the highest level of evidence.

The majority of the selected evidence for this project comprises of level I and level II evidence. One piece of evidence was level IV according to the JNHEBP research appraisal

Table 2.1

*Evidence Search Table*

Database	Yielded	Duplicates	Reviewed	Accepted
JBI	25	0	8	1
Cochrane	125	0	4	0
Trip	21	0	0	0
Medline	157	3	21	5
CINAHL	76	5	14	1
Citation Chasing	8	0	6	3
Total	412	8	53	10

tools. This was included because it offers clinical practice guidelines relevant to this project and is categorized as level IV because it qualifies as expert opinion.

### **Appraisal of Relevant Evidence**

The quality of the evidence (high, good, or poor; Grades A, B, or C, respectively), according to JHNEBP, is determined by whether the results were consistent or generalizable, a sufficient sample size was present, consideration of the study design, if there was adequate control, and the quality and comprehensiveness of the literature review done prior to initiating the study that indicates consistent recommendations (Dang & Dearholt, 2017). The tool asks the appraiser 12-15 questions dependent on the type of evidence being appraised in order to simply and logically level as well as appraise the evidence.

Depending on the appraiser's answers to the questions within the tool, certain conclusions can be drawn. There is a level of subjectivity and critical thinking on the part of the appraiser that can result in variability due to opinion. All evidence used for this project was determined to be of Grade A (high) or Grade B (good) quality. Table 2.2 summarizes included evidence for this EBP project.

### ***Level I Evidence***

**Ballard et al. (2019).** This article is a systematic review and meta-analysis published by Ballard et al. (2019) discussing the efficacy of the use of the Buzzy® device for pain relief in various needle-based procedures. For this systematic review, a systematic literature search was performed in databases including PubMed, Ovid MELINE, Ovid All EBM Reviews, Ovid Embase and Ovid PsycINFO, and Allied Health Literature (CINAHL) from the date of project initiation until December 18, 2017. Searches were completed with the assistance of a research librarian and with a tailored search for each database. Specific inclusion and exclusion criteria were implemented to include only RCTs that compared the Buzzy® device to a control group of infants, toddlers, children, and adolescents. The age range of participants in the included studies were determined by the following criteria, including individuals between 28 days and 18

years of age requiring a needle-based procedure. Needle-based procedures encompassed in this systematic review included immunizations, venipuncture, IV insertion, and IM or subcutaneous injections. Additionally, the systematic review included RCTs that assessed combination cold and vibration therapy. There was not a language restriction set on the literature search. Based on the inclusion and exclusion criteria, nine RCTs were included in the systematic review; seven of these were included in the meta-analysis.

From the nine selected studies, a total of 1,145 participants aged 3 to 18 years from 2011 to 2018 were included. Control groups compared to the Buzzy® device had an absent or nonpharmacological intervention, no intervention, vapocoolant spray or topical anesthetic, or distraction cards. Needle-based procedures across the studies included three with IV insertions, two with venipunctures, two with IV *and* venipunctures, and two with immunizations. The primary outcome measured was needle-related procedural pain intensity. This was evaluated either during or immediately after the procedure by self-reported pain via selected pain scale, parent-reported pain, or observer-reported pain. All selected self-reported pain scales were validated for use in the selected population. Statistical analyses showed a statistically significant effectiveness in pain reduction with the Buzzy® device. There was a reported SMD  $-1.12$ ; 95% CI:  $-1.53$  to  $-0.71$  where  $p < 0.0001$ . By the JHNEBP tool criteria, this systematic review was deemed level I, Grade A quality.

**Bergomi, Scudeller, Pintaldi, & Dal Molin (2018).** A RCT was conducted to compare efficacies between topical cryotherapeutic analgesia (Buzzy®) and animated cartoons as a distraction technique in reducing pain and anxiety in children undergoing venipuncture. The sample included children between the ages of 5 and 12 years, with a total of 150 participants. These participants were randomized into four groups: Buzzy® only, distraction via cartoons and Buzzy®, distraction via cartoons alone, and no intervention. Randomization was performed by an independent statistician through the RALLOC method in Strata® 13 using blocks. A number of opaque sealed envelopes were prepared to include the allocated groups and dispersed to the

appropriate participants and locations. All pain and anxiety scales used in the study were explained to parents and children prior to participation, with an emphasis that the primary outcome measure was pain. Secondary outcomes included parents' and nurses' perception of the child's pain and anxiety. Within the study, both primary and secondary outcomes measuring the child's pain utilized the Wong-Baker Faces Pain rating scale (WBFC). The Children's Emotional Manifestation Scale was used to determine the perception of the child's anxiety. Parental anxiety was measured using the Numeric Rating Scale and by asking them to estimate their own level of anxiety on a scale of 0 to 10.

Statistical analysis comparing the four groups was performed by way of one-way analysis of variance. Categorical variables were compared by way of the Pearson's  $\chi^2$  test; a  $p$ -value of  $<0.05$  was considered to be statistically significant. The Strata computer software was used to run the data. Results of the secondary analysis showed that the Buzzy® device was highly effective in children under the age of 9 ( $p = 0.04$ ). Additionally, a significant efficacy was found in the Buzzy® and animated cartoon group ( $p = 0.04$ ) for the nurse's perception of the child's pain, and in the Buzzy® group for the mother's perception of the child's pain ( $p = 0.002$ ). Based on the JHNEBP tool, this study is categorized as level I and was determined to be Grade A quality.

**Canbulat, Ayhan, & Inal (2015).** A RCT was performed to assess the ability of the Buzzy® device to reduce pain and anxiety in children undergoing peripheral intravenous cannulation. The sample for this study included children aged 7 to 12 years who required peripheral IV cannulation. Participants were excluded from the study if there was an abrasion where the device would be placed, if there was nerve damage on the affected extremity, critical or chronic illness lending toward poor health, neurodevelopmental delays, difficulties with verbal communication, use of an analgesic within the last 6 hours, or history of syncope due to blood specimen collection or immunization. Additionally, none of the participants had previous experience with peripheral IV cannulation.



A total of 176 children and their parents consented to participate and were randomly assigned to the intervention group (cold and vibration Buzzy® therapy) or the control group (no intervention). To assess pain, the child self-reported pain via the WBFC and the Visual Analog Scale (VAS) immediately post-cannulation procedure. To analyze the data, Statistical Package for the Social Sciences (SPSS) version 15.00 was utilized where  $p < 0.05$  was considered significant. Reported pain and anxiety levels in children were compared with the Student's  $t$  test. Nonparametric data, including sex and parental education levels, were compared with frequency testing and  $\chi^2$ . When pain and anxiety levels were compared with an independent  $t$  test, the children in the external cold and vibration group experienced significantly lower pain levels than the control group based on their self-reported pain (both WBFC and VAS scores where  $p < 0.001$ ). Using the JHNEBP tools, this article was categorized as level I, Grade A evidence.

**Sahin & Eser (2018).** A RCT was performed with the purpose of determining the effect of the Buzzy® device on injection site pain and satisfaction with injection experience in adults. To ensure the study was single-blind, evaluation of pain and satisfaction via VAS was carried out by another nurse who was educated beforehand on using the scale. For this study, participants were randomly assigned by age and gender into an intervention group (with the Buzzy®) and a control group (no intervention). Each participant received only one injection, which was given by the researcher to avoid any factors that could affect outcomes related to changing injectors. Evaluation of pain and satisfaction was performed by the nurse to ensure impartiality. The study sample consisted of 65 individuals who received IM injections of diclofenac sodium into the ventrogluteal site in the physical therapy department of a state hospital from November 2012 to January 2013. To be included, patients met the following criteria: have not had an IM injection within the last seven days; no complaints related to an IM injection-related complication such as pain at the injection site, abscess, infection, tissue necrosis, or hematoma; being conscious with no problems with communicating, vision, or

hearing deficits; between ages 25 and 85; accurate use of the VAS pain rating tool. One VAS tool was used immediately post-injection to rate pain levels. The second VAS tool was used for a satisfaction assessment.

Data was assessed using SPSS version 20.0. A  $\chi^2$  test was performed to assess homogeneity between the groups and the distribution of distinguishing patient characteristics. To make comparisons between the groups in regards to pain and anxiety, the Mann-Whitney *U* test was performed. Ultimately, results showed post-injection mean pain scores in application group of  $4.67 \pm 4.94$  and pain post-injection mean pain score in control group of  $17.69 \pm 9.85$ . Injection satisfaction mean scores in the application group were  $94.82 \pm 4.97$ , and injection satisfaction mean scores in the control group were  $85.06 \pm 13.39$ . In the application group, post injection pain was significantly lower and injection satisfaction significantly higher than in the control group. This piece of evidence was determined to be level I, Grade A by the JHNEBP tool criteria.

**Sivri Bilgen & Balci (2019).** A RCT was performed to assess and compare the efficacies of the Buzzy® device and the ShotBlocker® device on reducing pain with IM injections of penicillin in children. A power analysis was performed using the Power (v3.1.7) program to determine the appropriate sample size, a minimum of 48 individuals per group. The number was increased to 50 per group to account for participant losses. To ensure randomization, numbers from 1 to 150 were divided randomly into three groups using a computer-based program without number repetition. Participants were randomly assigned to their appropriate group: Buzzy® device, ShotBlocker® device, and control group. Parents and their children were informed about the procedures, and their written and verbal consent was obtained prior to participation. During a face-to-face interview with the researcher, an information form was completed with parents and children. Outcomes were measured using the Visual Analog Scale and Faces Pain Scale-Revised (FPS-R) to evaluate pain at one minute and five minutes post-injection. State-trait anxiety inventory for children (STAIC) prior to the

procedure was also measured to determine anxiety levels and identify significant differences between each group.

Data was measured using the SPSS for Windows, version 22 and the Number Cruncher Statistical System (NCSS) 2007 program for statistical analyses. Data from the study utilized the one-way analysis of variance and dependent samples t-test in those showing a normal distribution. In those without a normal distribution, a Kruskal-Wallis, Person's, and chi-square test was performed. The value of  $p < 0.001$ , Buzzy® showed the most statistically significant results in pain reduction and post injection satisfaction in children. Additionally, there was no significant statistical difference between the mean scores of the STAIC among groups before the procedure. Based on the JHNEBP tool criteria, this piece of evidence was determined to be level I, Grade A quality.

**Yilmaz & Alemdar (2019).** A RCT was performed to compare usefulness of the Buzzy® device, the ShotBlocker® device, and bubble blowing as distraction in children receiving intramuscular injections. The study sample included children ages 5 to 10 years undergoing intramuscular injection, as well as their parents. The inclusion criteria included children between the ages of 5 and 10 years who were patients in a pediatric emergency department receiving IM injections. Additionally, it was imperative that children were accompanied by parents or family members. Participants were excluded if they had received local anesthetics; if there was a skin infection or pathology at the site of injection; if there were diseases or significant trauma requiring immediate attention; showed signs of developmental delay; had chronic illnesses; had altered sensorium or neurosensory deficit at the site of injection; or if developmental delay prevented completion of the pain scale. To determine sample size, G\*Power (v3.1.9.2) was utilized. The approximate number of participants was calculated to be 40 according to Cohen's effect size coefficients. Children were placed randomly according to a computer program into four subgroups: Buzzy® device, ShotBlocker® device, bubble blowing, and no intervention. The

primary outcome measured was pain and the secondary outcome measured was fear. Instruments used to measure these outcomes included interview forms, procedural fear (Children's Fear Scale [CFS]), and self-reported pain scores via Oucher pain scale.

Statistical analysis was completed using SPSS for MS Windows XP. The Shapiro-Wilk test was used to assess distribution of the data. Additionally, comparisons of procedural fear (CFS scores) and pain (Oucher scores) was completed using a one-way analysis of variance (ANOVA) and the *post hoc* advanced analysis Bonferroni test for binary comparison was used for statistical analyses. Results showed that where  $p < 0.05$ , ShotBlocker®, Buzzy®, and bubble-blowing were all effective in reducing fear, with Buzzy® being the most effective. This study was determined to be level I, Grade A quality by the JHNEBP criteria.

### ***Level II Evidence***

**Öztürk, Baykara, Karadag, & Eyikara (2017).** A comparative experimental study was performed to determine the usefulness of applying manual pressure to the deltoid injection site for pain reduction during intramuscular injections of the hepatitis A and hepatitis B vaccinations in college students. The sample consisted of 123 first-year university students scheduled to receive their hepatitis A and hepatitis B vaccinations in the deltoid injection site. Students were assigned randomly to either a comparison group, who was given standard of care, or an experimental group, which received manual pressure at the injection site immediately prior to the injection for 10 seconds. A self-administered questionnaire comprised of two components was completed by each participant for data collection. The first component collected demographic data, and the second included a Numeric Rating Scale (NRS) for pain rating. The NRS was used to determine perceived pain just before injection and immediately post-injection by the student. Pain levels were also obtained by an independent specialist nurse who did not witness the injection. Using the NRS, the students indicated their pain level within two minutes of the procedure. To promote uniformity in manual pressure application, a dolorimeter was used to measure manual pressure with the investigator's right thumb prior to the study. It was

determined that the investigator would apply pressure with the right thumb as much as she could until the nail bed turned white.

Data was evaluated using SPSS 17.0 software. Due to abnormal distribution of the data, a Mann-Whitney *U*-test was used. When dependence between variables was evaluated, the chi-square test was utilized. The mean pain level of the experimental group after injection group was 3.17, and in the comparison group it was 3.78 on the NRS. This showed statistical significance where  $p < 0.05$ , indicating that manual pressure at the injection site was effective in reducing pain in young adult students receiving intramuscular injections. By the JHNEBP tool criteria, this piece of evidence was categorized as level II, Grade B evidence.

**Şanlıalp Zeyrek, Takmak, Kurban, & Arslan (2019).** A systematic review and meta-analysis were performed to determine the efficacy of various physical-procedural interventions during intramuscular injections in adults. The following databases were used for searches from inception to November 2017: Cochrane, SCOPUS, Medline (OVID, Ebsco), and Science Direct. Additionally, the reference lists of the received articles were searched for relevant evidence. The search strategy was adapted for electronic databases and included key terms *intramuscular injection\**, *pain*, *randomize\**, *trial*, and *experimental*. Abstracts titles were scanned by two authors to determine full-text inclusion and appraised for suitability. The inclusion criteria comprised of patients administered IM injections in any setting; patients were over the age of 18; physical-procedural interventions for reducing pain were used during the IM injection; RCT or quasi-experimental study design where the effect of any physical procedural intervention at the IM injection was examined; outcomes were related to pain at the injection site; full-text studies were accessible; and studies were written in the English language. Exclusion criteria removed evidence without physical-procedural intervention, where data collection was not possible, and specific information about the method was not provided.

In total, 15 articles were included: nine were RCTs and six were quasi-experimental. The total number of participants was 1,174 individuals aged 18 and older. The primary outcome

measure was pain, and the measurement scales used included the NRS, VAS, and verbal rating scale (VRS). Results found that all of the physical-procedural interventions reduced injection pain at a moderate level. Their results also discovered it was difficult to conclude a single intervention or method reduces pain in adults. The most effective methods were Z-technique, manual pressure, two-needle technique, post-injection massage, and ShotBlocker®. By the JHNEBP tool criteria, this systematic review was determined to be level II, Grade A quality.

**Taddio et al. (2015).** A systematic review of RCTs and quasi-randomized controlled trials was performed to evaluate a variety of procedural and physical interventions and their effect on pain levels during vaccinations in a number of different age groups. A search strategy was developed with assistance from a research librarian and performed in EMBASE, Medline, PsycINFO, CINAHL, and ProQuest Dissertations & Theses Global. Studies were included if they looked at individuals of all ages undergoing vaccination or the closest related skin-breaking procedure or context (such as venipuncture) and were RCTs or quasi-randomized study designs. A total of 31 studies were included: 24 included children, 4 included adults, and 3 included adults and children. The total number of participants was 11,880.

Critical outcomes measured included pain, distress, and fear utilizing a variety of tools based on age and study. Interventions with a statistical significance indicating pain reduction included no aspiration, injecting most painful vaccine last, simultaneous injections, vastus lateralis injection, positioning interventions, non-nutritive sucking, external vibrating device with cold (Buzzy® device), and muscle tension. The results for Buzzy® use in children ages 3 to 17 years were as follows: SMD  $-1.23$ ; 95% CI:  $-1.58, -0.87$ . By the criteria in the JHNEBP evidence leveling and appraisal tools, this systematic review is categorized as level II, Grade B quality.

#### ***Level IV Evidence***

**Stephenson (2019).** This evidence summary and best practice recommendation was selected to include an expert opinion about the topic in addition to the high-level pieces of

evidence listed above. The purpose of this summary was to answer the clinical question, “What is the best available evidence regarding strategies to reduce pain associated with intramuscular injections?” This evidence summary comes from the following pieces of evidence: a RCT with 60 participants, 30 receiving IM injection in the ventrogluteal site and 30 in the dorsogluteal site; a RCT with 75 participants who each received three randomized injection techniques; a RCT with 123 participants, 63 randomized to the experimental group and 60 to the control group; a quasi-experimental study with 48 participants; a systematic review and network meta-analysis including 23 RCTs; and a RCT with 65 participants.

Results of the studies for the best practice recommendation established there were several strategies utilized successfully to reduce pain associated with IM injections. These included the air-lock technique, Z-track technique, manual pressure, manual acupuncture, topical anesthetics such as lidocaine or EMLA cream, and the Buzzy® device for cryotherapy and tactile stimulation. The evidence recommends the use of clinical judgment and taking patient preference into account. It does not recommend one strategy over the other. The JHNEBP tools categorize this piece of evidence as level IV, Grade A evidence (Table 2.2).

Table 2.2

*Evidence Summary Table*

<b>Author(s)</b>	<b>Purpose</b>	<b>Design</b>	<b>Sample</b>	<b>Measurement/ Outcomes</b>	<b>Results/Findings</b>	<b>Level/ Quality</b>
Ballard, A., Khadra, C., Adler, S, Trottier, E. D., & Le May, S. (2019).	The aim of this systematic review was to analyze the efficacy of the Buzzy® device on pain and anxiety in multiple RCTs.	Systematic Review	The sample consisted of 1145 children aged 28 days to 18 years from 9 RCTs.	Multimodal; a variety of pain scales were used from the 9 RCTs to measure Buzzy® effect on pain, and 7 of the RCTs were used in the meta-analysis.	Overall effect of Buzzy® device on self-reported pain was significant: SMD -1.12; 95% CI: -1.53 to -0.71; $p < 0.0001$	Level I Grade A
Bergomi, P., Scudeller, L., Pintaldi, S., & Dal Molin, A. (2018).	To evaluate the efficacy of two interventions on pain with venipuncture in children: vibration with cryotherapeutic topical analgesia (Buzzy®) and distraction by means of animated cartoon.	RCT	Sample consisted of 150 children between the ages of 5 and 12 years.	Outcome measures included pain perception with Buzzy® device alone, animated cartoon distraction alone, and animated cartoon with Buzzy®. Pain perception was determined with the WBFC.	The secondary analysis showed that the Buzzy® device was highly effective in children under the age of 9 ( $p = 0.04$ ). Additionally, a significant efficacy was found in the Buzzy® and animated cartoon group ( $p = 0.04$ ) for the nurse's perception of the child's pain, and in the Buzzy® group for the mother's perception of the child's pain ( $p = 0.002$ ).	Level I Grade A



Canbulat, N., Ayhan, F., & Inal, S. (2015).	The purpose of this study was to determine the effect of the Buzzy® device on pain and anxiety levels of children during peripheral IV cannulation.	RCT	The sample included 176 children between 7-12 years of age randomly assigned to a control group with no intervention and an experimental group receiving treatment with Buzzy® device.	Outcomes measured included pain, measured with the WBFC and VAS. Anxiety was also measured using the CFS.	When pain and anxiety levels were compared with an independent <i>t</i> test, the children in the external cold and vibration group experienced significantly lower pain levels than the control group based on their self-reported pain (both WBFC and VAS scores where $p < 0.001$ ).	Level I Grade A
Öztürk, D., Baykara, Z. G., Karadag, A., & Eyikara, E. (2017).	The purpose of this study was to determine the efficacy of manual pressure at the deltoid injection site in decreasing injection site pain in young adult students receiving the hepatitis A and hepatitis B vaccines.	Comparative experimental study	Sample consisted of 123 students; 60 students were in the comparison group and given standard of care and 63 students were in the experimental group, receiving manual pressure at the injection site for 10 seconds before the injection.	Outcome measures included pain levels using the NRS. Pain levels were taken by an independent specialist nurse who did not witness the injection. Using this scale, the students indicated their pain level within two minutes of the procedure.	The mean pain level of the experimental group after injection was 3.17, and in the comparison group it was 3.78 on the NRS. This showed statistical significance where $p < 0.05$ , indicating that manual pressure at the injection site was effective in reducing pain in young adult students.	Level II Grade B
Şahin, M., & Eşer, İ. (2018).	To determine the effect of the Buzzy® device on injection site	RCT (Single-blind, randomized, prospective design)	65 individuals who received IM injections of diclofenac sodium	Pain: measured with the VAS. The first VAS was used to evaluate pain	Post injection mean pain score in application group: $4.67 \pm 4.94$ Post injection mean pain score in control group: $17.69 \pm 9.85$	Level I Grade A

	pain and resulting satisfaction with injection experience.		and ranged from ages 25-85 years.	after injection ranging from “no pain” to, “unbearable pain.” The second VAS was used to determine satisfaction with a range from “I’m very satisfied” to, “I’m not satisfied at all.” Both of the VAS were on a vertical line 100 mm long.	Injection satisfaction mean score application group: $94.82 \pm 4.97$ Injection satisfaction mean score control group: $85.06 \pm 13.39$  In the application group, post injection pain was significantly lower and injection satisfaction significantly higher than in the control group.	
Şanlıalp Zeyrek, A., Takmak, Ş., Kurban, N. K., & Arslan, S. (2019).	The purpose of this systematic review was to determine the efficacy of various physical-procedural interventions during intramuscular injections in adults.	Systematic Review	The sample included 15 articles; 9 were RCTs and 6 were quasi-experimental studies. The number of participants totaled 1,174 adults aged 18 and over.	The primary outcome measured was pain. Scales used to measure pain included the NRS, VAS, and VRS.	Results found that all of the physical-procedural interventions reduced injection pain at a moderate level, and that it was difficult to conclude that a single intervention or method reduces pain in adults. The most effective methods were Z-technique, manual pressure, two-needle technique, post-injection massage, and ShotBlocker®.  Z- technique (SMD = 0.563, 95% CI = 0.216–0.909, $p = .001$ )  Manual pressure (SMD = 0.523, 95% CI = 0.193–0.853, $p = .002$ )	Level II Grade A

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					Two-needle technique (SMD = 0.744, 95% CI = 0.335–1.154, $p = .001$ )	
					Post-injection massage (SMD = 1.818, 95% CI = 1.076–2.561, $p = .001$ )	
					ShotBlocker: (SMD = 1.021, 95% CI = 0.468–1.574, $p = .001$ )	
Sivri Bilgen, B., & Balci, S. (2019).	The purpose of this study is to determine the efficacy of both the Buzzy® and ShotBlocker® in reducing pain with intramuscular injections in children.	RCT	The sample consisted of 150 children ages 7-12 divided equally into three subgroups: Buzzy® group, ShotBlocker® group, and control group.	Outcomes were measured using the VAS and FPS-R to evaluate pain at one minute and five minutes post-injection. STAIC prior to the procedure was also measured to determine anxiety levels and identify significant differences between each group.	<p>VAS (1<sup>st</sup> minute) where <math>p &lt; 0.001</math>:  ShotBlocker®: 6.36 ± 3.24  Buzzy®: 3.68 ± 3.05  Control: 7.34 ± 3.11</p> <p>VAS (5<sup>th</sup> minute) where <math>p &lt; 0.001</math>:  ShotBlocker®: 3.38 ± 2.94  Buzzy®: 1.68 ± 2.28  Control: 4.88 ± 3.24</p> <p>FPS-R (1<sup>st</sup> minute) where <math>p &lt; 0.001</math>:  ShotBlocker®: 6.24 ± 3.20  Buzzy®: 3.64 ± 3.10  Control: 7.36 ± 3.09</p> <p>FPS-R (5<sup>th</sup> minute) where <math>p &lt; 0.001</math>:  ShotBlocker®: 3.24 ± 2.96  Buzzy®: 1.52 ± 2.23  Control: 4.84 ± 3.29</p>	Level I Grade A

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					Buzzy® showed the most statistically significant results in pain reduction and post injection satisfaction in children.	
					There was no significant difference between the mean scores of STAIC before the procedure (Shot-Blocker®=38.50±5.47; Buzzy®=37.74±6.07; control=40.16±6.24	
Stephenson, M. (2019).	The purpose of this JBI evidence summary and practice recommendation was answer the following question: What is the best available evidence regarding strategies to reduce pain associated with intramuscular injections?	Evidence summary and practice recommendation	A RCT with 60 participants; a RCT with 75 participants; a RCT with 123 participants; a quasi-experimental study with 48 participants; a systematic review and network meta-analysis including 23 RCTs; a RCT with 65 participants	Critical outcome of consideration was pain; measurement tools were multimodal and varied based on study	There are several strategies that have been used successfully to reduce pain associated with IM injections (air-lock technique, Z-track technique, manual pressure, topical anesthetics, and Buzzy® device). Evidence does not recommend one strategy over the other; the use of clinical judgment, taking patient preference into account, is recommended.	Level IV Grade A
Taddio, A., Shah, V., McMurtry, C. M., MacDonald, N. E., Ipp, M., Riddell, R. P.,	The purpose of this systematic review was to evaluate a	Systematic Review	The sample consisted of a total of 31 studies; 24	Critical outcomes included pain, distress, and	Interventions with a statistical significance indicating pain reduction included no aspiration, injecting most painful vaccine	Level II Grade B

Noel, M., & Chambers, C. T. (2015).	variety of procedural and physical interventions on pain levels during vaccination in a variety of age groups.	studies included children, 4 studies included adults, and 3 studies included adults and children. The number of participants totaled 11,880.	fear. A variety of tools were used to measure these outcomes based on age and study.	last, simultaneous injections, vastus lateralis injection, positioning interventions, non-nutritive sucking, external vibrating device with cold (Buzzy®), and muscle tension.	The results for Buzzy® use in children ages 3-17 years were as follows: SMD -1.23; 95% CI: -1.58, -0.87.	Level I Grade A
Yilmaz, G., & Alemdar, D. K. (2019).	The purpose of this study is to compare the efficacy of the Buzzy® device, ShotBlocker®, and bubble blowing in reducing pain in children.	Prospective RCT	The sample consisted of 160 children ages 5-10 years. There were four subgroups with 40 randomized participants in each: Buzzy® group, ShotBlocker® group, bubble-blowing group, and control group (no intervention).	The primary outcome measured in this study was pain with secondary outcome measure of fear. Instruments used to measure included interview forms, procedural fear (CFS), and pain scores via Oucher scale.	<p>Mean scores for pain (self-reported (SD)) where <math>p &lt; 0.05</math>:</p> <p>ShotBlocker®: 4.14 (2.12)  Buzzy®: 3.87 (1.79)  Bubble-blowing: 4.75 (1.74)  Control group: 6.72 (2.16)</p> <p>ShotBlocker®, Buzzy®, and bubble-blowing all had significant findings for reducing pain, with Buzzy® having the most significant results for pain reduction.</p> <p>Mean scores for fear according to CFS (self-reported (SD)) where <math>p &lt; 0.05</math>:</p> <p>ShotBlocker®: 1.66 (0.53)  Buzzy®: 1.35 (0.61)  Bubble-blowing: 1.88 (0.61)  Control group: 2.82 (0.66)</p>	Level I Grade A
ShotBlocker®, Buzzy®, and bubble-blowing were all effective						

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in reducing fear, with Buzzy®  
being the most effective.

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## **Construction of Evidence-based Practice**

### **Synthesis of Critically Appraised Literature**

#### ***Therapeutic Techniques During IM Injections***

The search for a method of pain relief during IM injections and other needle-based procedures has proven to be an endeavor with widespread attempts and a variety of outcomes. Based on the literature, therapeutic interventions and methods of pain relief regarding these procedures include distraction techniques, manual pressure at the injection site, acupressure, Z-track technique, the Buzzy® device, and the ShotBlocker® device (Öztürk et al., 2017; Şanlıalp Zeyrek et al., 2019; Stephenson, 2019). While many of the interventions revealed significant efficacies, few of them have adequate bodies of evidence supporting their widespread, versatile use in the clinical setting.

When looking at the body of literature and studies comparing interventions, there were two main interventions with authentic bodies of evidence and supporting efficacy: the Buzzy® device and the ShotBlocker® device (a plastic, horseshoe-shaped device used to apply manual pressure at the injection site). After finding high level, high quality pieces of evidence comparing these two interventions, it was clear the Buzzy® device was superior in efficacy in both the pediatric and adult populations (Sivri Bilgen & Balcı, 2019; Yılmaz & Alemdar, 2019).

The Buzzy® device combines cryotherapeutic topical analgesia with tactile stimulation to reduce pain at the injection site using principles of the Gate Control Theory illustrating significant outcomes across a variety of populations – pediatric and adult alike (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018; Taddio et al., 2015). The device comes in a bee-shaped design, with ice pack wings for cooling and a main body that vibrates; these work in combination to distract nerve fibers. The Gate Control Theory suggests pain sensation is transmitted from the peripheral nervous system to the central nervous system, where it is modulated by a gating system in the dorsal horn of the spinal cord and can reduce

the pain information transmitted to the brain (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018). Afferent pain-receptive nerves are blocked by fast non-noxious motion nerves; the prolonged cold exposure (30 to 60 seconds), stimulates C fibers to transmit a slow pain and noxious thermal information to the brain. Simultaneous to this reaction in the nervous system, the Buzzy® device also uses distraction techniques, which can also contribute to reducing fear and anxiety in those undergoing needle-based procedures (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018).

### ***Pain as Primary Outcome Measure***

Vaccine injections are the most frequent painful medical procedure performed worldwide (Taddio et al., 2015). Common factors affecting pain associated with IM injections include anxiety, patient position, medication volume and viscosity, chemical composition of the drug, solution of the drug, rate of delivery, injection technique, and location of the injection site (Öztürk et al., 2017; Şahin & Eşer, 2018; Taddio et al., 2015). Among the various studies and pieces of evidence appraised, the primary goal and outcome measured with needle-based procedures was the same: the participant experiencing pain relief.

Different tools and methods were utilized to measure pain depending on population, setting, and participant age group. For young pediatric populations, the Wong-Baker Faces Scale was used (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Sivri Bilgen & Balci, 2019; Taddio et al., 2015). This scale consists of six animated faces that range from neutral expression (0 = very happy/no pain) to a screaming face (10 = hurts more than you can imagine) (Canbulat et al., 2015). One study utilized the Oucher pain scale for measurement of pain scores. This scale is appropriate for use in children aged between 3 and 12 years and comprises of two distinct scales. The first scale uses a series of six photographs of a child in varied degrees of distress and is intended for children who cannot count. The second scale uses the numbers 0 and 10 to indicate levels of distress distributed among the photographs to identify pain level (Yilmaz & Alemdar, 2019). For adolescent and adult populations relevant for



this project, the most commonly used pain measurement tool was the Visual Analog Scale (Canbulat et al., 2015; Şahin & Eşer, 2018; Şanlıalp Zeyrek et al., 2019; Sivri Bilgen & Balcı, 2019). This scale consists of a line 100 mm long; one end of the line reads “No pain” and the other end of the line reads “Unbearable pain.” The participant is asked to mark the area on the line that most accurately correlates with their experienced level of pain. To determine an approximate pain level, a measurement is made from the “No pain” line to the participant’s indicated mark in millimeters (Şahin & Eşer, 2018).

In many of the studies, self-reported pain was recorded with observed pain scores, perceived fear levels, and perceived anxiety levels from parents or a nurse (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Yilmaz & Alemdar, 2019). By incorporating patient-stated pain scores with observer findings and secondary outcome measures, a more well-rounded approach at determining efficacy was employed for data analysis.

### ***Age Group Specificity***

Many of the studies performed look at pain reduction in children; regardless of age, patients in general are often fearful of injections because they are perceived as a pain producing procedure. It has been reported that 30.6% of patients – not just children – have injection fear (Şahin & Eşer, 2018). The versatile use of cryotherapeutic topical analgesia vibration is supported by the literature for effective means of reducing pain with needle-based procedures for patients or all ages (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018; Sivri Bilgen & Balcı, 2019; Taddio et al., 2015; Yilmaz & Alemdar, 2019). Much of the research found on the Buzzy® device involves pain reduction with needle-based procedures in children, but the described mechanism of action and effects of on the nervous system via Gate Control Theory are transferable and applicable to adolescent and adult populations undergoing the same types of procedures (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018).

**Best Practice Model Recommendation**

Reviewing the evidence determined best practice recommendations to reduce pain with IM injections involves several strategies that show promise. The evidence demonstrates a lack of definitive evidence to promote one strategy over the rest. Ultimately, a combination of clinical judgment and patient preference should be utilized when endeavoring to reduce injection site pain (Stephenson, 2019). Within the literature, there is significant support for best practice to utilize the Buzzy® device to reduce injection site pain (specifically intramuscular injections as immunizations) which applies across a variety of ages (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018; Sivri Bilgen & Balcı, 2019; Taddio et al., 2015; Yilmaz & Alemdar, 2019). By using a nonpharmacological intervention that works based on the Gate Control Theory, pain can be diminished without the associated risks of using another chemical substance and considering the practicality of time efficiency, accessibility of the setting, usefulness in multiple age groups, and ability to reuse the device (Canbulat, Ayhan, & Inal, 2015).

## **CHAPTER 3**

### **IMPLEMENTATION OF PRACTICE CHANGE**

A change in practice was initiated to reduce the amount of discomfort, pain, and injection fear associated with college-aged students receiving a vaccination. More literature has been published in recent years with the primary goal of pain reduction and an additional emphasis that healthcare professionals have an ethical obligation to diminish the level of pain their patients experience, regardless of age or procedure (Bergomi et al., 2018; Öztürk et al., 2017). Research shows that poor experience with needle-based procedures can lead to noncompliance with vaccinations later in life and vaccination hesitancy from parents to their children, bringing to light a significant public health issue (Ballard et al., 2019; McMurtry et al., 2015). The EBP project initiating a noninvasive, nonpharmacological intervention that combines more than one method of pain relief, both easy to use and economical, aids in vaccination compliance and positively impacts public health.

#### **Participants and Setting**

The EBP project was performed in a health center at a university in northern Indiana. There were a variety of key stakeholders that were essential to the efforts made toward integration of a practice change. In this office setting, there was one part-time physician, one full-time nurse practitioner, two part-time NPs, a full-time registered nurse, a full-time medical assistant, a medical assistant, and a NP acting as director of the health center. Participation from the registered nurse and medical assistant were essential as they are the primary administrators of vaccinations and other IM injections at the health center. The intervention selected for this project directly impacted the way they practice, so their participation and compliance were significant factors. Patients considered eligible for this project included (a) students enrolled at the university, (b) aged 23 and under, (c) students requiring a vaccination, (d) who had not received the vaccination they were receiving before. Patients were excluded

from participating if they (a) had extreme cold sensitivity, (b) nerve damage or sensory deficit that would affect sensation where the injection took place, (c) had neurodevelopmental delays or difficulties, (d) there was a lesion or break on the skin in the area the device would be placed for pain relief during the injection procedure.

### **Pre-Intervention Group Characteristics**

With the new virus COVID 19, the fall 2020 semester students to maintain enrollment at the university were required to have multiple vaccinations. Some of these vaccinations require an injection series including for example the meningitis-B (Men-B) vaccination. Freshman and incoming students who met the inclusion criteria were the targeted group for this project due to the need for vaccines, as many established students have previously received these vaccinations as a requirement for previous university enrollment. Students were considered eligible if receiving a vaccine series *or* if they were receiving more than one single-dose vaccination. All students who met the inclusion criteria were considered viable candidates for the project as long as there was a viable non-intervention vaccine to use as comparison with an intervention-correlated vaccine.

### **Intervention**

Prior to the start of implementation of the Buzzy® device component of the EBP project, an in-service was completed to educate the medical assistant and registered nurse on staff. The education was provided on how to use the Buzzy® device. An informative meeting took place about the pain scale being utilized, how to use the device, and to review standardized pre-intervention and intervention protocols. Questions were addressed and staff was able to practice with the device prior to using it on patients.

The intervention for this EBP project was selected based on a critical appraisal of a large body of literature. The result was the development of a standardized protocol for pre-intervention IM injection and a standardized protocol for using the intervention. By having standardized protocols, uniformity in administration between participants was more likely to be

achieved and high-integrity data collected. The intervention selected for this project was the Buzzy® device, which utilizes a combination of vibration (tactile stimulation) and cold (cryotherapy) therapies. The device is bee-shaped with ice pack wings and is a battery-operated motorized device that is reusable and easy to clean. The combination of vibration and prolonged cold exposure has been proven to be an effective means of pain relief, and the Buzzy® device has been shown to have statistically significant results in diminishing injection site pain in both children and adults (Sahin & Eser, 2018; Canbulat, Ayhan, & Inal, 2015; Tadio et al., 2015).

The first process of the intervention started when students arrived at the health center. When patients met the aforementioned inclusion and exclusion criteria they were asked to participate. The student was then given the authorization and consent form. If a signature was obtained, the participant proceeded to get their first injection of their required vaccine (Appendix A). After the procedure, their pain was measured via a self-reported visual pain scale and a questionnaire about previous experiences with vaccination and injections was completed. If applicable, their second appointment to complete the vaccination series was scheduled.

The second part of the intervention included when the participant obtained their second vaccination or injection in their vaccination series. For a number of participants this was immediately following their non-intervention vaccination and was a different type of vaccination on their other arm. For participants receiving a series, their second injection was received after the allocated time (for example, the Bexsero Men-B series requires one month between injections). Some participants compared the Buzzy® intervention with their vaccination to previous vaccine experience, but that experience had to be within the previous year and if the participant was confident they could accurately recall their previous experience. For all second injections, the Buzzy® device was used for pain reduction. Upon patient arrival, ice pack wings were removed from the freezer to allow thawing prior to the procedure. When the participant was ready for the injection, the device was placed at the injection site for simultaneous vibration from device and cooling from the ice pack wings. The device was left at the site for 30 seconds

prior to injecting; during the course of the injection, it was placed just above the injection site so that the analgesic effect could continue. Pain scores were reported immediately post-injection through a questionnaire (Appendix B). For all participants, pain scores were measured using a self-reported visual pain scale.

To promote uniformity within injection techniques as much as possible, standardized non-intervention and intervention protocols were developed based on guidelines. These were utilized so that during injections, elements such as needle length, needle gauge, injection site, and injection technique would affect patient experience and pain scores as little as possible (Appendices C and D).

Many students scheduled their vaccinations at the health center due to its proximity and convenience to campus instead of having to drive to another health practice location. Participants were recruited as they arrived for scheduled vaccinations. The participants had to be able to read and write in English to sign the authorization and consent form that would allow them to use the Buzzy® device for vaccine injection requirements for the university

### **Comparison**

The first step in the intervention allowed for patients to be measured at baseline before introducing the Buzzy® device to reduce pain with IM injections. The first injection each participant received was completed with no intervention based on standard of care techniques using a protocol distributed by the project manager. Immediately post-injection, pain scores were reported and recorded. The second step in the intervention measured pain with the participant's second injection while using the Buzzy® device. Again, pain scores were reported and recorded immediately post-injection. The comparison allowed for the end goal of decreased pain sensation experienced while being injected using the Buzzy® device. By comparing two injections under circumstances as similar to each other as possible aside from Buzzy® use, it was determined that the most accurate data could be collected because participants' pain scores with and without the intervention would not be subject to variability in external factors.

### Outcomes

The primary outcome measured for this EBP project was pain. For this project, a visual pain scale was utilized. The visual pain scale used for this project consists of a line that is 100 millimeters long. One end of the line reads “no pain.” In the middle of the line, it reads, “moderate pain,” and the other end reads “unbearable pain.” This tool has been found to be a reliable and valid means of measuring both acute and chronic pain in adults (Bijur et al., 2001). Without a reliable and valid measurement tool, it is challenging to effectively manage pain of any kind.

Participants scored their pain on the visual scale and their satisfaction immediately post-injection for both steps of the intervention, the intervention-free and Buzzy® intervention injections. They were asked to make a point on the line that most closely correlated with their pain level. The scores were collected by the nurse or medical assistant who performed the vaccination. This information was then placed in a locked filing cabinet in the director’s office in the health center where only the director and the project manager had access. The project manager of the EBP project then measured the completed visual pain scales by the participants. The score was obtained by measuring from the start of the “no pain” side to the participant’s mark made on the pain scale line. This measurement was made to the millimeter from zero to the participant’s mark.

The secondary outcome measured for this project was patient satisfaction. Directly underneath the visual pain scale where participants recorded their pain for each encounter there was a five-point Likert-type scale ranging from “Very Satisfied” to “Very Dissatisfied” where participants could indicate how they felt about their non-intervention injection experience and their Buzzy® injection experience. These were completed at the same time as the pain scores by each participant.

The questionnaire completed by participants obtained information on what vaccinations they have received in the past, when they received their last vaccination, whether they receive injections on a regular basis (including insulin injections, etc.), if needle-based procedures produce fear or anxiety, and other demographic information (Appendix B). The final scores and responses for both outcomes were recorded by the project manager. These along with the paired questionnaires were obtained and placed in a locked file within a secure location accessible to the project manager only.

Once data was collected, the primary and secondary outcomes were analyzed using a paired *t* test, which was appropriate because two data measures were being taken on each participant; there was no “experimental” and “control” group (Schmidt & Brown, 2019).

### **Time**

The project lasted for the duration of the fall semester, beginning on August 24, 2020 until November 24, 2020, which was the end of the fall semester. This time frame was selected for the project due to students returning to campus and requiring immunizations. Additionally, many students utilized the health center for their vaccinations due to a variety of factors, including convenience. Because of easy access, many students used the health center to complete their vaccination requirements without having to leave campus and because of continuity between the health center and the university.

### **Protection of Human Subjects**

For the duration of this project, efforts were made to protect all human subjects from excessive risk or harm of any kind. The project manager completed education for protection of human subjects and an ethics course as part of DNP coursework in spring 2020. The CITI program entitled “Social Behavioral Educational Research: Basic Course” was completed as part of the requirements to initiate this project. Additionally, the project manager completed an Institutional Review Board (IRB) questionnaire in July of 2020 to determine the level of approval required by the university. Once it was determined that this project did not meet the federal



criteria of research and that the study design and intervention would not lower the standard of care or put participants at risk, IRB exemption was granted.

Prior to integration of the Buzzy® device into practice, participants were educated on how the device works and what participation included through the authorization and consent form. Questions were answered to the participants' satisfaction and the authorization and consent form was signed. Participant confidentiality and voluntary participation were emphasized and confirmed. Participants were able to cease participation in the project at any time should they wish. The questionnaire and both pain scales were obtained and placed in a locked filing cabinet within a secure location accessible to the project manager only.

## CHAPTER 4

### FINDINGS

The purpose of this EBP project was to determine the efficacy of cryotherapy and vibration via Buzzy® device in reducing injection site pain with vaccinations in young adults. The desired primary outcome was reduced self-reported pain measured using a visual pain scale. Individuals who consented to participate first completed a questionnaire which included demographic characteristics and background information about previous experience with injections. The first pain measurement was reported pre-intervention when the participant received a vaccination. The second self-reported pain measurement was taken by the same participant after receiving a vaccination with the Buzzy® device. After completion of the questionnaire noted in the previous chapter's full description of the project intervention, analysis was completed for all variables to determine if there were pertinent and relevant outcome findings.

#### Participants

##### Size

Throughout the course of implementation, a total of 38 participants meeting the project implementation criteria were recruited and consented to participate. Each participant recorded pre-intervention vaccination pain scores as well as post-intervention pain scores after receiving a vaccination with the Buzzy® device.

##### Demographics

Demographic characteristics were collected for the sample using the questionnaire each participant completed when they consented to participate. The questionnaire was formatted to gathering information on the student identification number, student email, ethnicity, gender, and age. Other information on the questionnaire, descriptive information, gathered from the participants were recent vaccination, completed vaccinations, regular injection status, anxiety

frequency and associated sources with injections. There was a total of 10 males and 28 females, and ages of participants ranged from 18 to 23 years, with ages 18 and 19 being most common and accounting for 55% of the sample. The injection types for the pre-intervention and intervention groups varied between participants and non-intervention and intervention groups. The race/ethnicities within the sample included the following: 26 white, four of two or more races, three not listed, two Asian, one black, one Hispanic/Latino, and one international student.

The descriptive statistics on the questionnaire contained specific questions that pertained to how the participants felt about needle injections. When asked if injections cause fear or anxiety, 21.1% of the participants said always and 23.7% of the participants said sometimes. However, 28.8% of the participants said injections never cause them fear or anxiety and 21.1% of the participants said it rarely did. The next question in the questionnaire looked at the cause of the anxiety or fear. 44.7% of the participant's source of anxiety was pain of the injection and 21.1% had a previous bad experience. The full data of the descriptive statistics from the questionnaire of the sample group are detailed in Tables 4.1 and 4.2.

### **Changes in Outcomes**

This EBP project addressed the following PICOT question: In college-aged students receiving immunizations (P), does the Buzzy® device (I) when compared to non-intervention standard of care (C) effectively reduce injection site pain (O) over a 12-week time period (T)? The primary outcome measure was pain, and this was self-reported using a visual pain scale.

### **Statistical Testing and Significance**

Data were entered into the SPSS version 25 for statistical analysis. The text, *How to use SPSS: A step-by-step guide to analysis and interpretation* by Cronk (2019) was utilized to guide the process of data input, analysis, and interpretation of data. Variation existed between the types of non-intervention and intervention vaccinations between groups and individual

Table 4.1  
*Demographic Characteristics*

Demographic	Frequency (%)
Number of participants	38 (100%)
Age	
18	10 (26.3%)
19	11 (28.9%)
20	6 (15.8%)
21	1 (2.6%)
22	5 (13.2%)
23	4 (10.5%)
24	0 (0.0%)
25	1 (2.6%)
Gender	
Male	10 (26.3%)
Female	28 (73.7%)
Race	
Black	1 (2.6%)
Two or More Races	4 (10.5%)
Asian	2 (5.3%)
Hispanic or Latino	1 (2.6%)
International Student	1 (2.6%)
White	26 (68.4%)
Not Listed	3 (7.9%)

Table 4.2  
Descriptive Characteristics

Descriptive	Frequency (%)
Recent Vaccination	
Yes	26 (68.4%)
No	12 (32.6%)
Vaccinations Complete at Initial Visit	
Varicella	38 (100%)
Hepatitis A	38 (100%)
Hepatitis B	38 (100%)
Measles, Mumps, Rubella (MMR)	38 (100%)
Tetanus (DTaP, Tdap)	38 (100%)
Meningococcal B (Men-B)	15 (39.5%)
Meningococcal quadrivalent	36 (94.7%)
Receive Regular Injections	
Yes	2 (5.3%)
No	36 (94.7%)
Non-Intervention Injection Type	
Bexsero (Men-B)	21 (55.3%)
Trumenba (Men-B)	2 (5.3%)
HPV	3 (7.9%)
Influenza	9 (23.7%)
Immunotherapy/Allergy	1 (2.6%)
Tetanus	2 (5.3%)
Buzzy® Injection Type	
Bexsero (Men-B)	21 (55.3%)
Trumenba (Men-B)	1 (2.6%)
HPV	2 (5.3%)
Influenza	13 (34.2%)
Immunotherapy/Allergy	1 (2.6%)
Tetanus	0 (0.0%)
	3 (7.9%)
Anxiety with Injections	
Always	8 (21.1%)
Sometimes	9 (23.7%)
Neutral	2 (5.3%)
Rarely	8 (21.1%)
Never	11 (28.9%)
Source of Anxiety with Injections	
Pain from Injection	17 (44.7%)
Previous Bad Experience	8 (21.1%)
Other	2 (5.3%)
Not Applicable	11 (28.9%)

participants. When variation exists, the statistical test used is a one-way ANOVA, which was applied to the data analysis between the non-intervention pain scores and non-intervention injection type. The same statistical test was performed for the Buzzy® intervention pain scores and injection types. This was completed to determine if there was statistical significance associated between pain score and injection type. In analysis of non-intervention injection types and pain scores, the overall significance of the one-way ANOVA was 0.092 where  $p < 0.05$ , showing there is not sufficient evidence to indicate a significant relationship between pain score and injection type in the non-intervention data set. For the one-way ANOVA performed on the Buzzy® intervention injection type and associated pain scores, the significance was 0.170 where  $p < 0.05$ , also showing there is not sufficient evidence to indicate a significant relationship between injection type and pain score.

In addition to this, a Chi-square was performed between non-intervention injection type and Buzzy® intervention injection type to determine if there was a statistical significance between the varied injection types in both groups. The Pearson Chi-square value was 8.173  $df = 20$ ; sig. = 0.004 where  $p < 0.05$ . This indicated a statistically significant difference in variation of injection type between the non-intervention and Buzzy® data sets.

**Primary outcome.** The primary outcome measure for this project was pain with the use of the Buzzy® device for the injection, measured with a visual pain scale. This scale consisted of a line 100 millimeters long. One end of the line read “no pain.” In the middle of the line, it read, “moderate pain,” and the other end read “unbearable pain.” Participants indicated their pain on the scale immediately after their injection was completed. A paired samples  $t$  test was conducted to compare non-intervention pain scores and Buzzy® pain scores. Findings showed that  $t = 8.674$ ,  $df = 37$ , and a mean decrease in pain of 2.32 ( $SD = 1.65$ ) where  $p < 0.05$ . The mean non-intervention injection pain score was 4.71 ( $SD = 1.86$ ) and the mean Buzzy® injection pain score was 2.39 ( $SD = 1.51$ ). These findings indicated a statistically significant relationship in improvement with pain scores for IM injections when using the Buzzy® device.

**Secondary outcome.** The secondary outcome measure for this project was participant satisfaction with the use of the Buzzy® device for the injection. This was measured via a five-point Likert-type scale with options Very Satisfied, Satisfied, Neutral, Dissatisfied, and Very Dissatisfied where participants could indicate how they felt about their non-intervention injection experience and their Buzzy® injection experience. These were completed at the same time as the pain scores by each participant. A paired samples *t* test was used to compare mean scores between the two groups. When performing data analysis, the number 1 indicated Very Satisfied and the number 5 indicated Very Dissatisfied, the mean non-intervention satisfaction score was 2.45 (*SD* = 1.11) and the mean satisfaction with the Buzzy® was 1.55 (*SD* = 0.69) where  $p < 0.05$ . The results showed  $t = 4.969$ ,  $df = 37$ , and a mean difference between the two groups of 0.90 (*SD* = 1.11). This indicates there was a statistically significant relationship in improvement with satisfaction with use of the Buzzy® device for IM injections.

## CHAPTER 5

### DISCUSSION

This EBP project was conducted with the purpose of answering the PICOT question, "In college-aged students (P), does the Buzzy® device (I) when compared to non-intervention standard of care (C) effectively reduce injection site pain (O) over a 12-week time period (T)?" A protocol was developed and utilized to determine the efficacy of vibration and cryotherapy via the Buzzy® device in reducing self-reported pain with immunizations. This chapter will expound upon project findings and statistical analysis, as well as consider the application of the EBP model used to guide this project. Strengths and limitations of the project will be discussed along with implications for future research, practice, theory, and education.

#### Explanation of Findings

Project findings supported the effectiveness of using the Buzzy® to deliver a combination of vibration and cryotherapy to reduce pain levels during vaccinations in college-age students. Additionally, project findings showed a statistical significance in affecting the level of satisfaction participants had with their experience getting their vaccination. Participant findings including sample size and demographic characteristics will be further discussed later in the chapter.

#### Participant Findings

Based on information from the current body of literature, there was variation in sample sizes used in RCTs and in the RCTs used for systematic review. Most sample sizes ranged from 120-170 participants, so the sample size for this project with 38 participants is relatively small. The project did not take place in a large health corporation or large office setting, so it is logical that the sample size would be lesser than in the evidence used in the literature review. Additionally, this project was conducted in a small age range because it looked at college-aged students ages 18-25. Another large contributing factor was the project took place during the



COVID-19 pandemic. This pandemic limited students to online learning and ability to be present on campus to visit the health center. Not only was the COVID-19 pandemic a factor, the project took place in the fall of 2020 during the height of the pandemic when numbers were the highest in the state of Indiana in making recruitment of participants more difficult. All of these factors likely contributed to having a smaller sample size.

The sample for this project comprised of 73.7% female and 26.3% male participation. Evidence included in the literature review had a variety of gender-related proportions. For example, Yilmaz and Alemdar (2019) also had higher levels of female participation with a narrower differential with 52.5% being female and 47.5% being male. Öztürk et al. (2017) had higher female participation at 87.3% female and 12.6% male in the experimental group and 91.7% female and 8.3% male in the comparison group. Additionally, Şahin and Eşer (2018) had participation of 60.6% female and 39.4% male in the application group and 68.8% female and 31.3% male in the control group. The higher proportions in the research studies that females were more likely to participate than males were consistent with those in this EBP project.

In terms of demographic data that considered race and ethnicity, none of the reviewed evidence included this information. In this project, 68.4% of participants reported that their ethnicity was white or Caucasian, which is a substantial amount. However, this proportion is consistent with the population in the area and enrolled at the university. At the university in northern Indiana where his EBP project was conducted, 70.6% of students are Caucasian (Enrollment by Race/Ethnicity, 2020), so this was an anticipated finding.

### **Pain Results**

Statistically significant results were found between the non-intervention and Buzzy® intervention groups in terms of self-reported pain on the visual pain scale. The reported pain scores indicated that there was a notable decrease in pain when participants received an injection with the Buzzy® device rather than without an intervention. The mean non-intervention injection pain score was 4.71 ( $SD = 1.86$ ) and the mean Buzzy® injection pain score was 2.39

( $SD = 1.51$ ). The results of this outcome measure were consistent with the results found in the literature review that concluded the Buzzy® was an effective means of pain reduction with IM injections (Ballard et al., 2019; Bergomi et al., 2018; Canbulat et al., 2015; Şahin & Eşer, 2018; Sivri Bilgen & Balcı, 2019; Taddio et al., 2015; Yilmaz & Alemdar, 2019). Therefore, it can be determined that these results had sufficient evidence to support the benefit of using the Buzzy® device for pain reduction in college-aged students.

It is also important to discuss the other statistical tests performed. Because there were differences between the type of injections in the non-intervention data set and the Buzzy® device data set, a one-way ANOVA was performed between the non-intervention pain scores and non-intervention injection type, as well as the Buzzy® intervention pain scores and injection types. This was performed in order to detect whether there was statistical significance associated between pain score and injection type for both data sets. For non-intervention injection types and pain scores, it was determined that there was not sufficient evidence to indicate a significant relationship between pain score and injection type in the non-intervention data set. For the one-way ANOVA performed on Buzzy® intervention injection type and associated pain scores, the significance also indicated there was not sufficient evidence to indicate a significant relationship between injection type and pain score. These findings reinforced that injection type for both data sets was not an indicator of pain and did not influence individual self-reported pain scores.

In addition to this, a Chi-square was performed between non-intervention injection type and Buzzy® intervention injection type to determine if there were significant differences between injection type and frequency given in both data sets. The Pearson Chi-square value (8.173,  $df = 20$ ; sig. = 0.004 where  $p < 0.05$ ) indicated a statistically significant difference in variation of injection type and frequency between the non-intervention and Buzzy® data sets. The most likely source of this was that there were nine participants who had the influenza vaccination as their non-intervention injection and there were 13 who had their influenza vaccination as their

Buzzy® injection. While this was noted, it was not listed as a limitation because other statistical tests determined that there was not a significant relationship between injection type and pain score.

### **Patient Satisfaction**

Patient satisfaction was the secondary outcome measure for this project and was measured on a five-point Likert-type scale. The mean non-intervention satisfaction score was 2.45 and the mean satisfaction with the Buzzy® was 1.55. The mean difference between the two groups was 0.90. The non-intervention value fell between “Satisfied” and “Neutral” on the scale and the value obtained after use of the Buzzy® fell between “Very Satisfied” and “Satisfied.” The values obtained indicate that there was a statistically significant relationship between non-intervention satisfaction and satisfaction with the Buzzy® device. This evidence supports that participants were more satisfied with their experience while using the Buzzy® device than without the device, which is logically congruent with the overall statistically significant decrease in pain.

### **Strengths and Limitations of the DNP Project**

There were a variety of strengths and weaknesses that arose throughout project implementation that can be explicated and utilized to guide future projects related to this topic.

#### **EBP Model**

The JHNEBPM was utilized as a framework to guide the development, implementation, and evaluation of this project. By providing a comprehensive yet flexible outline, this EBP model was useful in creating a stepwise progression that the project manager could use to evaluate progress and adjust the execution of this project as necessary to for successful implementation.

**Strengths.** The JHNEBPM was a good fit for this project for several reasons. The model is relatively easy to understand, helping to guide a novice project manager in project planning, implementation, practice change, project evaluation, and data analysis. Because of this, the detailed steps outlined by the model were integral in guiding the consideration of aspects that

may have been overlooked or disregarded. There are three phases in the JHNEBPM: practice questions, evidence, and translation. Within these three phases are 19 steps that were closely followed through the implementation of this EBP project (Dang & Dearholt, 2017; Melnyk & Fineout-Overholt, 2019). The practice question phase laid the foundation of this project by identifying a practice problem that was important for implementation in practice. This was brought to the project manager's attention by way of the staff at the university health center. A self-reported history of discomfort and anxiety with IM injections and vaccinations created a passionate idea identifying a viable intervention addressing this issue. After doing a thorough review of the literature and considering possible interventions, the strongest and largest amount of evidence pointed toward the Buzzy® device. This practice change was suggested and a plan for the project and implementing practice change was developed. Through the evidence phase of the model, evidence was collected and appraised. After this was complete, a summary and synthesis of the evidence was completed to aid in the direction of recommendations for practice change. The project manager, site facilitator, and staff together determined whether the practice change was realistic, manageable, and appropriate for their patients and setting. After discussing a plan of action with the site facilitator and staff, the university generously purchased the Buzzy® devices for the project. During implementation, modifications were made to include multiple injection types, but the premise remained the same. The project manager was able to gain access to the electronic medical record and do the majority of injections to promote continuity throughout the project as well, which helped with adopting the translation process. Results of the project were collected by the project manager and evaluated through SPSS for statistical significance. Findings were reported to key stakeholders and methods of dissemination were identified and discussed. Since then, the project site has continued use of the Buzzy® for vaccinations, immunotherapy injections, and other needle-based procedures performed at the clinic. Without the use of the JNHEBPM to develop, implement, and evaluate

this EBP project, the continued use of the Buzzy® device at the health center for injections and needle based procedures would not be presently in use helping college age students every day.

### **Strengths of the Project**

There were a number of strengths of this project that became evident throughout the course of implementation and evaluation. One of the largest strengths were the amount of support from the site facilitator and other staff on site. They were enthusiastic about the project, asked questions, and willingly used the Buzzy® device to participate in data collection. The staff when educated on the EBP project and use of the Buzzy® device, did not show opposition to change and supported the positive evidence provided about the Buzzy® device. Their willingness to adjust the standard of care typically given for vaccinations played a significant part in contributing to project success as many times one of the major setbacks in implementation is reluctance to change. Additionally, participants that were recruited as they arrived for vaccinations and met the inclusion criteria were generally eager and willing to participate, which made the project possible.

One of the most important strengths of this project was its simplicity in many aspects from the intervention, to the education given to staff, and to the questionnaires given to the participants. The EBP was straightforward and easy to understand, which tied together many of its success including the strengths noted above, staff participation and individuals agreeing to participate. The questionnaire was limited in questions for the participants to complete and there were minimal places where they had to write information. With this formatted questionnaire, it was less daunting for students when filling out, was simple, and could be completed in a timely manner. When the staff used the Buzzy® device, it did not add time to the overall completion of injections so it was easy to incorporate without sacrificing time or staying on schedule, which were important factors in integrating the device into practice. The two outcome measurements that were self-reported and independent of the facility's charting system were helpful in not

adding time to documentation for the staff and allowed participants to be engaged in data collection.

To minimize the effects of external factors, standardized non-intervention and intervention protocols were derived from guidelines in order to rule out factors such as needle gauge, needle length, variation in injection site, different techniques between injection administrator, etc. Handouts in the form of a 21 step standardized injection protocol non-intervention and a 23 step standardized injection protocol Buzzy® device were provided to the staff after education for during the intervention. By educating staff, providing these simple step-by-step handouts, and promoting communication between project manager, staff, and site facilitator, adjustments were made efficiently, the project stayed on track, the injections continued to be given properly with the device, and goals of this project were accomplished.

### **Limitations of the Project**

While there were a number of strengths associated with this project, there were also several limitations that should be addressed. First, modifications were made to accommodate the potential of the university health center closing. Unfortunately, this project took place during a pandemic, COVID-19, which created uncertainty throughout the United States and for this project. Because of the threat of COVID-19 and the possibility of campus closure, the first adjustment made was to include several injection types. Another major adjustment was the varying time periods between first and second injections between individual participants so that sufficient data could be collected before the would-be closure occurred.

Initially prior to the COVID-19 accommodations that needed to occur due to the unknowns, the plan for the EBP project was utilizing the Men-B vaccination series as it was the same vaccine injection and time period and is required for school enrollment. Because of COVID-19, the EBP project changes had differences in injection types between data sets and for individual patients. Even though protocols were implemented to promote continuity in factors such as needle size and length, having different vaccinations that could vary in serum viscosity

and have the potential to influence pain levels was not ideal. To make sure this was accounted for, data analysis was performed, which did not show significant relationships between individual injection types and reported pain. In the future given the small sample size of this EBP project, this could be looked into further with a larger sample size to see if there was statistical significance between using different vaccinations among the participants.

Other limitations present in the EBP would be the sample size and demographics including BMI. With a larger sample size more data could be collected that could change the statistical significance of the EBP project primary and secondary outcomes. The EBP sample size of 38 participants provided sufficient evidence but having a larger pool of data to analyze could provide more accurate outcomes. Also, certain demographics that have the potential to affect pain, such as body mass index (BMI) was not collected as part of data for this project. It has been determined that thin patients can report less pain than their normal-weight or obese counterparts (Şahin & Eşer, 2018). As noted in a strength of the project, keeping to a simplistic project to not only gain support of the site in which it was implemented at, but having willingness of participants wanting to be a part of the study was needed especially with the limitations due to COVID-19 unknowns. For this reason the question of BMI was left out of the questionnaire during data collection. This information was not collected but could have been an indicator of perceived pain that affected patient outcomes.

### **Implications for the Future**

This EBP project provided valuable information for both the advanced practice nursing population and the global healthcare community by exploring pain relief during vaccination. Future implications for practice, research, theory, and education will be discussed, as well as recommendations to improve future EBP projects and practice changes.

### **Practice**

Using a combination of prolonged cold exposure and vibration via the Buzzy® device has been supported as a best practice option for reducing pain with vaccinations by current and

high-quality literature. This project served as a means to make this the standard of practice for these procedures at the clinical site the project took place. The clinical site supported the project and the cost of the Buzzy® devices was covered by the university. Since conclusion of the project, the project site has continued use of the Buzzy® device in practice.

To aid with future EBP projects and integration into practice, a number of considerations should be addressed. Even though sufficient evidence was collected, more accurate outcomes could be obtained from having a larger sample with more ethnic, age-related, and gender-related diversity. Additionally, promoting continuity of injection type or determining variability of pain experienced between injection types would be helpful in determining true efficacy of the device.

### **Research**

Further research on other non-pharmacological interventions would aid in determining the efficacy of the Buzzy® in the endeavor of truly establishing best practice. One of the other interventions presented in the literature was the ShotBlocker®. There was not sufficient evidence to support its use in lieu of the Buzzy® device but more research on this device could present helpful information. Additionally, it would be helpful to look more closely at anxiety associated with needle-based procedures and how closely it correlates with pain. Many perceptions of pain from IM injections can come from anxiety as noted in the literature. Common factors that affect pain associated with IM injections include anxiety, previous poor experiences, patient position, medication volume and viscosity, chemical composition of the drug, available solution of the drug, rate of delivery, injection technique, and anatomic location of the injection site (Sahin & Eser, 2018). Data from this project showed that 65.8% of participants reported anxiety due to injection pain or previous bad experience; this is a significant contributor to patient experience and pain perception and should be considered for future research. Moreover, it would be helpful to look into the pain caused by serum viscosity that could differ between injection types and pain associated with different injection sites. This project performed IM



injections in the deltoid muscle, but there are several sites that could have been utilized and this may affect the amount of pain an individual experiences during an injection. Lastly, as previously mentioned, there has been evidence that explores the difference in pain sensation with distinctions in BMI. It is possible that patients with lower body fat percentage or composition experience more pain than their counterparts with higher fat percentage that fall into normal and obese categories; this should also be considered in the future.

### **Theory**

The JHNEBPM was instrumental in the successful implementation of this project and in integrating the Buzzy® device into practice. By detailing 19 steps, it ensured that this project was implemented to its fullest extent without overlooking important aspects of changing practice. The versatility of this model makes it an excellent candidate for other future EBP projects because its concepts can be applied in a myriad of settings. For a more experienced project manager, the rigor of 19 steps and three phases may not be necessary to successfully implement EBP, so this should also be considered before selecting this model for an EBP project.

### **Education**

Education is an essential part of patient care and successfully implementing practice change. Participants in this project were thoroughly educated prior to participating in this project. This included information such as practice treatment, possible reactions to vaccinations, how the Buzzy® device works, and the details of the project included in the authorization and consent form that was signed prior to participation. Prior to project implementation, staff were educated on protocols for non-intervention and Buzzy® injections, and a copy of these were also kept in the immunization room for reference if needed. Additionally, a pamphlet on how to use the Buzzy® that was included with the device from the company for staff reference. The combination of these things allowed participants and staff to enter into this project fully informed

about the changes to practice, and any questions that arose were answered by the project manager.

### **Conclusion**

The implementation of this EBP project allowed the project manager, site facilitator, project site staff, and participants to see firsthand the value of using prolonged cold exposure and vibration by means of the Buzzy® device to reduce pain during the administration of vaccines. The site facilitator and staff have expressed their satisfaction with the device and project outcomes, as well as their intent for continued future use. Participants verbalized their approval of the device and hopes to use it in the future for their vaccinations. To conclude, the results of this project provided sufficient evidence to support the use of the Buzzy® device to reduce pain and increase satisfaction during vaccinations in college-age students. These findings are consistent with the existing body of literature. Continued use of the device in practice is encouraged for best-practice purposes. It is recommended to providers and staff to incorporate prolonged cold exposure and vibration to reduce pain with vaccinations in an efficient and affordable way by means of the Buzzy® device.

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## **BIOGRAPHICAL MATERIAL**

Katherine Long attended Trinity Christian College in Palos Heights, Illinois and graduated in 2017 with a Bachelor of Science in Nursing (BSN). After graduation she returned to her hometown in Northwest Indiana and began her Master of Science in Nursing at Valparaiso University. She transferred into the Doctor of Nursing Practice (DNP) program in spring of 2018 as a full-time student and will graduate with her DNP in May of 2021. Since enrolling as a graduate student, she has worked for the Girl Scouts of Greater Chicago and Northwest Indiana as a health supervisor and nurse. Katherine is a student member of the American Association of Nurse Practitioners (AANP) and an active member of Sigma Theta Tau International Honor Society of Nursing Zeta Epsilon chapter. She gave a poster presentation of her evidence-based practice project regarding injection site pain in college-aged students at the University of Iowa Health Care National EBP Conference in April 2021. Following graduation, she aspires to enter the clinical setting and develop a specialized skillset in dermatology where she can further and serve her community.

## ACRONYM LIST

BMI: Body Mass Index

CDC: Centers for Disease Control

CFS: Children's Fear Scale

DNP: Doctor of Nursing Practice

EBP: Evidence-Based Practice

FPS-R: Faces Pain Scale-Revised

IRB: Institutional Review Board

IM: Intra muscular

IV: Intravenous

JBI: Joanna Briggs Institute

JHH: John Hopkins Hospital

JHNEBP: Johns Hopkins Nursing Evidence-Based Practice

JHNEBPM: Johns Hopkins Nursing Evidence-Based Practice Model

Men-B: Meningitis-B

NP: Nurse Practitioner

NRS: Numeric Rating Scale

PET: PET process

RCT: Randomized Controlled Trial

SPSS: Statistical Package For the Social Sciences

STAIC: State-trait Anxiety Inventory for Children

VAS: Visual Analog Scale

VRS: Verbal Rating Scale

WBFC: Wong Backer Faces Scale

**APPENDIX A****Authorization & Consent for Use of Buzzy® Device****Patient Name:** \_\_\_\_\_ **Birthdate:** \_\_\_\_\_**Student ID#:** \_\_\_\_\_**Project Title:** Don't be Such a Buzzy®kill: Using Cryotherapy and Vibration to Reduce Pain During Vaccinations in College-Age Students.**Project Manager:** Katy Long, BSN, RN, DNP Student Valparaiso University College of Nursing and Health Professions

**Purpose:** This is a consent form for participation in an evidence-based practice project. Should you decide to participate, it will provide important information about the project and tell you what to expect as a participant. You are being asked to join an evidence-based practice project for individuals receiving a vaccination that will assess the ability of the Buzzy® device to reduce pain during the procedure.

**Voluntary Participation/Withdrawal:** Participation in this project is voluntary. Please read and consider the information carefully. You may ask questions before making any decision regarding participation at any time during or after the implementation of this project. You are free to stop participating at any time without penalty, and your future visits at the health center will not be impacted.

**Procedure:** Should you participate in this project, you are consenting to use the Buzzy® device to decrease pain during vaccination. Prior to injection, the icepack portion of the Buzzy® device will be removed from the freezer to thaw before placing directly onto the skin. The Buzzy® device will then be placed at injection site for 30 seconds prior to the injection, allowing the area to be slightly numbed before injecting. During the procedure, the Buzzy® device will be placed slightly above the injection site. Both the icepack and vibration aspects will be operating and may provide additional distraction from the procedure. Immediately following the procedure, you will report your level of pain on a Visual Analog Scale (VAS), displayed as a line ranging from "no pain" to, "worst pain."

**Duration:** If you decide to participate in this project, the duration is from your attendance at an initial focus group until your scheduled appointment to receive your vaccination. This is the only time that contact with the patient will occur, with no necessary follow-up.

**Risk:** The risks associated with participating in this project are minimal. They may include the side effects of skin contact with the cold temperature of an icepack or concerns regarding discomfort associated with the vibration mechanism of the Buzzy® device.



**Benefits:** The benefits of participating in this project include the utilization of evidence-based care that works to reduce pain associated with intramuscular injection and improve patient experience.

**Confidentiality:** The personal information and answers given on the questionnaire may be reported and utilized by the project manager, but any information that can be used to personally identify you as the participant will remain strictly confidential. Personal information will be coded to maintain your confidentiality, and documents will be stored in a secured location available only to the project manager.

**Contacts and Questions:** For questions and concerns about the project, the project manager, Katy Long, can be reached at (219) 869-3144 or [katy.long@valpo.edu](mailto:katy.long@valpo.edu). You may also contact the health center with questions at (219) 464-5060. Heather Stricker, the faculty advisor for this project, may be contacted at [heather.strickler@valpo.edu](mailto:heather.strickler@valpo.edu).

**Consent to Participate:** You have read this form and are aware that you are being asked to participate in an evidence-based practice project. You understand the information that has been given to you and have had the opportunity to ask questions and have had them answered to your satisfaction. By signing and submitting this form, you are agreeing to participate in this project. A copy of this form will be offered for your records.

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Guardian Signature (if applicable)

\_\_\_\_\_  
Date

**Contact Information:**

Student Name \_\_\_\_\_

Cell Phone Number \_\_\_\_\_

Student ID # \_\_\_\_\_

Student Email \_\_\_\_\_

Can we contact you via text message?

Yes

No

**Demographic Information:**

Race/Ethnicity (Circle):

American Indian	Asian
Black	Hispanic or Latino
Native Hawaiian/Other Pacific Islander	Non-resident alien (international student)
Two or more races	White
Prefer not to say	Not listed

Gender (Circle):      Male                  Female

Age: \_\_\_\_\_

**APPENDIX B**

**Questionnaire:**

1. Have you recently gotten a vaccination?

Yes

No

2. If yes, what was your last vaccine? \_\_\_\_\_

3. When did you receive that vaccination? \_\_\_\_\_

4. Which vaccinations have you **completed**? Check all that apply.

Varicella (Chicken Pox)	
Hepatitis A	
Hepatitis B	
Measles, Mumps, Rubella (MMR)	
Tetanus (DTaP, Tdap)	
Meningococcal B (MenB)	
Meningitis/Meningococcal quadrivalent	

Have you completed the *first step* in your Meningococcal B series, but not the entire series yet? (Circle)

Yes

No

I have gotten both

5. Do you get injections on a regular basis of any kind (blood draws, insulin, allergy shots, chemotherapy, etc.)?

Yes

No

If yes, what kind of injections do you receive? \_\_\_\_\_

6. Do needle-based procedures (such as an injection or shot) give you fear or anxiety in any capacity?

Always

Sometimes

Neutral

Rarely

Never

7. If answered yes to the above question, what do you believe from the answers below causes you the most anxiety about having a needle-based procedure?

- a) The pain of the actual injection
- b) Postinjection soreness at the injection site
- c) Burning at the injection site
- d) Previous bad experience with injection
- e) Other

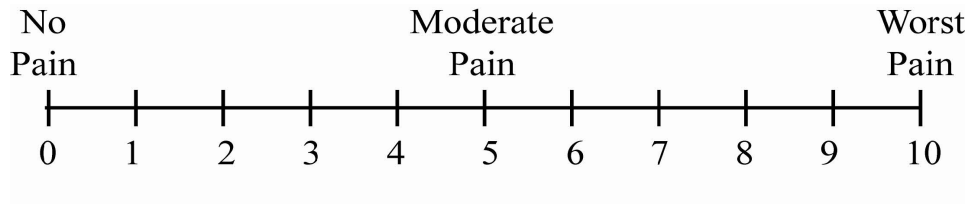
8. Would you like to make an appointment at the health center for your next vaccination or next step in the sequence of your vaccination series?

Yes

No

9. If yes, would you like to sign up for a text message reminder?      Yes                      No

Rate the pain of your last (most recent) injection:

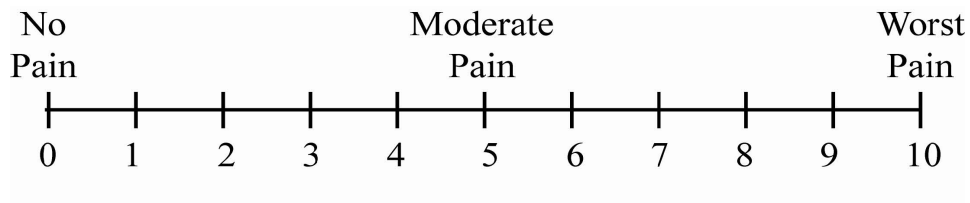


Injection type/name: \_\_\_\_\_ Date: \_\_\_\_\_

How satisfied were you with the comfort level of your last (most recent) injection?

Very Satisfied      Satisfied      Neutral      Dissatisfied      Very Dissatisfied

Rate the pain of your injection while using the Buzzy® device:



Injection type/name: \_\_\_\_\_ Date: \_\_\_\_\_

How satisfied were you with the comfort level of your injection with the Buzzy® device?

Very Satisfied      Satisfied      Neutral      Dissatisfied      Very Dissatisfied

## APPENDIX C

### Standardized Injection Protocol: Non-Intervention

1. Gather equipment (gloves, alcohol prep, injection supplies, etc.)
2. Confirm patient identity and explain the procedure
3. Check the injection order in the patient's chart, particularly: drug, dose, date and time of administration, route and method of administration, diluent as appropriate, validity of prescription, signature of provider.
4. Perform hand hygiene and put on clean gloves as required
5. Ensure patient privacy
6. Select appropriate administration site (for purposes of EBP project, typically deltoid site) and identify appropriate landmarks
7. Determine appropriate needle length based on medication volume, body mass, and depth of injection site
8. When using an ampule/vial to load the syringe prior to intramuscular (IM) injection, avoid drawing up any air bubbles into the syringe. Change the needle prior to performing the IM injection to ensure the needle is sharp and free from medication residue/particulates.
9. Remove the appropriate garments to expose the injection site.
10. Assist the patient into position to facilitate the injection into the chosen site, and encourage patient to relax the target muscle.
11. If required, cleanse site with an alcohol swab for 30 seconds. Allow area to dry for 30 seconds.
12. Perform the injection using the Z-track technique. Using the index finger and thumb of non-dominant hand, stretch the skin around the injection site so it is tight.
13. Holding the syringe like a dart in the dominant hand, inform the patient and quickly plunge the needle at an angle of 90° into the skin. Aspiration is generally not required unless injecting the vascular dorsogluteal site.
14. Depress the plunger at approximately one ml every 10 seconds, and slowly inject the drug.
15. While withdrawing the needle, release the retracted skin at the same time to seal off the puncture track.
16. Apply gentle pressure at the injection site, and then apply a small plaster over the puncture site.
17. Do not recap needle. Discard all sharps into sharps container.
18. Remove gloves and dispose correctly according to local policy, along with other non-sharps.
19. Perform hand hygiene.
20. Chart and sign medication record appropriately.
21. Evaluate for any adverse response to medication.

Derived from:

The Joanna Briggs Institute. Recommended Practice. Injection: Intramuscular. The Joanna Briggs Institute EBP Database, JBI@Ovid.2019; JBI2138.

## APPENDIX D

### Standardized Injection Protocol for Buzzy®

1. Gather equipment (gloves, alcohol prep, injection supplies, etc.)
2. Confirm patient identity and explain the procedure
3. Check the injection order in the patient's chart, particularly: drug, dose, date and time of administration, route and method of administration, diluent as appropriate, validity of prescription, signature of provider.
4. Perform hand hygiene and put on clean gloves as required
5. Ensure patient privacy
6. Select appropriate administration site (for purposes of EBP project, typically deltoid site) and identify appropriate landmarks
7. Determine appropriate needle length based on medication volume, body mass, and depth of injection site
8. When using an ampule/vial to load the syringe prior to intramuscular (IM) injection, avoid drawing up any air bubbles into the syringe. Change the needle prior to performing the IM injection to ensure the needle is sharp and free from medication residue/particulates.
9. Remove the appropriate garments to expose the injection site.
10. Assist the patient into position to facilitate the injection into the chosen site and encourage patient to relax the target muscle.
- 11. Remove Buzzy® wings from freezer and attach to body of Buzzy® device. Instruct patient to hold vibrating Buzzy® device over injection site for 60 seconds. After 60 seconds, have the patient move the device above the injection site.**
12. If required, cleanse site with an alcohol swab for 30 seconds. Allow area to dry for 30 seconds.
13. Perform the injection using the Z-track technique. Using the index finger and thumb of non-dominant hand, stretch the skin around the injection site so it is tight.
14. Holding the syringe like a dart in the dominant hand, inform the patient and quickly plunge the needle at an angle of 90° into the skin. Aspiration is generally not required unless injecting the vascular dorsogluteal site.
15. Depress the plunger at approximately one ml every 10 seconds, and slowly inject the drug.
16. While withdrawing the needle, release the retracted skin at the same time to seal off the puncture track.
17. Apply gentle pressure at the injection site, and then apply a small plaster over the puncture site.
18. Do not recap needle. Discard all sharps into sharps container.
- 19. Have patient remove Buzzy® device and turn it off. Take the device and disinfect appropriately using alcohol or another type of sterilizing wipe. Return wings to freezer after cleaning.**
20. Remove gloves and dispose correctly according to local policy, along with other non-sharps.
21. Perform hand hygiene.
22. Chart and sign medication record appropriately.
23. Evaluate for any adverse response to medication.

Derived from:

The Joanna Briggs Institute. Recommended Practice. Injection: Intramuscular. The Joanna Briggs Institute EBP Database, JBI@Ovid.2019; JBI2138.

APPENDIX E



**CITI PROGRAM**

Completion Date 03-Apr-2020  
Expiration Date N/A  
Record ID 36155479

This is to certify that:

**Katy Long**

Has completed the following CITI Program course:

**Group 1: Social Behavioral Educational Researchers** (Curriculum Group)  
**Group 1: Social Behavioral Educational Researchers** (Course Learner Group)  
**1 - Basic Course** (Stage)

Under requirements set by:

**Valparaiso University**

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

**CITI**  
Collaborative Institutional Training Initiative

Verify at [www.citiprogram.org/verify/?w18e3bf00-5b54-499b-b48e-4700ce326d1c-36155479](http://www.citiprogram.org/verify/?w18e3bf00-5b54-499b-b48e-4700ce326d1c-36155479)