DECREASING VACCINATION RELATED PAIN IN A PEDIATRIC COMMUNITY HEALTH CLINIC

A DOCTOR OF NURSING PRACTICE PROJECT SUBMITTED TO THE OFFICE OF GRADUATE EDUCATION OF THE UNIVERSITY OF HAWAIʻI AT MĀNOA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF NURSING PRACTICE

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Acknowledgement & Dedication

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Abstract

Background: More than 90% of toddlers, 50% of school-aged children, and 25% of adults show signs of distress related to vaccinations. Most adults who fear needles develop this phobia during childhood, resulting in 10% of the population avoiding vaccinations and other procedures involving needles. The combination of the pain and anxiety exhibited by children is a concern for parents, and can lead to nonadherence to future vaccinations. **Objectives:** The purpose of this evidence-based quality improvement project was to introduce the ShotBlocker® into daily use to reduce vaccination related pain among pediatric patients under the age of 18 receiving any vaccinations at the Wahiawā Center for Community Health's pediatric clinic by implementing a vaccination pain-mitigating protocol. **Methods:** Between June 7, 2019 and August 21, 2019, MAs provided vaccinations on pediatric patients using the vaccination-pain mitigating protocol. Every parent or guardian who accompanies a pediatric patient to the pediatric clinic requiring one or more vaccinations was informed by the MA that their child's vaccination would incorporate the ShotBlocker®. After the child received their vaccination(s), the MA asked the parent and/or child the questions indicated on the post-vaccination survey. **Results:** A convenience sample of 65 patients under the 18 years old participated. 40.7% (n=24) found the ShotBlocker® to be effective, while 33.9% (n=20) participants found that the ShotBlocker was ineffective and 25.4% (n=15) participants indicated no difference between vaccination(s) with the ShotBlocker® and without the ShotBlocker®. **Conclusion:** This EBP project demonstrated a reduction in pain in 40% of the sample largely consisting of adolescents between the ages of 11-12 years old. By adding this initial step into any pediatric vaccination protocol, vaccination pain can be reduced promoting a higher likelihood of return for vaccinations in the future.

Introduction

Vaccination injections are one of the most feared and painful medical procedures during childhood (Taddio et al., 2010). According to the Centers for Disease Control and Prevention (CDC) (2017), children receive up to 30 injections between four to six years of age. More than 90% of toddlers, 50% of school-aged children, and 25% of adults show signs of distress related to vaccinations (Jacobson et al., & Vaccine Research Group, 2001; Taddio et al., 2009). Most adults who fear needles develop this phobia during childhood, resulting in 10% of the population avoiding vaccinations and other procedures involving needles (Taddio et al., 2009). The combination of the pain and anxiety exhibited by children is a concern for parents, and can lead to nonadherence to future vaccinations (Taddio et al., 2009; Stevens & Marvicsin, 2016; Luthy, Eden, Macintosh, & Beckstrand, 2014). This paper presents a proposal for a possible solution to vaccination related pain for immunizations received during a well-child visit that was implemented at an Oahu pediatric clinic by the introduction of a vaccination-pain mitigating protocol. This protocol required vaccinations to be performed using a device known as the ShotBlocker® which has been advertised to alleviate pain from needle injections (Bionix, n.d.). By reducing vaccination pain, adherence to childhood vaccinations would be facilitated.

Description of Problem

There are currently no consistent protocols for vaccination pain management used by healthcare providers. The CDC (2018) does, however, recommend various evidence-based techniques considered helpful such as cooling injection sites, topical lidocaine-prilocaine emulsion, and vapocoolant spray, among others. These techniques are not used often because of time, effort, or associated costs (Wallace, Allen, Lacroix, & Pitner, 2010). The Wahiawā Center for Community Health's pediatric clinic in Hawai'i is a pediatric clinic that administers

vaccinations without using a standardized pain-mitigating protocol. In this clinic, on average, each provider sees about 20 patients daily resulting in a total of 40 patients a day divided among the two providers in the clinic. Of the 40 patients seen daily, approximately 20 patients receive vaccinations (50%); 10% refuse vaccinations. According to the CDC (2018), 518 kindergarten students at public and private schools in the Hawai'i islands received vaccination exemptions during the 2017-2018 school year; out of the 518 exemptions, only four were medically related. Although the 518 exemptions only contributed to approximately 1% of unvaccinated students on the Hawai'i islands, the number continues to rise (Parachini, 2019). Public health experts fear an increase in vaccination exemptions will place all students and families at risk of contracting infectious diseases (Parachini, 2019). Sharing similar concerns for underwhelming vaccinations rates, and a goal of increasing vaccination rates in their clinic, the providers of the Wahiawā Center for Community Health's pediatric clinic welcomed the idea of implementing a vaccination-pain mitigating protocol to help increase vaccination rates in pediatric patients under the age of 18 years old seen in their clinic.

Review of Literature

A literature search was conducted using PubMed and CINAHL of published studies between 1994 and 2018, using the search terms *"vaccination" and "pain" and "distraction" and "children"*, yielded 24 studies from PubMed and eight from CINAHL. Inclusion criteria consisted of studies investigating non-pharmacological pain-relieving strategies for vaccination-related pain for children or adults, and of intramuscular and subcutaneous immunization in an outpatient clinic setting. Articles focusing on in-patient, intravenous, prescription pain relief were excluded. No restrictions were imposed regarding the type of article (full article, abstract). Of the 32 total articles, 18 met the inclusion criteria. Additional searches were conducted using

related search terms stemming from the originally found articles. Thirty-three articles were reviewed, critiqued, and graded using Mosby's Level of Evidence (Appendix A; Figure B1).

Synthesis of Literature

Several studies have looked at non-pharmacological distraction techniques in reducing injection pain perceived by children. These methods can be broken up into three major categories: 1) tactile distractions, 2) auditory and visual distractions, and 3) activity distractions.

Tactile Distraction

A number of studies have found that through the use of tactile distractions, vaccination pain is perceived to be significantly lower (Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017; Drago, Singh, Douglass-Bright, Yiadom, & Baumann, 2009). One device studied by several research groups was the ShotBlocker® which was found to alleviate the pain and anxiety caused by needle injections in neonates (Caglar et al., 2017), children two months to 12 years of age (Drago et al., 2009), and adults 18 years old to 80 years old (Çelik & Khorshid, 2015). Cobb and Cohen (2009), however, found the ShotBlocker® had no effect on reducing pain or anxiety in school-aged children between the ages of four years old to 12 years old. Berberich and Landman (2009) implemented a multimodal approach utilizing a vapocoolant spray and pronged arm gripper in addition to a vibration instrument to the unvaccinated arm which was found to reduce pain and anxiety in patients ages four to six years.

Visual and Auditory Distraction

Research has shown perceived pain and the presence of crying was significantly lower with auditory and visual distractions (Özdemir & Tüfekci, 2012; Shahid, Benedict, Mishra, Mulye, & Guo, 2014). Shahid et al. (2014) included the use of iPads that allowed children to watch movies or play games while receiving their injection. This study also showed

significantly reduced levels of anxiety as reported by the parents. Additionally, parents rated their children's duration of crying to be much shorter compared to the control group. Similarly, the cry duration of infants was found to be shorter when the infant was vaccinated on an exam table that was beneath musical mobiles (Özdemir & Tüfekci, 2012).

Activity Distraction

Certain actions such as prompting a child to cough or blow air from their mouth were found to be effective in reducing vaccination pain and anxiety in children four to seven years of ages (French, Painter, & Coury, 1994; Sparks, 2001; Wallace, et al., 2010). Early work suggested that an air blowing technique was effective even in environments with increased anxiety such as being near other crying children (French et al., 1994). With techniques prompting children to perform specific actions, the children's cooperation and an understanding of instructions is crucial, thus children less than the age of three may not be able to participate (Burns et al., 2016; Wallace et al., 2010).

Consistency in Evidence

Researchers from these studies agree that by managing vaccination anxiety and pain, the perceived quality and satisfaction with a medical procedure like vaccinations will improve, potentially increasing subsequent vaccination compliance rates (Taddio et. al, 2012; Mcmurtry, Riddell, Taddio, Racine, Asmundson, Noel, Shah, 2015; Stevens, & Marvicsin, 2016; Luthy et al., 2014). Although various techniques have been presented, many of these techniques are tested concurrently, making it difficult to determine which procedure clearly reduced vaccination pain, anxiety or fear (Luthy et al., 2014). Although more research could demonstrate the most effective method of acute vaccination pain relief (Caglar et al., 2017; Wallace et al., 2010; Cohen

et al., 1999; Özdemir & Tüfekci, 2012), there is sufficient evidence for vaccination pain mitigation.

In future studies, additional variables for pain assessment may be useful in obtaining more conclusive evidence of the ShotBlocker® (Caglar et al., 2017). In the meantime, quality improvement methodology can be used to help close the gap in implementing pain prevention strategies during routine vaccination procedures for children (Schurman et al., 2017).

Weaknesses and Gaps

Across these studies, various types of vaccinations were given with a combination of different techniques resulting in inconsistency of results and ambiguity regarding a 'best method' for vaccination pain mitigation across a range of ages (Cobb & Cohen, 2009; Berberich & Landman, 2009; Luthy et al., 2014). Some techniques required staff to provide a lengthy explanation which may not be realistic in some clinical settings, while others required a series of complex strategies to manage vaccination pain experienced by patients in the clinical setting. Many nurses do not have the time, skills or knowledge to incorporate such practices routinely in their daily patient care (Schurman et al., 2017). Additionally, extraneous barriers such as other patients crying, communication between children who have been vaccinated and those who have not, and the inability to blind the vaccinator and parents in the study may have affected the perception of pain scores (Drago et al., 2009; French et al., 1994; Cohen et. al, 1999; Özdemir & Tüfekci, 2012).

Evidence Based Practice

This evidence-based project provided Medical Assistants (MAs) at the Wahiawā Health's pediatric clinic devices known as the ShotBlocker® and training for them to be able to follow the manufacturer's instructors to administer vaccinations with the ShotBlocker® on pediatric

patients under the age of 18 years. The ShotBlocker® is marketed to "instantly" alleviate pain from needle injections (Bionix, n.d.). This device has been studied by several researchers who found it to be easy-to-use, inexpensive, low-risk, and potentially effective in reducing acute pain in children receiving intramuscular vaccinations (Caglar et al., 2017; Drago et al., 2009). Caglar et.al (2017) found that children's anxiety levels and post-injection heart rates while receiving vaccinations with the ShotBlocker® were lower than the ones who received vaccinations without the ShotBlocker®. The ShotBlocker® has been one of the recommended pain mitigating devices for use with pediatric intramuscular injection to reduce injection pain by the American Academy of Pediatrics (AAP) (Schecter et al., 2010).

Conceptual Framework

The Iowa Model of Evidence-Based Practice was created by a team of nurses with a goal to improve patient care with data findings from research (Titler et al., 2001). This model was used to guide the implementation of the ShotBlocker® at the Wahiawā Center for Community Health's pediatric clinic. This model consists of seven key steps to help guide evidence-based practice which are as follows: 1) identify triggering issues/opportunities; 2) state the question or purpose; 3) form a team; 4) assemble, appraise, and synthesize body of evidence; 5) design and pilot the practice change; 6) integrate and sustain the practice change; 7) disseminate results (Appendix B2 and B3) (Titler et al., 2001; Doody & Doody, 2011; Buckwalter et al., 2017). These steps help in problem identification and solution development as it relates to incorporating evidence findings into practice to improve patient care.

PICO Question

Will implementing a vaccination-pain mitigating protocol into Wahiawā Center for Community Health's pediatric clinic be systematically and efficiently incorporated into clinic

work flow by all MAs on at least 80% of patients under the age of 18 years receiving any vaccinations during a well-child clinic visit between June 2019 to August 2019?

Subsequently, in order to facilitate future vaccinations, will 80% of parents/child dyads perceive their vaccination pain level to be less than previous vaccinations?

Methods and Procedures

Purpose Statement and Objectives

The purpose of this evidence-based quality improvement project was to introduce the ShotBlocker® into daily use to reduce vaccination related pain among pediatric patients under the age of 18 receiving any vaccinations at the Wahiawā Center for Community Health's pediatric clinic by implementing a vaccination pain-mitigating protocol. The objectives of this DNP project were to:

1) educate 100% of licensed medical staff on the importance of pain mitigation for pediatric patients on June 7, 2019; 2) train 100% of licensed medical staff who provide vaccinations to pediatric patients at the Wahiawā Center for Community Health's pediatric clinic on how to perform vaccinations with a pain-mitigating protocol (by use of a sterile ShotBlocker®) on June 7, 2019; 3) use the vaccination-pain mitigating protocol in the pediatric clinic on at least 80% of patients obtaining vaccinations by counting the number of unused ShotBlockers® compared to the number of patients given vaccinations in the clinic indicated by the electronic medical record between June 7, 2019 and August 21, 2019; 4) evaluate children's response to the Shotblocker® by surveying parents' or child's perception of children's vaccination-pain directly after vaccination between June 7, 2019 to August 21, 2019; 5) survey Medical Assistants (MAs) on August 21, 2019 to evaluate the protocol's ease of use, reasons for not using device on eligible patients, and effectiveness of the protocol to alleviate pain compared to vaccinations completed

prior to the implementation of this project. Reference Appendix C and Appendix D for a detailed description and timeline for each objective.

Sampling Plan

Setting. This evidenced-based project was conducted at the Wahiawā Center for Community Health's pediatric clinic between June 7, 2019 and August 21, 2019. Wahiawā Center for Community Health is located in the center of Oahu, serving residents throughout Wahiawā and surrounding communities. This is a non-profit, Federally Qualified Health Center (FQHC), community-owned hospital with numerous specialty clinics including a pediatric clinic (Wahiawā Center for Community Health, 2019). This pediatric clinic consists of one Doctor of Medicine (MD), one Pediatric Nurse Practitioner (PNP), two Medical Assistants (MAs), and varying number of front desk staff members. The MD and PNP were assisted by the two MAs who provide the majority of the vaccinations to their pediatric patients. The members of this team saw patients from post-birth checkups to 18 years of age with varying levels of mental and physical well-being. Based on information provided by the PNP, this clinic saw an average of 20 patients daily for vaccination related visits.

Sample. The accessible population included: 1) MAs working directly under the MD and PNP; and 2) Parents or guardians accompanying the pediatric patients into the clinic. A convenience sample of 65 patients under the 18 years old participated in this project. Some of the limitations associated with convenience sampling is the possibility of bias from the data collection as all the data was collected from a specific group of individuals with similarities such as living in the Wahiawā area near the health clinic and sharing a pediatric healthcare provider at a FQHC which could have resulted in some sampling errors (Convenience sampling-Research Methodology, n.d.). Lastly, the data collected may not be generalizable across a more diverse

population since a majority of the participants were Asians as indicated by the U.S Census Bureau (U.S Census Bureau QuickFacts: Wahiawā CDP, Hawaii, 2018). Inclusion criteria included: 1) Parents or guardians of a patient who was receiving at least one vaccination at the Wahiawā Health's pediatric clinic on that day of that visit and agreed to allow the MA to use the ShotBlocker® on their child; 2) MAs must have been trained, and exhibited an understanding for the protocol by appropriately demonstrating the protocol to the project's student Nurse Practitioner (NP) during the MA training. Exclusion criteria were: 1) Parents of patients who were over 18 years of age; 2) Pediatric patients not accompanied by a parent or guardian; 3) Parents or guardians whose child received a vaccination with this protocol during a previous visit; 4) Parents who refused to let MA use the device on their child; 5) Licensed professionals who were not trained with this protocol.

Procedures

Human Subjects Consideration. The author has completed the Collaborative Institutional Training Initiative (CITI) Training for research ethics and compliance, and Health Insurance Portability and Accountability Act (HIPAA) Training on patient privacy protections. This DNP project involved making judgments about a program to improve or further develop program effectiveness and inform decisions about future programming within an organization (University of Hawaii Human Studies program, personal communication, August 2, 2018). All these tasks were related to quality improvement, de-identified / anonymous responses regarding perceived pain, and did not involve any EMR information about the child or parent. As such the type of vaccination given to the child will not be recorded for the purposes of this EBP. Thus, this project did not require IRB approval and review.

Measurement Tools. Two measurement tools were used in assisting with collecting data: 1) Outcome Survey; 2) Post- vaccination survey incorporating the Wong-Baker FACES Pain Rating Scale.

The Outcome Survey conducted after the completion of the project consisted of six 5-point Likert Scale questions, one multiple choice question, and a section for comments. The questions rated the MAs' opinions on the protocol's ease of use, reasons for not using device with eligible patients, and effectiveness of the protocol compared to vaccinations given prior to the implementation of this project. The 5-point Likert Scale questions had answer choices ranging from "1: strongly disagree" to "5: strongly agree". This survey provided quantitative data and qualitative data from the MAs at the completion of the project (Figure E1). This outcome survey was created specifically for this project by the Student NP with the help of the Project Chair, thus, no data can be provided on the reliability and validity of the survey.

Lastly, the Wong-Baker FACES Pain Rating Scale was used to quantify patient's pain rating post- immunization and retrospectively from previous immunizations. This tool has been previously used, tested, and found to be reliable by Garra et al., (2010) with 95% confidence interval [CI] = 0.86 to 0.93 while the original creators of this scale indicated a validity of 60% and reliability of 87.5% (Wong & Baker, 1988). The Wong-Baker FACES scale is copyrighted, however permission was not needed for healthcare students (Figure E2). The questions using the Wong-Baker FACES scale were created by Dr. Stephanie Burgess, DNP, CPNP-PC and adapted into this project with permission (Figure E4).

Data Collection Procedures. ***Pre-implementation***. On May 20, 2019, 100 ShotBlockers® were ordered through an online medical supply retail company called Bionix (Bionix, n.d), 100 post-vaccination surveys/retrospective surveys were printed in preparation for

the project (Figure E3), and two 8.5 x 11 exam-room posters were be printed and laminated (Figure E7). Each sterile-wrapped ShotBlocker® was stapled to a numbered post-vaccination survey/retrospective survey for ease of transportation from the medication room to the exam room for use.

MAs were provided education on the effects of pediatric pain management on vaccination compliance, and trained on the protocol on June 7, 2019. This protocol training included directions on how to use and dispose of the ShotBlocker® which was created by the manufacturers (Figure E5). MAs were told that the ShotBlockers® were to be used solely for vaccination purposes on pediatric patients under the age of 18 years old with verbal acknowledgement from the parent or guardian, each ShotBlocker® could have been used multiple times on the same patient; thus, each ShotBlocker® was patient-specific and was not reused on any other patients. The MAs were encouraged to ask questions, and practice with the ShotBlocker® then asked to simulate giving a vaccination with the ShotBlocker®. MAs were also trained on how to ask the post-vaccination/retrospective survey questions to the parents (Figure E3). The post-vaccination/retrospective questions were answered by the parents of the child; however, if the child was able to answer these questions on his or her own, the MA could refer to the child to obtain the answers for the survey. A five question post-training survey was provided to each MA determining if the MA has gained understanding of how to use the ShotBlocker®, and the correlation between vaccination pain management and vaccination compliance (Figure E6). Answers were reviewed with MAs prior to dismissal from the training session.

Placement of project supplies was determined during the pre-implementation phase. The PNP indicated that the best placement for the surveys, and ShotBlockers® was in the medication

room. Descriptive posters approximately 8.5 inches x 11 inches were created and were placed on the back of the door in each exam room (Figure E7). The poster showed a ShotBlocker®, image of child obtaining a vaccination with the ShotBlocker® and four bullet points describing the ShotBlocker®. These posters were laminated for infection-control purposes, and placed on the back of each door in each exam room for parents and children to see as they waited for their providers. The purpose of the poster was to encourage parents to ask about the ShotBlocker® if the MA forgot to bring one into the room for the vaccinations.

Implementation. Between June 7, 2019 and August 21, 2019, MAs provided vaccinations on pediatric patients using the vaccination-pain mitigating protocol. Every parent or guardian who accompanies a pediatric patient to the Wahiawā Center for Community Health's pediatric clinic requiring one or more vaccination was informed by the MA that their child's vaccination would incorporate the ShotBlocker®. A poster referencing the ShotBlocker® was displayed in the examination room behind the door (Figure E7). The MA read a short script to the parent or guardian ensuring that all parents and patients received the same information; each script was printed on the survey (Figure E8). Once ready, the MA followed the ShotBlocker®'s manufacturer protocol by cleansing the injection site with an alcohol square, removing the device from its original seal, placing the bumpy side of the C-shaped device firmly against the child's skin around the site of injection, then immediately injecting the needle between the center of the C-shaped device (Figure E5 and E9). If multiple vaccinations were needed, the MA repeated the protocol using the same device. After the child received their vaccination(s), the MA who provided the vaccination(s) asked the parent and/or child the questions indicated on the post-vaccination/retrospective survey. This survey contained the request for the child's age, number of vaccinations obtained during a visit, a post-vaccination question regarding the perception of

the child's pain after the vaccination and a retrospective question regarding the perception of the child's pain after their last vaccination (Figure E3). The answers from the child or parent were marked by the MA onto the survey by circling the answer choices corresponding to the answer provided. If the parent or child declined to answer, or was unable to answer the two survey questions for other reasons, the MA marked the "unable to access" option. The ShotBlocker® was discarded into a regular trash receptacle or given to the parent to be brought back for future use if desired. The completed surveys were then placed into the MA's desk for the duration of the clinic day, then given to the PNP to be locked away until student NP collected the surveys. At the end of the implementation period (August 21, 2019), the MAs were also asked to complete a seven-question Outcome Survey to assess their opinions regarding their use of protocol and the children's reactions to the device (Figure E1).

Project Design

This project consisted of quality improvement components and evidence-based practice changes. The project heavily relied on existing literature to identify an efficient and effective approach to vaccination related pain mitigation in a pediatric population (Appendix A). Staff members from the pediatric clinic involved with the implementation process were educated on the importance of vaccination-pain mitigation, process for data collection, and were asked to provide verbal feedback biweekly to evaluation this evidence based practice project. Evaluation of this project included change in pain level with the use of the ShotBlocker®, as well as staff adherence to the protocol.

Results and Evaluation

The project took place between June 7, 2019 to August 21, 2019 at Wahiawā Health with 65 participants as determined by the number of surveys collected. Between those dates, it was

determined by the clinic's medical records that there were 216 pediatric patients who received vaccinations equating to a 30.09% ShotBlocker® use.

Vaccination survey results

Though 65 surveys were collected, 6 surveys were not included in the analysis due to missing data; thus, only 59 surveys were analyzed. Table 1 shows the age ranges of children who received vaccinations with the ShotBlocker® compared to the percentage of total shots given. It can be noted that children between the ages of 11-12 years received the most amount of vaccinations with the ShotBlocker®, 31% (n=18), followed by children between ages 3-5 years, 19% (n=11) whereas infants under 11 months received the most vaccinations, 28%, without the ShotBlocker® (Table 2).

Patients rated the level of pain from the vaccinations with the ShotBlocker® and pain from a previous vaccination. Pain levels were indicated by a number between zero being the lowest level of pain and ten being the highest level of pain. Based on the numbers indicated by the patients or parents, it was noted that the ShotBlocker® was effective on 40.7% (n=24) of patients, while 33.9% (n=20) of the participants found that the ShotBlocker was ineffective and 25.4% (n=15) of the participants indicated no difference between vaccination(s) with the ShotBlocker® and without the ShotBlocker® (Table 3).

Lastly, it was determined that the age categories and the difference in pain levels as well as the number of shots and difference in pain levels shows insignificant correlation as indicated by Pearson's correlation coefficient of R=0.026 and R=0.375, respectively.

Medical Assistant Outcome Survey Results

Four Medical Assistants participated in the implementation of this protocol. They were approached weekly to provide feedback on the protocol as well as how effective they thought the

device was in decreasing vaccination pain. Collectively, they agreed that the ShotBlocker® was more effective on older children about ages 5 years or older and less effective on infants.

After the implementation period of the project, three Medical Assistants and the Nurse Practitioner supervising the project completed outcome surveys with questions regarding the overall use of the ShotBlocker® in their clinic (Table 4). The Medical Assistants agreed that the ShotBlocker® was easy to use, easy to remember to use, has the potential to improve the immunization procedure, would likely use the ShotBlocker® in the future if given the chance, and saw that it was realistic to continue using the ShotBlocker® in their clinic setting (Table 4). Reasons reported for not using the ShotBlocker® included forgetting to use the device and not having enough time. Written reasons for not using the ShotBlocker® written on the survey indicated that there was a turnover in staff and an overload of duties for the Medical Assistants.

Discussion

In this project, 30% of the vaccinations given incorporated the pain mitigating device. Several reasons could be responsible for this rate not meeting the goal of 80%. The first as mentioned by the Medical Assistants were in fact that they did not see a change in infant pain levels as indicated by crying infants. This resulted in the use of the devices mostly on older children between 11-12 years of age (31%) and least on children between 12 months and 23 months (5%). Additionally, a change in staffing at the pediatric clinic resulted in the most recent Medical Assistant joining the team came after the start of this project; thus, the use of the ShotBlocker® with vaccinations may have been a new concept to the new Medical Assistant's work flow resulting in a decreased use of the devices.

Of the 30% (n=59) who did receive vaccinations with the ShotBlocker®, 24 individuals (40.7%) found that the ShotBlocker® reduced vaccination pain. The other 33.9% (n=20)

reported more pain with the use of the ShotBlocker® and 25.4% (n=15) reported no difference in pain from a previous vaccination and the vaccination given with the ShotBlocker®. With the varying number of Medical Assistants providing the vaccinations, various pressures placed on to the ShotBlocker® may have resulted in differing pain results. For example, if the ShotBlocker® was pressed onto the skin with great force, the ShotBlocker® could cause more pain than the vaccination itself, however, this pain variation may be difficult for children to differentiate and verbally describe. Alternatively, if the ShotBlocker® was not applied with enough pressure, it may not have been effective in 'blocking' the pain caused by the needle; thus, there may not have been a difference in pain levels from a shot received without the ShotBlocker®, and a shot received with the ShotBlocker®. Additionally, the survey did ask participants to recall the pain associated with their last vaccination which may be hard for younger children who might have a harder time recalling past events resulting in misleading survey answers (Fivush, 1998).

Lastly, it was determined that there was an insignificant correlation between the age of the child and the pain difference, R=0.026, and the number of shots and pain difference, R=0.375. This ultimately meant that a younger age was not associated with a higher pain rating while those receiving more vaccinations did not feel more pain. These results could be due to the small sample size obtained for this project. It has been indicated in previous studies that some vaccinations hurt more than others and thus if a vaccination that hurt less was given first, then the subsequent vaccinations would yield less pain as well; the opposite would also be true (Ipp, Parkin, Lear, Goldbach, & Taddio, 2009). In this project, the order of shots given to the participants were not tracked or monitored; thus, the variation in shots received by participants could have impacted the pain they reported.

Conclusion

Receiving vaccinations can be a stressful experience for many. Vaccination pain mitigation should be a method used with the pediatric population to help alleviate some of this stress. With easy to use, affordable methods such as the ShotBlocker®, vaccination pain can be reduced. The added benefits of reducing vaccination related pain are significant as mentioned in the study by Taddio et al. (2009), Stevens & Marvicsin (2016) and Luthy, Eden, Macintosh, & Beckstrand (2014). Thus, if a consistent vaccination pain reducing protocol could be maintained in a pediatric clinic, there could be a decrease in undesirable immunization experiences which could ultimately lead to higher rates of subsequent immunizations resulting in a decrease in immunization preventable diseases (Burgess, Nativio & Penrose, 2014).

If this protocol were to be incorporated into the pediatric clinic permanently, it would need to be incorporated into routine training to ensure that all team members are able to use the device effectively. Additionally, a reminder should be added to the electronic health record system to help remind the Medical Assistants to use the device when vaccinations are ordered by the provider.

In future evidence based projects, other pain mitigation devices could be used with adolescents/young adults to determine if increased staff compliance and decreased reported pain could be achievable. Alternatively, patients could choose from a selection of distracters they find appealing allowing them to customize their pain-mitigating options for their vaccinations. Another project could investigate how the order of vaccines (least painful vaccinations to most painful vaccinations) or single versus multiple vaccinations paired with a distracter could change the levels of pain felt by younger patients.

In summary, this EBP project demonstrated a reduction in pain of a portion of the sample largely consisting of adolescents with a trend reporting less pain as indicated in the results section. Adolescents are a key group to target as with improved compliance should getting them in the door for doctors visit and could potentially making them more positive on annual vaccinations such as flu shots. By adding this initial step into any pediatric vaccination protocol, vaccination pain can be reduced promoting a higher likelihood of return for vaccinations in the future (Taddio et al., 2009; Stevens & Marvicsin, 2016; Luthy, Eden, Macintosh, & Beckstrand, 2014). Lastly, this evidence based practice project met all requirements of the DNP Essentials of Doctor Education of Advanced Nursing Practice, which included population and patient assessment, design of intervention, implementation of the design, and evaluation of the quality improvement project using nursing interventions with a goal of improving the outcomes in healthcare for an underserved, pediatric population (American Association of Colleges of Nursing, 2006; Appendix F).

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Appendix A

Literature Review Matrix

Citation	Question/Purpose	Level of Evidence	Study Design	Sample	Findings	Limitations	Conclusion
Taddio, A., Chambers, C. T., Halperin, S. A., Ipp, M., Lockett, D., Rieder, M. J., & Shah, V. (2009). Inadequate pain management during routine childhood immunizations: The nerve of it. *Clinical Therapeutics, 31*(B), S152-S167. doi:10.1016/j.clinthera.2009.07.022	"This narrative review summarizes existing knowledge about: (1) the epidemiology of childhood immunization pain; (2) the pain experience of children undergoing immunization; (3) current analgesic practices; (4) barriers to practicing pain management in children; and (5) recommendations for improvements in pain management during immunization" (Taddio, A., Chambers, C. T., Halperin, S. A., Ipp, M., Lockett, D.,	Level 1	Systematic Review	Search of MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. Data collected for children and infants	"Vaccine injections are the most common iatrogenic procedure performed in childhood and a major source of distress for children (of all ages), their parents, and the participating health care professionals, as well as a direct cause of vaccine nonadherence. In addition, lack of adequate pain	Not indicated by researchers	Immunization is a global health priority. Medical care can be improved if pain management becomes a routine aspect of the delivery of vaccine injections (Taddio et. al, 2009).

	Rieder, M. J., & Shah, V., 2009).				management during immunization exposes children to unnecessary suffering and the potential for long-term consequences , such as fear of needles" (Taddio et. al, 2009).		
Taddio, A., Ipp, M., Thivakaran, S., Jamal, A., Parikh, C., Smart, S., Katz, J. (2012). Survey of the prevalence of immunization non-compliance due to needle fears in children and adults. *Vaccine, 30*(32), 4807-4812. doi:10.1016/j.vaccine .2012.05.011	"To address this knowledge gap given the continual increase in the number of vaccines being recommended and the potential for needle fear to negatively impact vaccine uptake. The primary objectives were to determine the prevalence of needle fears in adults and children undergoing immunization and the reported impact of needle fear on	Level 4	Cross-sectional survey	"In this cross-sectional survey, a convenienc e sample of parents (n = 883) and children (n = 1024) attending a public museum in Toronto, Canada answered questions about needle	"Altogether, 24% of parents and 63% of children reported a fear of needles. Needle fear was the primary reason for immunization non-compliance for 7% and 8% of parents and children, respectively"	"First, responses of children and adults were not validated, raising the possibility of reporting bias. Second, the chosen study site (i.e., OSC) may have led to recruitmen t of a study	"Interventions aimed at improving education about, and access to, analgesic interventions during immunization injections performed in childhood are recommended in order to prevent the development of needle fears and vaccine non-compliance"

	vaccine compliance. Secondary objectives were to describe parental attitudes about, and experiences with, immunization in their children" (Taddio, Ipp, Thivakaran, Jamal, Parikh, Smart, & Katz, 2012).			fears and non-compliance with immunization due to needle fear" (Taddio et. al, 2012).	(Taddio et. al, 2012).	sample with limited applicability to the general population " (Taddio et. al, 2012).	(Taddio et. al, 2012).

Baxter, A. L., Cohen, L. L., Burton, M., Mohammed, A., & Lawson, M. L. (2017). The number of injected same-day preschool vaccines relates to preadolescent needle fear and HPV uptake. *Vaccine, 35*(33), 4213-4219. doi:10.1016/j.vaccine.2017.06.029	"sought to examine the relationship of preschool vaccine history, parent and preadolescent needle fear, and subsequent compliance with optional vaccines" (Baxter, Cohen, Burton, Mohammed, & Lawson, 2017).	Level 2	Randomized Control Trial	120 children aged 10–12 years	"This study found that preadolescent fear related to childhood single-day injection history in a dose-dependent manner, but the infant and total number of childhood vaccinations did not predict fear. Parents of preadolescents underestimated their children's anxiety, and parent and child anxiety correlated poorly: parents skewed toward ''not anxious" while the	1) "unable to evaluate whether low-fear subjects in our study had interventions to reduce preschool injection pain or mitigate the intensity of multiple injections". 2) Small sample size (Baxter et. al, 2017)	"The more same-day preschool injections between 4 and 6 years of age, the more likely a child was to fear needles five years later. Preadolescent needle fear was a stronger predictor than parent vaccine anxiety of subsequent HPV vaccine uptake" (Baxter et. al, 2017).

					preadolescents skewed to the ‘‘most anxiety possible”. Preadolescents’ needle fear was a stronger predictor of subsequent uptake of the HPV vaccine than parent vaccine anxiety (Baxter et. al, 2017)."		

Mcmurtry, C. M., Riddell, R. P., Taddio, A., Racine, N., Asmundson, G. J., Noel, M., . Shah, V. (2015). Far from "just a poke". *The Clinical Journal of Pain, 31*. doi:10.1097/ajp.0000000000000272	"The purpose of this paper was to provide an overview of pain and fear in the context of needle procedures. This article will provide a conceptual foundation for understanding: (a) painful procedures and their role in the development and maintenance of high levels of fear; (b) treatment strategies for preventing or reducing the experience of pain and the development of fear; and (c) interventions for miti- gating high levels of fear once they are established." (Mcmurtry, Riddell, Taddio, Racine, Asmundson, Noel & Shah, 2015).	Level 1	Systematic Review	Unspecified	"First, the general definitions, lifespan development and functionality, needle procedure-related considerations, and assessment of the following constructs are provided: pain, fear, anxiety, phobia, distress, and vasovagal syncope. Second, the importance of unmitigated pain from needle procedures is highlighted from a developmental perspective.	Not indicated by researchers	Health care providers need to incorporate pain management strategies into their clinical practice; parents and individuals being immunized should also be taught appropriate strategies (Mcmurtry et. al, 2015).

					Third, the prevalence, course, etiology, and consequences of high levels of needle fear are described. Finally, the management of needle-related pain and fear are out- lined to provide an introduction to the series of systematic reviews in this issue" (Mcmurtry et. al, 2015).		

Taylor, E. M., Boyer, K., & Campbell, F. A. (2008). Pain in hospitalized children: A prospective cross-sectional survey of pain prevalence, intensity, assessment and management in a Canadian pediatric teaching hospital. *Pain Research and Management, 13*(1), 25-32. doi:10.1155/2008/478102	"The aim was to highlight areas of good practice, identify areas for improvement and inform development of hospital standards, education, future audits and the research agenda" (Taylor, Boyer, & Campbell, 2008).	Level 4	Cross-sectional survey	241 medical and surgical inpatients	"found that pain occurred commonly across all age groups and services. Pain was infrequently assessed. Analgesic therapy was largely single agent and intermittent, although very helpful when given (Taylor, Boyer, & Campbell, 2008)."	1) generalizability inherent in a single-center study 2) pain management index (PMI) used in the study has not been validated for use in a pediatric setting (Taylor, Boyer, & Campbell, 2008).	It was concluded that pain was infrequently assessed.
Caglar, S., Büyükyılmaz, F., Coşansu, G., & Çağlayan, S. (2017). Effectiveness of ShotBlocker for immunization pain in full-term neonates: A randomized controlled trial. *Journal Of Perinatal*	The objective of this randomized control trial was to examine the effectiveness of the ShotBlocker® in mitigating injection site pain when providing the Hepatitis B vaccine via IM to healthy full-term neonates	Level 2	Randomized control trial	This study took place in a private Istanbul hospital with a participant pool of 100 healthy term neonates	This study found that in regards to pain scores, neonates in the experimental group scored lower than the control group and	1) The nurses who assessed the neonates' responses and provided NIPS scores were not	This team concludes that the ShotBlocker® was effective in reducing injection pain related to Hepatitis B vaccine in term neonates

& Neonatal Nursing, 31(2), 166-171. doi:10.1097/JPN.0000000000000256	(Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017).			(Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017).	post injection heart rates of neonates in the experimental group showed to be lower than the control group (Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017).	blinded to the intervention. 2) The injections were given within 15 minutes of delivery. This may not be possible in other nurseries (Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017).	(Caglar, Büyükyılmaz, Coşansu, & Çağlayan, 2017).
Çelik, N., & Khorshid, L. (2015). The use of ShotBlocker for reducing the pain and anxiety associated with intramuscular injection. *Holistic Nursing Practice, 29*(5), 261-270. doi:10.1097/HNP.0000000000000105	Çelik & Khorshid (2015) hypothesized that the use of ShotBlocker would reduce the pain and anxiety in adults while administering intramuscular injections.	Level 2	Randomized, placebo controlled trial	In a 20 month randomized, placebo controlled trial consisting for 180 adults aged 18 to 80 (Çelik &	It was found that the experimental group had significantly lower pain than those in the other two groups. Anxiety levels in the experimental	None listed by authors	Based on this data, the researchers suggest that using the ShotBlocker® during intramuscular injection will reduce patients' pain intensity but will not

				Khorshid, 2015).	group increased after the injection but did not change in the other two groups. Lastly, heart rate was not affected by the ShotBlocker ® (Çelik & Khorshid, 2015).		reduce anxiety or heart rate and thus the ShotBlocker® is recommended as a pain-relieving tool for intramuscular injection in adults (Çelik & Khorshid, 2015).

Cobb, J., & Cohen, L. (2009). A randomized controlled trial of the ShotBlocker for children's immunization distress. *Clinical Journal Of Pain, 25*(9), 790-796. doi:10.1097/AJP.0b013e3181af1324	The purpose of this study was to provide a thorough evaluation the ShotBlocker (Cobb, J., & Cohen, L., 2009).	Level 2	Randomized Control trial	Cobb & Cohen (2009) included 89 participants ranging from the age of 4-12 years' old who were receiving immunizations at a pediatric practice.	This team found that there was no group difference evident in any measurements of child pain or anxiety between any of the three groups . No group differences were evident on any of the measures of child pain or anxiety when controlling for child age, nor were there any significant interactions of treatment condition with child age. On the observational distress	1) The sample was homogenous in terms of class and race, with a primarily White sample and more than half the sample reporting a family income greater than $90,000 annually. 2) the wide age range of the sample, 4 to 12 years of age, because there is a great deal of variability	Concluded the data from this study did not support the effectiveness of the ShotBlocker for acute pediatric pain relief (Cobb, J., & Cohen, L., 2009).

					measure, analysis of covariances revealed significantly higher distress in the injection than preinjection or postinjection phases, and postinjection distress was higher than preinjection phase distress, irrespective of treatment condition. (Cobb, J., & Cohen, L., 2009).	in prior immunization experiences in children of different ages, which likely impacts their level of distress. 3) both intramuscular and subcutaneous injections were included. 4) given that this was a busy pediatric practice, the staff might have hurried through the explanation of the device to	

						the participants, which may have minimized potential placebo effect. In contrast, the medical setting provided a realistic evaluation of the effectiveness of the ShotBlocker in a real-life setting (Cobb, J., & Cohen, L., 2009).	

Drago, L., Singh, S., Douglass-Bright, A., Yiadom, M., & Baumann, B. (2009). Efficacy of ShotBlocker in reducing pediatric pain associated with intramuscular injections. *American Journal Of Emergency Medicine, 27*(5), 536-543. doi:10.1016/j.ajem.2008.04.011	The objective of this study was to determine the efficacy of ShotBlocker® in reducing pediatric pain with intramuscular (IM) injections (Drago, Singh, Douglass-Bright, Yiadom, & Baumann, 2009).	Level 2	Randomized control trial	A randomized control trial included 165 children between ages 2 months to 12 years of age requiring intramuscular injections (Drago, Singh, Douglass-Bright, Yiadom, & Baumann, 2009).	The study found that perceived pain scores indicated by nurses and caregivers were higher in the control group than the experimental group. However, children 36 months and older did not report a difference in pain score. Additionally, the study included that nurses did not perceive the implementation and use of the ShotBlocker ® to be difficult	1) The study was population was a convenience sample which introduces the possibility that the data does not reflect the general population. 2) Lack of blinding - no way to blind parents, children, or nurses using a placebo device (Drago et al., 2009).	Nurses reported mean pain scores of 2.6 without the ShotBlocker compared to 1.8 with the ShotBlocker. Caregivers also noted reduced pain scores of 2.6 vs 2.1, with the implementation of the ShotBlocker (Drago et al., 2009).

					(Drago et al., 2009).		
Emel, T., Nese, C., & Leyla, K. (2017). Effects of ShotBlocker on relief of pain due to Hepatitis B vaccine injection into deltoid muscle. *International Journal Of Caring Sciences, 10*(3), 1669-1675.	This study looked at the effects of the ShotBlocker in regards to its' relief of pain from Hepatitis B vaccination via IM within an adult population (Emel, Nese & Leyla, 2017).	Level 2	randomized-controlled and single-blind	The researchers used a randomized-controlled and single-blind design consisting of 242 participants between the ages of 18-31 years old (Emel, Nese & Leyla, 2017).	Results from this study indicated that pain severity were not significantly different between experimental and control group. Additionally, women from both groups experience a higher level of pain. They also noticed	1) BMI significantly affected pain severity in both control and experimental groups ($p<0.05$) 2) nurses using ShotBlocker needed to have good manual skills	In conclusion, the researchers of this study found that the use of the ShotBlocker® did not affect the severity of pain from Hepatitis B vaccines given intramuscularly to adults (Emel, Nese & Leyla, 2017).

					increased BMI related to decrease pain severity (Emel, Nese & Leyla, 2017).	(Emel, Nese & Leyla, 2017).	
Shahid, R., Benedict, C., Mishra, S., Mulye, M., & Guo, R. (2014). Using iPads for distraction to reduce Pain during immunizations. *Clinical Pediatrics, 54*(2), 145-148. doi:10.1177/0009922814548672	The purpose of this study was to determine if using an iPad would minimize child's pain and distress during immunizations as perceived by the parent (Shahid et al., 2014).	Level 6	Survey	A total of 103 parents completed a survey regarding their perception of their child's pain during immunizations (Shahid et al., 2014).	"Regression analysis showed that the use of iPad distraction significantly reduced the parent's perception of their child's level of anxiety, need for being held, and amount of crying during immunizations compared to no distraction."	1) 2 groups of patients enrolled in the control group or intervention group were a convenience sample and not randomized to one group or the other. 2) The survey tool and questions were created	"Distraction by using an iPad during immunizations reduces the parent's perception of their child's pain and distress. This type of distraction tool can also improve the parent's satisfaction with the pain control provided for their child while receiving their vaccines." (Shahid et al., 2014).

					(Shahid et al., 2014).	specifically for this study and have not been validated or shown to be reliable in other studies (Shahid et al., 2014).	
Wallace, D. P., Allen, K. D., Lacroix, A. E., & Pitner, S. L. (2010). The "cough trick:" A brief strategy to manage pediatric pain from immunization injections. *Pediatrics, 125*(2), 367-373. doi:10.1542/peds.2009-0536	This within-subject design investigated the effect of a "cough trick" technique on self-reported pain of children receiving routine immunization (Wallace, Allen, Lacroix, & Pitner, 2010).	Level 2	randomized, controlled, unblinded, within-subject study	68 children receiving prekindergarten (ages 4 –5) or pre–junior high school (ages 11–13) immunizations	"In the initial analysis, the procedure was found not to be effective. However, post hoc tests revealed that the procedure was effective at a statistically and clinically significant level for participants identified as Hispanic white or non-	1) Some children, after learning that the injection would not occur until they coughed, delayed their cough or refused to comply, apparently to avoid the injection. 2) ~40% of invited	"The results of this study suggest that the cough trick can be an effective strategy for the reduction of pain for some children undergoing routine immunizations." (Wallace, Allen, Lacroix, & Pitner, 2010).

					Hispanic white but not for those identified as non-Hispanic black. Participants and clinic nurses found the procedure acceptable and effective." (Wallace, Allen, Lacroix, & Pitner, 2010).	parents declined participation into study due to the fear of the time needed (Wallace, Allen, Lacroix, & Pitner, 2010).	
French, G. M., MD, Painter, E. C., RN, MSN, & Coury, D. L., MD. (1994). Blowing away shot pain: A technique for pain management during immunization. *Pediatrics, 93*(3), 384-388.	This randomized control study looked at the effect air-blowing has on minimizing vaccination pain in preschool children receiving immunization (French, Painter & Coury, 1994).	Level 2	Randomized control trial	149 children from 4 to 7 years old.	"Children who were taught to blow out air during their shots had significantly fewer pain behaviors and demonstrated a trend toward lower subjectively reported pain. There were no significant	1) Infants that were being immunized near the subject increasing the anxiety of the subjects. 2) the OSBD scale used in this study has been well studied in	"A simple distraction can be effective in helping children cope with pain in immunization. This technique to relieve the pain and distress associated with even a brief painful procedure should be encouraged."

					difference in the nurse or parent visual analog scale scores." (French, Painter & Coury, 1994).	rating pain behaviors during lumbar punctures and bone marrow aspirations but not in vaccinations (French, Painter & Coury, 1994).	(French, Painter & Coury, 1994).
Cohen, L. L., Blount, R. L., Cohen, R. J., Schaen, E. R., & Zaff, J. F. (1999). Comparative study of distraction versus topical anesthesia for pediatric pain management during immunizations. *Health Psychology, 18*(6), 591-598. doi:10.1037//0278-6133.18.6.591	"This study compared distraction, an anesthetic (eutectic mixture of local anesthetics [EMLA]), and typical care during pediatric immunizations" (Cohen, Blount, Cohen, Schaen, & Zaff, 1999).	Level 2	Comparative study	"Participants were 39 4th graders receiving a 3-injection vaccination series over a 6-month period" (Cohen, Blount, Cohen, Schaen, & Zaff, 1999).	"Distraction resulted in more nurse coaching and child coping and less child distress than did EMLA or typical care on an observational measure. EMLA did not result in increased child coping or decreased distress. In	"1) It was not possible to control or evaluate children's comments to one another about the procedure. Likely that rumors had an impact, either positively or negatively,	"... children preferred the treatments to typical care, whereas the nurse appreciated aspects of each of the conditions. Finally, distraction was more economical than EMLA." (Cohen, Blount, Cohen, Schaen, & Zaff, 1999).

					fact, the nurse coached more, and trends suggested that children coped more with typical care than with EMLA. Whereas participant ratings and heart rate did not differ among conditions, all 3 conditions demonstrated improvements over time with these measures." (Cohen, Blount, Cohen, Schaen, & Zaff, 1999).	on the outcome variables. Similarly, children's observations of peers' status after the procedure likely influenced distress. 2) homogeneity of the sample" (Cohen, Blount, Cohen, Schaen, & Zaff, 1999).	

Özdemir FK, Tüfekci FG. (2012) .The effect of using musical mobiles on reducing pain in infants during vaccination. *Journal of Research in Medical Sciences, 17*, 662-7	"The aim of the study was to test the effectiveness of a musical mobile as a distraction tool on pain reduction in infants during a vaccine injection" (Özdemir & Tüfekci, 2012).	Level 3	quasi-experimental model	120 infants	"The pain scores of the infants in the test group were lower than the scores of the infants in the control group and after the procedure. The crying duration was also shorter among infants in the test group than among infants in the control group during the vaccination injection" (Özdemir & Tüfekci, 2012).	1) Pain scoring is subjective and based on observation. 2) There were some difficulty balancing the behavior of parents during the procedure (Özdemir & Tüfekci, 2012).	"A lower pain score and shorter crying duration in response to vaccination in a room furnished with a musical mobile indicates that distracting attention via a musical mobile is a practical way to reduce pain during routine medical interventions in infants" (Özdemir & Tüfekci, 2012).

Berberich, R., & Landman, Z. (2009). Reducing immunization discomfort in 4- to 6-year-old children: A randomized clinical trial. *Child: Care, Health and Development, 35*(6), 890-890. doi:10.1111/j.1365-2214.2009.01023_1.x	The goal was to test a multifaceted distraction method designed to reduce injection-associated pain in school-aged children (Berberich, R., & Landman, Z., 2009).	Level 2	Randomized Clinical Trial	A clinical trial evaluated 41 children, 4 to 6 years of age, who were given 3 standard prekindergarten immunizations; 21 were assigned randomly to an office routine control group, whereas 20 received a multifaceted, discomfort-reducing intervention.	According to patient and parent Faces Pain Scale-Revised scores and nonblinded, video-taped observations scored according to the face-legs-activity-crying-consolability method, the intervention group showed highly significant reductions in pain and discomfort, compared with the control group (patient self-report, P .0013; parent report, P .0002; observation	May 2007 to August 2007	This multifaceted distraction intervention reduced significantly the pain and discomfort of childhood immunizations in children 4 to 6 years of age.

					score, P .0001).		
Jacobson, R. M., Swan, A., Adegbenro, A., Ludington, S. L., Wollan, P. C., & Poland, G. A. (2001). Making vaccines more acceptable — methods to prevent and minimize pain and other common adverse events associated with vaccines. *Vaccine, 19*(17-19), 2418-2427. doi:10.1016/s0264-410x(00)00466-7	Address non-adherence with pediatric vaccine schedules, identify useful predictors for both the preparatory and procedural distress	Level 4	Cohort study	150 children each in of two age-groups: 15 – 18 months and 4 – 6 years of age.	found that approximately 20% of the subjects suffered serious distress or worse. During the procedural phase, approximately 90% of the 15-to-18 month old children and 45% of the 4-to-6 year old children showed serious	Not specified	The data presented in Part 1 reinforce previous concerns expressed by parents, clinicians, nurses, and public health care providers: a significant proportion of children suffer substantial pain and distress from vaccination. The review provided in Part 2 demonstrates that potential

					distress or worse.		cost-effective measures do exist. The review also indicates that more study is necessary to determine the effectiveness, practicality, and acceptability of their routine use.

Taddio, A., Appleton, M., Bortolussi, R., Chambers, C., Dubey, V., Halperin, S., Hanrahan, A., Ipp, M., Lockett, D., MacDonald, N., Midmer, D., Mousmanis, P., Palda, V., Pielak, K., Riddell, R. P., Rieder, M., Scott, J., … Shah, V. (2010). Reducing the pain of childhood vaccination: An evidence-based clinical practice guideline. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne, 182*(18), E843-55.	The objective was to develop a clinical practice guideline, based on systematic reviews of the literature, as interpreted by experts, to assist clinicians in managing procedure-related pain and distress among children undergoing vaccine injections.	Level 7	Evidence Based Study Guidelines	The scope was limited to acute (immediate) pain and distress at the time of vaccine injection in children 0 to 18 years of age	Vaccine injections performed in childhood are a substantial source of distress. Untreated pain can have long-term consequences including preprocedural anxiety, hyperalgesia, needle fears, and avoidance of health care. Simple, cost-effective, evidence-based pain-relieving strategies are available. Recommendations in this guideline are based on a “3-P” (pharmacologic, physical	1) The recommendations included in this guideline are limited by the evidence that was available at the time of publication of the three systematic reviews. 2) For some pain-relieving strategies (e.g., use of sweet-tasting solutions, tactile stimulation), they could not determine with confidence the optimal administrat	"Pain during vaccination is an important concern across the lifespan. This guideline provides recommendations for interventions that can mitigate vaccination pain. Many interventions are feasible across vaccination settings."

					and psychological) approach.	ion technique and the upper and/or lower age limits for effectiveness from the existing evidence. 3)Some of the research studies upon which the recommendations are based were limited in terms of the inclusion of children and parents with different demographic characteristics and backgroun	

						ds 4)literature search did not identify studies examining the impact on injection-related pain of the environment or setting in which vaccination was performed (e.g., clinic, school), characteristics of the needle and selected aspects of the injection technique (e.g., gauge, length,	

						angle of injection) or the body region where the vaccine was injected (e.g., arm, thigh).	

Stevens, K. E., & Marvicsin, D. J. (2016). Evidence-based recommendations for reducing pediatric distress during vaccination. *Pediatric Nursing,42*(6), 267-299.	Providing strategies based on 41 clinical guidelines that would help parents, children, and clinicians enhance coping strategies from vaccination pain. 2 sets of handouts were designed to enhance education of stand and parents. These guides were produced using 41 clinical guidelines, reviews and randomized trials. These handouts provided information on parent and staff intervention, before, during and after vaccinations focusing on techniques deemed effective, cost-efficient and adaptable.	Level 1	Meta-Analysis	A literature search of CINAHL, Medline, PubMed, and the Cochrane Database was performed using combinations of the following terms: pediatric, vaccination, immunization, coping, and needlestick. Guidelines, reviews, meta-analyses, and randomized con- trolled trials (RCTs) were used	Not specified	Most articles did not include ways to verbally introduce or implement distraction techniques. Rather, a typical description dryly describes a method as “uses toy” or “adult makes comments about toy."	Not specified

				to produce two sets of tailored handouts. Study populations ranged from new-born to 18 years, varying according to age-appropriateness of interventions. Studies used a wide variety of objective pain scales in addition to parent-reported and patient-reported subjective scales. 41 clinical guidelines assessed.			

Luthy, Eden, L., Macintosh, J., & Beckstrand, R. (2014). Minimizing pain during childhood vaccination injections: Improving adherence to vaccination schedules. *Pediatric Health, Medicine and Therapeutics, 127*. doi:10.2147/phmt.s50510	This review evaluates various pain relieving interventions and provide health care providers age appropriate guidance on pain relieving interventions during vaccinations.	Level 1	Systematic Review	There were 29 studies that met the inclusion criteria. Vaccination pain relieving strategies can be grouped into four main categories: 1) topical anesthetics, 2) distraction, 3) positioning, and 4) pH of vaccination.	Newborns should be held in the parent's arms during vaccinations. KC seems to be effective in lowering distress and pain as well as administration of sucrose or breastfeeding during vaccination administrations. Infants who are breastfed or administered sucrose during vaccinations seem to have lower distress and pain. The positioning of infants 2–6 months of age does not	1) Research on methods of pain reduction during vaccination is lacking. While there are numerous interventions for reducing vaccination pain and various pain evaluation tools, there is a lack of continuity in the available research. Studies investigating different techniques for pain	"Pain experienced at a young age can have psychologically detrimental effects. Vaccinations are the most common painful procedure for infants and children and often result in decreased adherence to the vaccination schedule. The HCP has a responsibility to incorporate effective pain-relieving strategies with vaccinations. The information presented in this review provides HCPs with age appropriate guidance on pain-relieving interventions

					seem to change the pain score or decrease crying time. Multifaceted interventions seem to be effective in young children during vaccinations. They should be placed in a sitting position and offered a party blower. If time allows, lidocaine-prilocaine cream can be applied prior to injection. Adolescents should be offered the opportunity to listen to their choice of music	relief during vaccination use varied study designs, evaluation tools, and age ranges. 2) some studies incorporated several different intervention techniques, making it difficult to determine which intervention clearly reduced vaccination pain. 3) many of the studies regarding vaccination pain have small	during vaccinations. Many of these strategies are cost-efficient, timely, and effective, making them successful pain-management techniques."

					before, during, and after the vaccination procedure, as this seems to be effective in lowering pain and distress. Additionally, if time allows, lidocaine-prilocaine cream can be applied prior to injection.	sample sizes.	

Kristjánsdóttir, Ó, & Kristjánsdóttir, G. (2011). Randomized clinical trial of musical distraction with and without headphones for adolescents' immunization pain. *Scandinavian Journal of Caring Sciences, 25*(1), 19-26. doi:10.1111/j.1471-6712.2010.00784.x	The aim of this study was to evaluate the usefulness of an easy and practical musical distraction in reducing adolescents' immunization pain. Furthermore, to examine whether musical distraction techniques (with or without head-phones) used influenced the pain outcome.	Level 2	Randomized clinical trial	Hundred and eighteen 14-year-old adolescents, scheduled for polio immunization, participated	Results showed adolescents receiving musical distraction were less likely to report pain compared to the control group, controlling for covariates. Comparing musical distraction techniques, eliminating headphone emerged as a significant predictor of no pain. Results suggest that an easy and practical musical distraction intervention, implemented	1) Adolescents' immunization pain intensity ratings were very low, which is consistent with previous findings showing low needle pain scores among older children and adolescents. 2) the covariates controlled for were limited by its emphasis on psycho-logical dimensions affecting	In conclusion, musical distraction in general and specifically used without headphones was a significant predictor of feeling less pain during polio immunization, whereas the use of headphones was not. These findings suggest that a cost-effective, time-efficient and easy-to-use nonpharmacological intervention may provide some comfort to adolescents during these routine distressing health care procedures.

					without headphones, can give some pain relief to adolescents during routine vaccination.	children's pain perception. In regards to the nurses, they were blinded to the study hypothesis but not to the interventio n groups. 3) the data collection took a few days and was carried out in a busy school health clinic. This made it difficult to control the adolescent s' comments to one another about the	

						procedure and impossible to rule out the impact of rumors, either positive or negative, on the outcome variables. 4)	

Şahiner, N. C., Inal, S., & Akbay, A. S. (2015). The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. *Journal of PeriAnesthesia Nursing, 30*(3), 228-235. doi:10.1016/j.jopan.2014.05.011	Procedures involving needles are the most common and major sources of pain in children. External cold and vibration via Buzzy (MMJ Labs, Atlanta, GA) is a method that combines cooling and vibration.	Level 2	prospective, randomized controlled trial. Children were randomized into two groups: experimental (external cold and Buzzy) and control (no intervention)	7 year old children needing DTaP (total sample of 104)	The experimental group showed significantly lower pain and anxiety levels than the control group during immunization.	The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.	The combined stimulation of skin with external cold and vibration can be used to reduce pain and anxiety during pediatric immunization.

Cassidy, K., Reid, G. J., Mcgrath, P. J., Finley, G. A., Smith, D. J., Morley, C., . . . Morton, B. (2002). Watch needle, watch tv: Audiovisual distraction in preschool immunization. *Pain Medicine, 3*(2), 108-118. doi:10.1046/j.1526-4637.2002.02027.x	To evaluate the effectiveness of audiovisual distraction compared with a blank TV screen in the reduction of pain associated with intramuscular immunization.	Level 2	Randomized Controlled Trial	Five-year-old children (N= 62), undergoing diphtheria, polio, tetanus, and pertussis immunization, and their parents.	There were no significant group differences for any pain or distraction measures. The relative risk estimate for clinically significant pain among the distraction group was 0.64 (range: 0.23–1.80). Higher levels of distraction (i.e., greater time looking at the TV screen) related to lower levels of pain on all three pain measures. Only correlations with objective pain	1) The lack of sensitive and reliable pain measures; 2) The absence of objective distraction measures; and 3) The failure to consider the clinical significance of the results.	Watching cartoons did not distract children during needle injection nor reduce their pain. Looking at the TV screen was related to lower behavioral pain scores in the total sample.

					measures were statistically significant.		

Chambers, C. T., Taddio, A., Uman, L. S., & Mcmurtry, C. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: A systematic review. *Clinical Therapeutics, 31*. doi:10.1016/j.clinthera.2009.07.023	conducted a systematic review to determine the efficacy of various psychological strategies for reducing pain and distress in children during routine immunizations.	Level 1	Systematic Review	MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Con-trolled Trials databases were searched to identify randomized controlled trials (RCTs) and quasi-RCTs that determined the effect of psychological interventions on pain and distress during injection of vaccines in	Twenty RCTs involving 1380 infants and children (1 month to 11 years of age) were included in the systematic review. Breathing exercises were effective in reducing children's self-reported pain. Self-reported distress ratings appeared to be lower with breathing exercises, but the difference was not statistically significant. No evidence was found to	Limitations of the current review include its focus on trials with infants and school-aged children (age range, 1 month to 11 years) as participants; no trials of psychological interventions for reducing pain and distress associated with immunization in adolescents were identified. Adolescent	Evidence suggests that breathing exercises, child-directed distraction, nurse-led distraction, and combined cognitive-behavioral interventions are effective in reducing the pain and distress associated with routine childhood immunizations. Although additional well-designed trials examining psychological interventions are needed, parents and health care professionals should be advised to incorporate psychological interventions to

				children 0 to 18 years of age, using validated child self-reported pain or observer-reported assessments of child distress or pain. We examined the efficacy of 7 psychological interventions: (1) breathing exercises; (2) suggestion; (3) child-directed distraction; (4) parent-led distraction; (5) nurse-led	support suggestion as a psychological intervention for reducing pain associated with pediatric immunization. Child-directed distraction was effective in reducing self-reported pain. Parent-led distraction was effective in reducing observer-rated distress, but not other measures of pain or distress. Nurse-led distraction was effective in reducing distress	s must also undergo immunizations, and the value of psychological interventions for reducing their pain and distress during these procedures should be examined.	reduce the pain and dis- tress experienced by children during immunization.

				distraction; (6) parent coaching; and (7) combined cognitive-behavioral interventions. All meta-analyses were performed using a fixed-effects model.	ratings as assessed by the observer, the parent , and the nurse. Parent coaching was effective in reducing observer-rated distress , but not other measures of pain or distress. Combined cognitive-behavioral interventions were effective in reducing children's self-reported pain, observer-rated distress		

Riddell, R. P., Taddio, A., Mcmurtry, C. M., Chambers, C., Shah, V., & Noel, M. (2015). Psychological interventions for vaccine injections in young children 0 to 3 years. *The Clinical Journal of Pain, 31*. doi:10.1097/ajp.0000000000000279	This systematic review evaluated the effectiveness of distraction for reducing infant distress during vaccinations in young children aged 0 to 3 years.	Level 1 and Level 3	Systematic Review of randomized and quasi-randomized controlled trials	Database searches identified relevant randomized and quasi-randomized controlled trials. Three separate clinical questions related to variants of the psychological strategy of dis-traction (directed video; directed toy; nondirected toy) were pursued. Distress was identified as the critical outcome to	Ten studies were included in the review. For directed video distraction, moderate quality evidence suggested that distress was lowered in the treatment group. For directed toy distraction, the analysis of low-quality evidence for a combined preprocedure + acute + recovery phase of distress suggested that distress was lowered in the treatment	"The quantity and quality of the studies are not adequate to base strong recommendations in either direction. Moreover, as noted earlier, the age of children in most of these studies encompassed large developmental spans during infancy. Despite this knowledge, the paucity of literature did not	"Generally low-quality to very–low-quality evidence suggests that there may be an effect of directed (toy and video) and nondirected toy distraction for children aged 0 to 3 years, for certain phases of the vaccination."

				assess the benefits of distraction and extracted from relevant trials. Distress was analyzed by phase of procedure (distress preprocedure; distress acute; distress recovery; idiosyncratic phases based on some or all of the 3 aforementioned phases). Ten studies were included in the review.	group. An effect for nondirected toy distraction was also seen, analyzing very–low-quality evidence, for the acute distress phase.	permit more finely grained age analyses in this review. Another limitation that is pertinent to understanding distraction on the infant is the role of holding. The position of the child is a crucial element to the execution of distraction; therefore, future researchers on this topic are	

						strongly encouraged to provide this methodological detail."	

Taddio, A., Mcmurtry, C. M., Shah, V., Riddell, R. P., Chambers, C. T., Noel, M., . . . Bleeker, E. V. (2015). Reducing pain during vaccine injections: Clinical practice guideline. *Canadian Medical Association Journal, 187*(13), 975-982. doi:10.1503/cmaj.150391	The current guideline expands on and updates the 2010 guideline with recommendations across the lifespan.	Level 1	Systematic Review	The researchers identified relevant articles by searching MEDLINE, Embase, PsycINFO, CINAHL and ProQuest Dissertations & Theses Global from their date of inception until Feb. 26, 2015	"1) Pain at the time of vaccine injection is a common concern and contributes to vaccine hesitancy across the lifespan. 2) Evidence-based and feasible interventions are available to mitigate pain and are part of good vaccination clinical practice. 3) This guideline includes recommendations for pain mitigation based on five domains of pain management interventions	"The guideline recommendations are limited to the available evidence, and certain recommendations have more research support than others. There was a noticeable gap in research evidence for adolescent and adult populations, and mass vaccination settings, even though concerns about pain	This guideline provides recommendations for interventions that can mitigate vaccination pain. Many interventions are feasible across vaccination settings.

					(procedural, physical, pharmacologic, psychological and process): the “5P” approach."	and fear are well documented and contribute to vaccine hesitancy. Data are needed on the painfulness of different vaccines (including their route of administration), aspects of vaccine injection technique (e.g., speed of injection and injection in a single limb for multiple vaccine injections), and vaccine	

						formulations and delivery systems that minimize pain."	

Chambers, C. T., Taddio, A., Uman, L. S., & Mcmurtry, C. (2009). Psychological interventions for reducing pain and distress during routine childhood immunizations: A systematic review. *Clinical Therapeutics, 31*. doi:10.1016/j.clinthera.2009.07.023	The purpose of this review is to bring a developmental lens to the challenges in assessment and non-pharmacologic treatment of pain in young children.	Level 1	A systematic review	"the initial search resulted in 118 articles including 92 research studies, 5 informational articles, and 21 review articles"	"Assessment of developmental cues is essential. For example, crying, facial expression, and body posture are behaviors in infancy that indicate pain: However in toddlers these same behaviors are not necessarily indicative of pain. Preschoolers need observation scales in combination with self-report while for older children self-report is the gold standard.	1) Grey literature was not included which could have included additional and updated information, 2) Only English sources considered	"A developmental approach to assessing and treating pain is critical. Swaddling, picture books, or blowing bubbles are easy and effective when used at the appropriate developmental stage and relieve both physical and emotional pain. Untreated pain in infants and young children may lead to increased pain perception and chronic pain in adolescents and adults. Continued research in the non-pharmacological treatment of pain is an important part of the

					Pain management in infants includes swaddling and sucking. However for toddlers, preschoolers and older children, increasingly sophisticated distraction techniques such as easily implemented non-pharmacologic pain management strategies include reading stories, watching cartoons, or listening to music."		national agenda."

A Taddio, AF Ilersich, AN Ilersich, J Wells. From the mouth of babes: Getting vaccinated doesn't have to hurt. *Can J Infect Dis Med Microbiol 2014;25*(4):196-200.	To explore children's experiences of vaccination and preferences for analgesia.	Level 6	Qualitative sampling	A total of 17 children (four to 14 years of age) at an independent school in Toronto (Ontario) participated in three focus-group interviews.	"Children easily recalled previous vaccinations and discussed fear and distress experienced by themselves and others. Children believed that parents and immunizers should prepare them ahead of time and use interventions to manage and monitor pain. They also wanted adults to support their efforts to lead pain management. Children discussed benefits of	1) Only one school in Toronto was included; possible that not all perspective students were identified. 2) the responses of children who participated in the pilot may have been influenced by a desirability to respond in a socially desirable way (ex. make the issue of pain larger). 3) the changes to	"Children reported that managing vaccination pain is important and that analgesic interventions should routinely be used. Incorporating pain management in the process of vaccination has the potential to improve children's experiences with vaccination and pro- mote more positive attitudes and behaviors."

					managing pain, including reduced unnecessary suffering, improved vaccination experience, reduced risk of developing needle fears and reduced noncompliant behaviors. They were knowledgeable about strategies for reducing pain including distraction, topical anesthetics and injection techniques. They contrasted vaccination with and without pain management, and indicated	the school-based clinic that occurred in the study school could be accommodated by school administrators and the regional public health unit; however, they may be more difficult to implement in other schools and/or public health units, limiting the generalizability of the results.	

					a preference for pain management. "		

Waxman, J. A., Dilorenzo, M. G., Riddell, R. R., Flora, D. B., Greenberg, S., & Garfield, H. (2017). Preschool needle pain responding: Establishing 'normal'. *The Journal of Pain, 18*(6), 739-745. doi:10.1016/j.jpain.2017.01.010	This study provides descriptive data for preschool vaccination pain responding as well as examines longitudinal relationships over early childhood.		longitudinal study	Infants were recruited at 2, 4, or 6 months of age. Of the 760 dyads recruited, 548 were seen at the 12-month vaccination and 302 were seen at the preschool vaccination (ages 4–5 years)	"There were no significant associations between 12-month and preschool pain responding. These results highlight the steep trajectory of development between these different stages of early childhood and the variability of pain responding at the preschool vaccination."	"Despite the large sample size, generalizability will be affected by the high education level of the sample, as well as any bias associated with being in a family that was able to be observed longitudinally from infancy to preschool-age vaccinations."	"Demonstrating significantly different pain patterns from infancy, 25% of preschoolers are displaying suboptimal regulation trajectories. This considerable minority poses a significant concern because of the established trajectory of phobia onset in middle childhood."

Schurman, J. V., Deacy, A. D., Johnson, R. J., Parker, J., Williams, K., Wallace, D., . . . Mroczka, K. (2017). Using quality improvement methods to increase use of pain prevention strategies for childhood vaccination. *World Journal of Clinical Pediatrics, 6*(1), 81. doi:10.5409/wjcp.v6.i1.81	To increase evidence-based pain prevention strategy use during routine vaccinations in a pediatric primary care clinic using quality improvement methodology.	Level 1	Evidence Based Study Guidelines	The PCC's 41 physicians and 18 nurse practitioners, with the assistance of approximately 45 nurses, conduct more than 45000 patient visits annually.	1) Overall parent-/caregiver-reported satisfaction with the vaccination visit as a whole remained high and stable from baseline to post-intervention (94% endorsing a 1 or 2 on a 5-point scale with lower values indicating greater satisfaction). 2) Approximately 1 year following transition of control and responsibility to PCC staff under the	1) Problem with validity of nursing self-report at baseline,	Quality improvement methodology can be used to help close the gap in implementing pain prevention strategies during routine vaccination procedures for children. Findings from this project suggest that, despite the evidence stressing the importance of incorporating evidence-based strategies to manage the pain a patient experiences in the clinical setting, many nurses do not possess the skills and knowledge to incorporate these practices

					leadership of the Process Owner, staff demonstrated some important shifts in their own attitudes and their perceptions of parents/caregiver attitudes within the context of pain prevention.		effectively in their daily patient care.

Burgess, S., Nativio, D. G., & Penrose, J. E. (2015). Quality improvement project to reduce pain and distress associated with immunization visits in pediatric primary care. *Journal of Pediatric Nursing*, *30*(2), 294-300. doi:10.1016/j.pedn.2014.09.002	This quality improvement project implemented an evidence-based immunization protocol aimed at decreasing pain and distress associated with immunizations for children ages 4 to 6 by utilizing distraction and a benzocaine-based anesthetic spray.	Level 1	Evidenced based study; Convenience sampling; quasi-experimental project	parents of 30 children between ages 4-6 years old	"Statistical analysis by paired t-test indicated a statistically significant decrease in reported distress by both the child and the caregiver utilizing the immunization protocol."	Not indicated by researchers	"Finding an immunization procedure that not only garners staff buy-in but also produces statistically significant less distress for both the child and the caregiver is a positive step toward promoting on-time immunization. If used consistently and properly, this immunization procedure has the potential to decrease negative immunization experiences, increase on-time immunization and decrease the incidence of vaccine preventable diseases."

Sparks, L. (2001). Taking the "Ouch" out of injections for children. MCN, *The American Journal of Maternal/Child Nursing, 26*(2), 72-78. doi:10.1097/00005721-200103000-00005	This research compared the effect of two forms of distraction on injection pain in a convenience sample of preschool children.	Level 3	A quasi-experimental study	105 children (53 girls and 52 boys) ages 4 to 6 years needing DPT immunizations. Data were collected at three sites: two school-based immunization clinics and one public health center with a walk-in immunization program.	Both forms of distraction, touch and bubble-blowing, significantly reduced pain perception. There were no interaction effects of either age or gender. Fear was a significant covariate, but distraction was effective even when fear was not held constant.	The study findings are limited to healthy preschool children from one suburban setting. Other limitations include use of a convenience sample and the numbers of nurses who gave the injections. While the equipment and procedures were identical, individual differences in injection technique may have existed. Another	Distraction appears to be an effective method for decreasing injection pain in young children. It is an easy, practical nursing intervention to help children cope with this common, painful experience.

						limitation was the use of the CMFS with 4-year-olds because the reliability and validity for this age group has not been established.	

Appendix B

Tables and Figures Related to the DNP Project

Level of evidence (LOE)	Description
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trial) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results.
Level II	Evidence obtained from at least one well-designed RCT (e.g. large multi-site RCT).
Level III	Evidence obtained from well-designed controlled trials without randomization (i.e. quasi-experimental).
Level IV	Evidence from well-designed case-control or cohort studies.
Level V	Evidence from systematic reviews of descriptive and qualitative studies (meta-synthesis).
Level VI	Evidence from a single descriptive or qualitative study.
Level VII	Evidence from the opinion of authorities and/or reports of expert committees.

Figure B1. Mosby's Level of Evidence

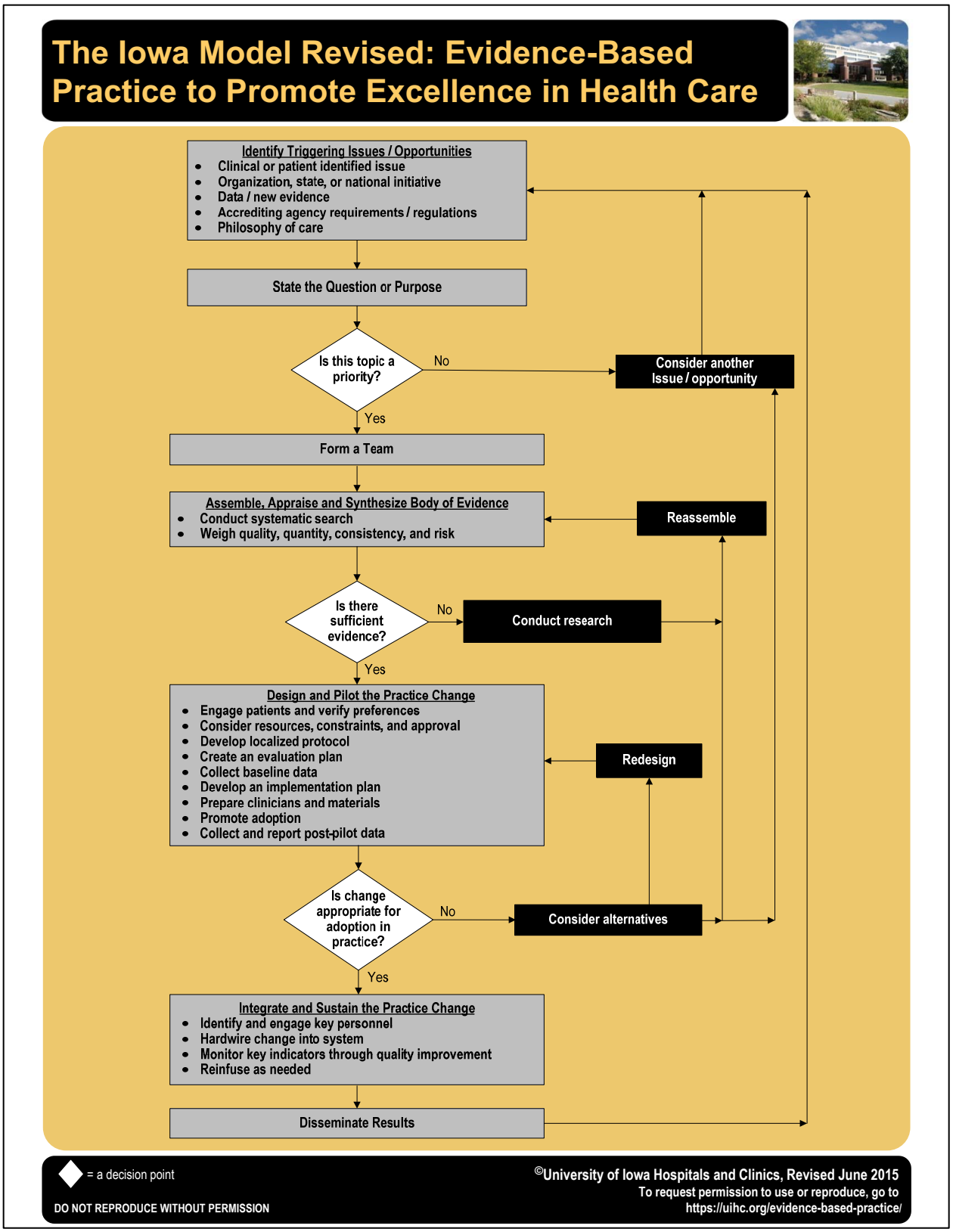
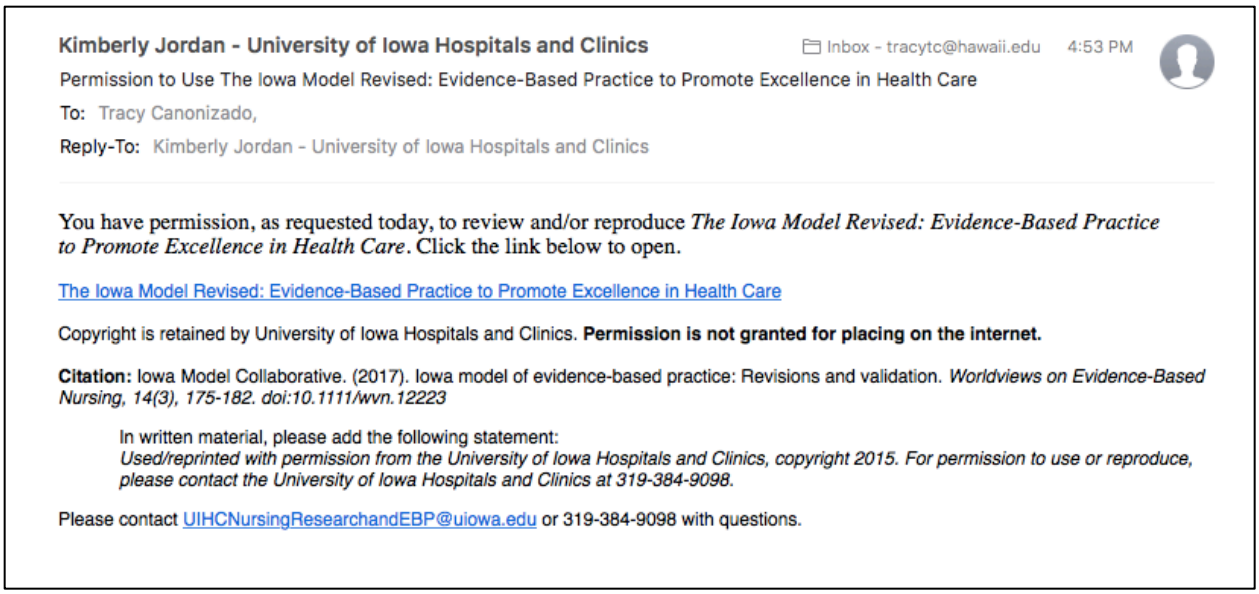


Figure B2. The Iowa Model Of Evidenced-Based Practice to Promote Quality Care



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In written material, please add the following statement:
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Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

Figure B3. Permission for use of Iowa Model

Appendix C

Logic Model

Goal: To reduce pain among pediatric patients receiving vaccinations at the Wahiawā Health's pediatric clinic by implementing a vaccination pain-mitigating protocol between June 2019 to August 2019.				
Objectives	**Activities**	**Inputs/Resources**	**Outputs**	**Outcomes**
Before June 2019, resources needed to accompany the vaccination-pain mitigating protocol will be created and purchased accordingly.	Write out a script for MAs to read when introducing the protocol to the patient/parent dyads. Create a poster for introducing the ShotBlocker® to the parents placed in the exam room (behind door). Combine the two surveys for parents to complete after immunization. Purchase brochure stands Purchase ShotBlockers®	Time expended by NP Student to create the script, handouts, pamphlets. Cost to print these items, brochure stands, and ShotBlockers® which are about 50 cents each not including shipping fees. ** Surveys have been created already; permission from Author has been obtained.	A script for the MAs Poster for parents Half-sheet of all surveys Brochure stands (x2) ShotBlockers® (x100)	**Short Term:** All scripts, posters and surveys for the parents are free of major grammatical errors by June 2019. 100% of the ShotBlockers ® arrive before June 15, 2019. **Medium Term**: All resources created and purchased will be sufficient through the entirety of the project. **Long Term**: After August 2019, staff or office manager will reach out to NP student asking for details on obtaining the pamphlets, and purchasing the ShotBlocker®

				suggesting the continuation of the project in the clinic.
Between June 1-15, 2019, train two (100%) licensed medical staff at the Wahiawā Health's pediatric clinic on how to perform vaccinations with protocol and the importance of this vaccination pain mitigation.	Teach two MAs the protocol. MAs will take turns practicing the protocol in the companies of NP student. MAs will be educated on the importance of reducing vaccination pain and the theory behind how the ShotBlocker® works.	Time needed to teach the protocol. Time needed to be spent reviewing and practicing the protocol. Time needed to evaluate the MAs as they practice the protocol and answer questions.	MAs will be able to conduct vaccinations using the protocol. MAs will have the knowledge of what the purpose of the ShotBlocker® is, and the importance of vaccination pain mitigation.	**Short Term:** 100% MAs will be able to perform the protocol while referencing to the protocol as needed. 100% of MAs will be able to reiterate 90% of the information presented to them about the ShotBlocker®, and the importance of vaccination pain mitigation as measured by interviewing MAs post training. **Medium Term**: 50% of MAs will not need to reference the protocol in order to perform the vaccinations. MAs will be able to answer 75% of questions presented by the parents/child regarding the ShotBlocker® and the importance reducing

				vaccination pain as measured by post-education quiz. **Long Term**: 50% of MAs will insist on having a vaccination pain protocol to follow after August 2019 as measured by the Outcome Survey. 50% of medical staff will advocate for vaccination pain mitigation by researching other ways to reduce vaccination pain if this protocol does not remain in place.
Between June 16 to August 16, 2019, licensed medical staff performing vaccinations will implement this vaccination-pain mitigating protocol in the pediatric clinic on 80% of pediatric vaccinations.	MAs will implement the protocol on any pediatric patients requiring a vaccination at time of visit. Student NP will evaluate protocol while it is in place by interviewing MAs biweekly and asking MAs how the	Time spent driving to clinic ensuring that all supplies are replenished. Cost of gas driving back and forth to clinic. Time spent checking in with staff members.	A decreased amount of ShotBlockers® at the clinic due to use on pediatric patients.	**Short Term:** MAs able to implement protocol with 80% of vaccinations between June 16, 2019 to August 16, 2019. **Medium Term**: Continuation of protocol use after the end of the project for 50% of vaccinations after August 2019.

	process is going regarding the implementation process. Student NP will restock clinic with surveys, and ShotBlocker® biweekly			**Long Term**: • Increase vaccination rates by 10% within the clinic measured by comparing yearly trend analysis. • Awareness brought to 10% of parents and 50% of staff regarding vaccination-related pain mitigation as determined by continuation of any form of vaccination-pain mitigating techniques or protocols.
Between June 16 to August 16, 2019, at least 80% of parents/patient complete the pre- and post-vaccination survey.	Parents of pediatric patients obtaining vaccinations will complete the post-implementation and retrospective surveys. Student NP will collect surveys biweekly and restock clinic with more surveys if needed.	Time expended by parents as they read surveys and complete surveys. Cost of gas driving back and forth to clinic to pick up the surveys. Cost of reprinting surveys.	Parents complete post- surveys and retrospective surveys then return surveys to the MAs immediately after completion. MAs store the surveys in the appropriate location designated for completed surveys.	**Short term:** 50% of parents will see that the ShotBlocker® has reduced some vaccination related pain as measured by the results on the post-immunization and retrospective surveys. 80% of parents/guardians read the handouts regarding the ShotBlocker®

		** Surveys have been created already; permission from Author has been obtained.		between the introduction of protocol and before the start of vaccinations as measured by any questions or concerns. 80% of parents/guardians complete the post-immunization and retrospective surveys as measured by a visual count comparing the number of surveys obtained to the number of ShotBlockers® used. Example: 5 devices used should equal 5 completed surveys. **Medium term:** 50% of parents/patients returning to the clinic will ask about the ShotBlocker®, or alternative pain mitigating alternatives for their child if the child is obtaining a vaccination after August 2019.

				Long term: Increase vaccination rates by 10% within the clinic comparing trend analysis yearly.
Between August 17-31 2019, 50% of licensed medical staff who used the vaccination-pain mitigating protocol will find that the protocol is realistic to continue implementing in their clinic.	MAs will complete the 7-question Outcome Survey.	Time needed to print surveys, drive to clinic, speak with MAs, collect surveys. Cost associated with printing surveys, gas use to drive to clinic. ** Surveys have been created already; permission from Author has been obtained.	MAs complete Outcome survey	**Short Term:** 100% of staff who completed vaccinations with the protocol will complete the entirety of the Outcome survey on the same day presented with the survey. **Medium Term**: 50% of staff "Agrees" or "Strongly agrees" that the vaccination protocol improved the immunization procedure as measured by the Outcome Survey. **Long Term**: Survey results will elicit funding for the continuation of the protocol after August 2019.

Appendix D

Gantt Chart

Sub-Tasks	Responsible Person	Start Date	Due Date	Comments
Major Task #1: Creating, purchase essential tools needed for implementation				
Create a script for the MAs	DNP Student	3/6/19	3/10/19	Create a script for the MAs to read in order to accurately articulate the protocol to the parents of the patients.
Create poster(s) endorsing the ShotBlocker®	DNP Student	3/11/19	3/15/19	Create poster showing the ShotBlocker®.
Compile surveys and demographics	DNP Student	3/16/19	3/20/19	Create half page of all surveys so that parents will be able to complete the surveys in a logical order, without surveys getting lost. Create two surveys for the MAs. One survey to "test" MA's knowledge after they have been trained on how to use the ShotBlocker, the second will be a modified version of the Outcome survey. Permission has been obtained by this person for use of these surveys in this project. Surveys will need to be printed and brought to the clinic.
Contact the ShotBlocker®	DNP Student	The day I get my project approval		Contact the ShotBlocker® company to purchase 100 devices. Each device is usable multiple times on the same patient during multiple visit.
Attach each device to the survey	DNP Student	The day the shipment comes in		Attach each device to the survey booklet, then discretely number each survey to keep track of how many devices have been used.

Print all surveys, posters, and other resources needed for training and implementation	DNP Student	6/1/19	6/15/19	Card stock for parent surveys, cardstock for display poster, regular printer paper for MA's surveys.
Major Task #2: Train MAs on Protocol				
Placement of tools in clinic	DNP Student, MAs	6/1/19	6/15/19	Locate a place in the clinic near where the MAs keep their vaccination supplies to display my vaccination-mitigating toolkit. (Medication room has been identified by Content Expert).
Training MAs	DNP Student, MAs	6/1/19	6/15/19	Train, answer questions, tell them implementation dates. Find a time (probably lunch) to train. Must remember to lunch/snack/thank you item for them.
Major Task #4: Implement Protocol				
Implement!	MAs	6/16/19	8/16/19	It's time to implement!
Visit clinic	DNP Student	6/16/19	8/16/19	Visit clinic once every other week to see how the implementation is going. Collect surveys that have been completed.
Check supplies	DNP Student	6/16/19	8/16/19	Ensure there are enough supplies by bringing in more during each visit.
Surveys collection	MAs	6/16/19	8/16/19	MAs to complete the post- and retrospective immunization survey by asking parent or child about pain level.
Major Task #5: Evaluate project				
Interview MAs	DNP Student, MAs	8/17/19	8/31/19	Interview MAs to get their general view of how the entire project went. What went well and what didn't as well as answer questions they may be presented or come up with while they are implementing the protocol.
Provide MAs with a survey and collect	DNP Student, MAs	8/17/19	8/31/19	Provide MAs with a survey to evaluate the protocol. Purchase lunch, gift for each MA, NP and MD for all the help.

surveys with the data they provided				
Major Task #6: Writing Up the Results/Discussion				
Analyze results	DNP Student, Chairperson	9/1/19	10/31/19	Review the results from the surveys with Chairperson.
Write up the results and discussion	DNP Student	11/1/19	12/6/19	Write up the results from the project and the conclusion.

Appendix E

Tools Needed For Implementation

1.) Overall, I noticed less crying in children receiving shots with the ShotBlocker®

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

2.) The ShotBlocker® was easy to use.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

3.) It was easy for me to remember to use the ShotBlocker®

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

4.) The ShotBlocker has the potential to improve our immunization procedure.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

5.) I am likely to continue to use the ShotBlocker® in the future.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

6.) I think it is realistic to continue to use the ShotBlocker in our clinic setting.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

7.) Please select reason(s) why the ShotBlocker® was not <u>always</u> used: *(Select all that apply)*

a) Forgot to use it
b) Too difficult to use it
c) Not enough time to use it
d) Parents refused
e) Child refused
f) Not applicable – used ShotBlocker® on all shots

Other comments:

_____

_____

_____

Thank you for all your help! This project would not have been possible with you!

Figure E1. Outcome Survey

Healthcare Student Download

Thank you for contacting our foundation and completing the web form. We are happy to give students permission to use our scale and waive any licensing or fee requirements.
Please follow these four conditions:

- The information below is for your use only. Please do not share this with other organizations.
- Use the authorized image of the scale provided below.
- Use the scale as the instructions indicate, without modifications.
- Do not use the scale for profit.

Here is the JPEG of the scale in English for your use: Wong-Baker FACES® Pain Rating Scale (http://wongbakerfaces.org/wp-content/uploads/2016/05/FACES_English_Black.jpg).

Instructions for the use of the scale (http://wongbakerfaces.org/wp-content/uploads/2014/10/FACES_English_Blue_w-instructions-copy.jpg)
Frequently Asked Questions (http://wongbakerfaces.org/us/faq/) (http://wongbakerfaces.org/wp-content/uploads/2016/05/FACES-FAQs-rev-052416.pdf)

You may find some of our products helpful in your work. You can check them out here: Wong-Baker FACES Products (https://www.scrubpocket.com/wongbakerfaces-s/1852.htm?searching=Y&sort=5&cat=1852). There is a discount for products purchased in bulk.

The following example citation may be helpful to you, if you are creating a bibliography for a paper:

Wong-Baker FACES Foundation (2018). Wong-Baker FACES® Pain Rating Scale. Retrieved [Date] with permission from http://www.WongBakerFACES.org.

Please let me know if you need anything else, including language translations of the scale.

Kind regards,

(http://wongbakerfaces.org/wp-content/uploads/2014/10/Connie-Signature_written.jpg)

Figure E2. Wong-Baker FACES Pain Scale waiver for permission of use.

How old is the child? _____

How many shots is the child getting? _____

Ask parent/guardian or child…

How much pain did the child feel after **TODAYS** shot?
(Circle the face indicated)

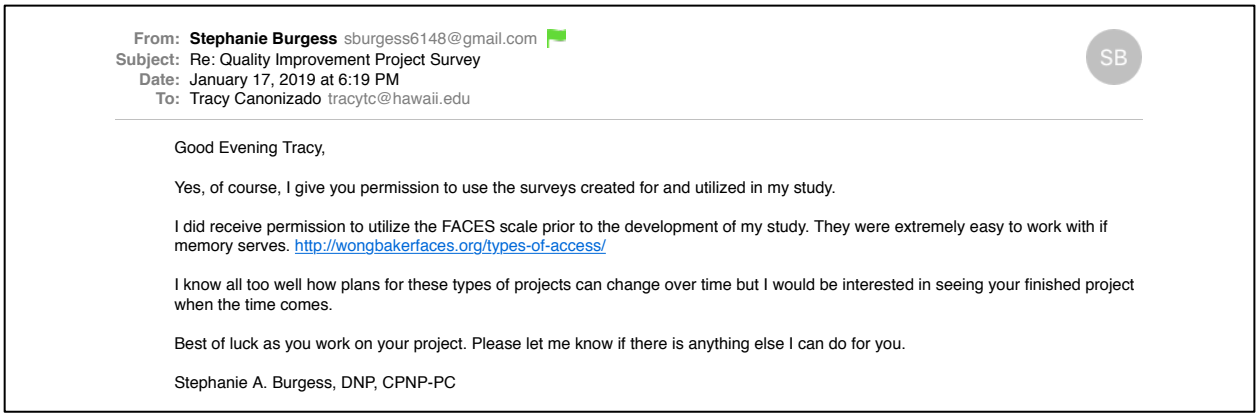
◯ Unable to assess

Ask parent/guardian or child…

How much pain did the child feel after **LAST** shot?
(Circle the face indicated)

◯ Unable to assess

Figure E3. Post-Immunization and Retrospective Survey adapted from Burgess et al., 2014



From: **Stephanie Burgess** sburgess6148@gmail.com
Subject: Re: Quality Improvement Project Survey
Date: January 17, 2019 at 6:19 PM
To: Tracy Canonizado tracytc@hawaii.edu

SB

Good Evening Tracy,

Yes, of course, I give you permission to use the surveys created for and utilized in my study.

I did receive permission to utilize the FACES scale prior to the development of my study. They were extremely easy to work with if memory serves. http://wongbakerfaces.org/types-of-access/

I know all too well how plans for these types of projects can change over time but I would be interested in seeing your finished project when the time comes.

Best of luck as you work on your project. Please let me know if there is anything else I can do for you.

Stephanie A. Burgess, DNP, CPNP-PC

Figure E4. Permission from Dr. Stephanie Burgess, DNP, CPNP-PC

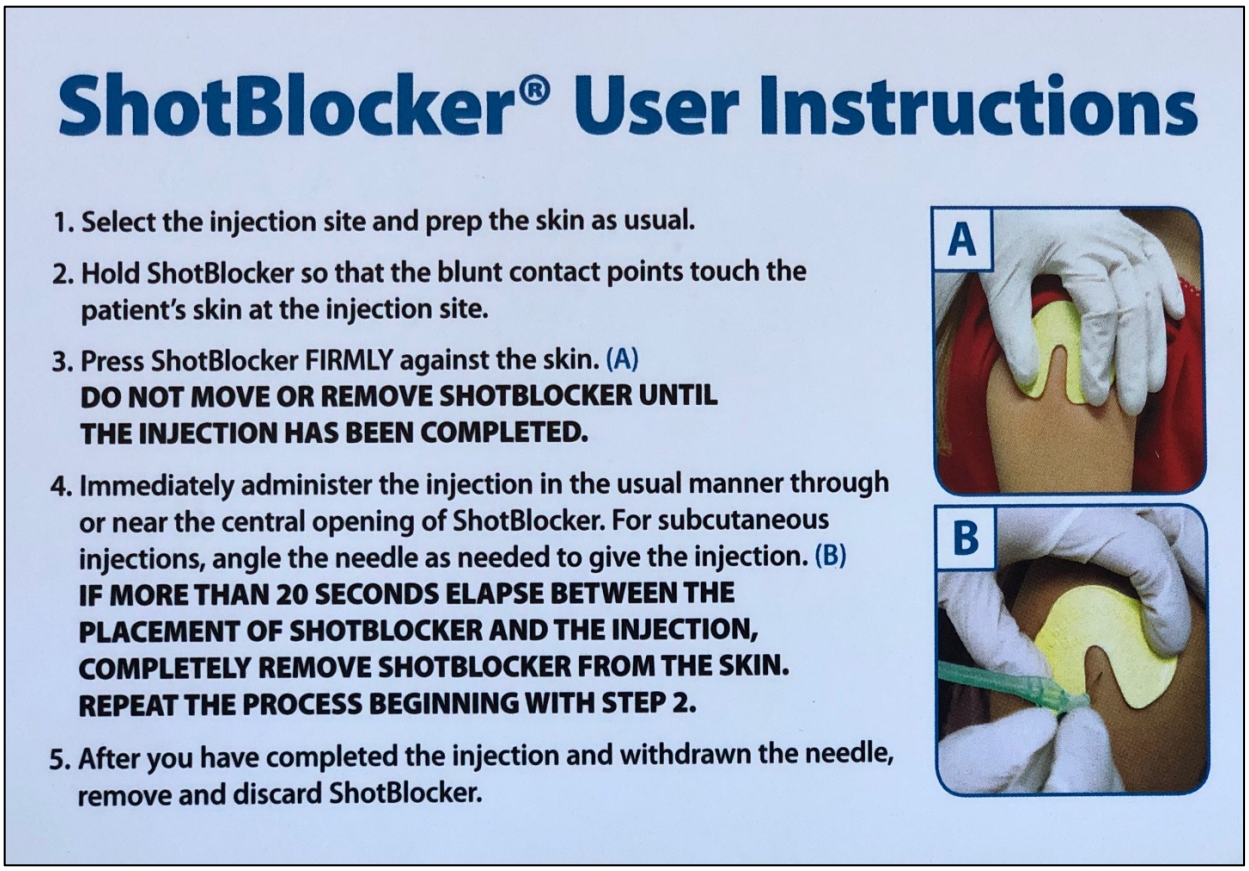


Figure E5. Directions from the manufacturer on how to correctly use the ShotBlocker®

Your position in this clinic _____

1. What is the ShotBlocker® used for?
A) It's a toy to give to child if he/she does not cry during vaccination
B) It's to clean the vaccination site
C) It "blocks" pain when vaccination is given

2. What side of the ShotBlocker is pressed onto the patient's skin?
A) The pointy side with the blunt ends
B) The smooth side
C) Why would you put this on the patient?!

3. Put an "X" to show where the vaccination should be injected:

4. Why do we care about reducing vaccination pain for children?
A) Studies have shown that by reducing vaccination related pain, children will be less likely to develop needle phobia when they grow up. By reducing needle phobia, there can be a greater chance of vaccination compliance.
B) Kid's do not think vaccinations are painful.
C) We don't care.

5. How much will it cost the patient to use the ShotBlocker®
A) Insurance will pay for it
B) Clinic will pay for it
C) It's FREE for the patient

Figure E6. Post MA teaching quiz

SHOTBLOCKER

REDUCES PAIN FROM THE SHOT

Distracts your child from the "OUCH" feeling of a shot

Does not penetrate skin

Does not harm your child

And it's free!

Ask about it before your child recieves any shots today!

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Figure E7. Poster endorsing ShotBlocker to be placed on the back of the door in each exam room.

Your child's vaccination will be accompanied by a device known as a ShotBlocker.

This device is to help reduce pain from the vaccination.

It will not go through the skin.

It is free to use this device and if you like it, please take it home then bring it back next time.

I will ask you two questions at the end to see if you thought the ShotBlocker® was helpful.

Figure E8. MA's Introduction Script

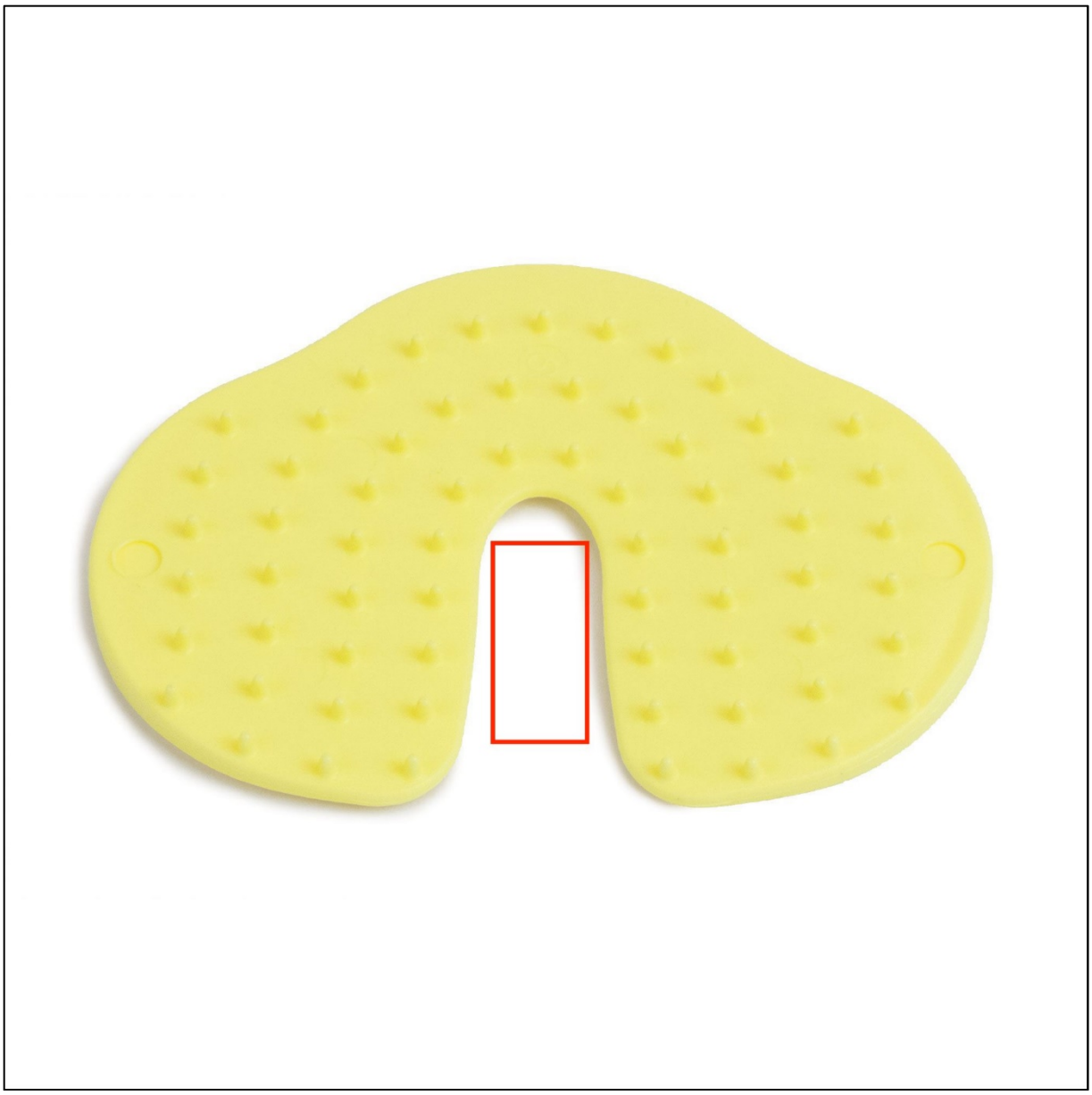

Figure E9. ShotBlocker device showcasing suggested injection site within red rectangle

Appendix F

Tables of Results and Evaluation

Table 1 Demographic Data Summary

Ages	Age Categories	% for ShotBlocker® used/N	% for total shots given/N
0 - 11 months	Infants	14% (n=8)	28% (n=61)
12 - 23 months	Under 2 yrs	7% (n=4)	14% (n=31)
24 months	2 years	5% (n=3)	5% (n=11)
3 - 5 years	Preschool	19% (n=11)	
	Schoolers		18% (n=39)
6- 10 years	Elementary	8% (n=5)	
	Schoolers		10% (n=21)
11 - 12 years	Middle Schoolers	31% (n=18)	12% (n=26)
13 - 18 years	High Schoolers	17% (n=10)	13% (n=27)

Table 2 Percentage of Vaccinations in Each Age Category

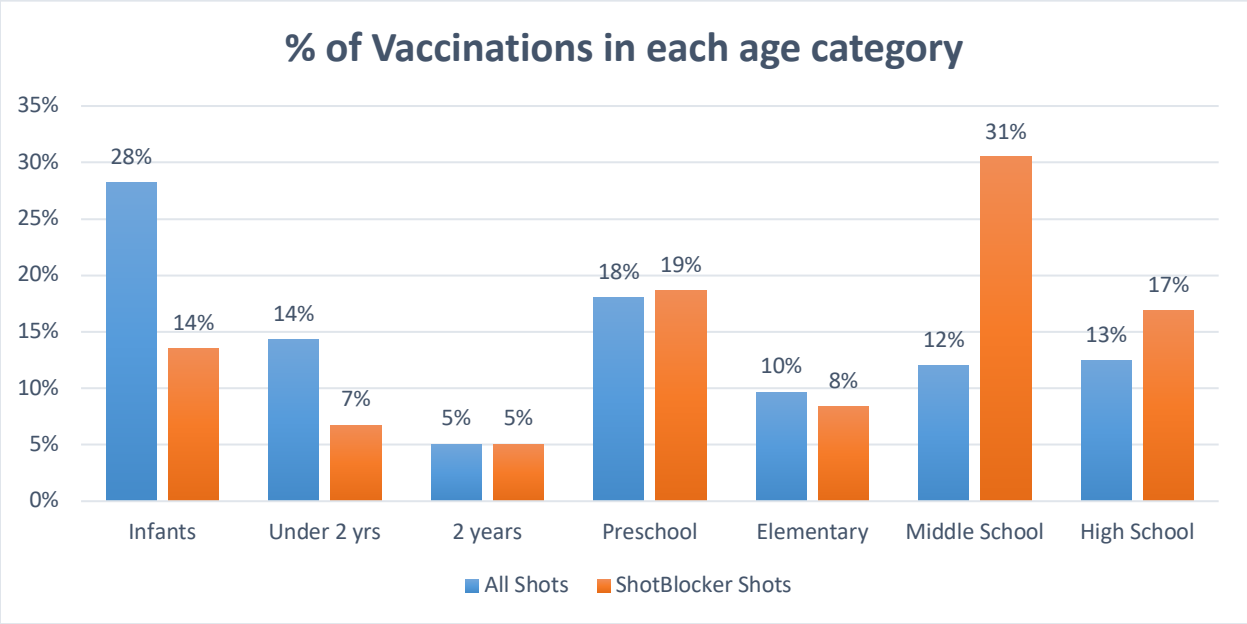

Table 3 # of Patients & the effect of the ShotBlocker

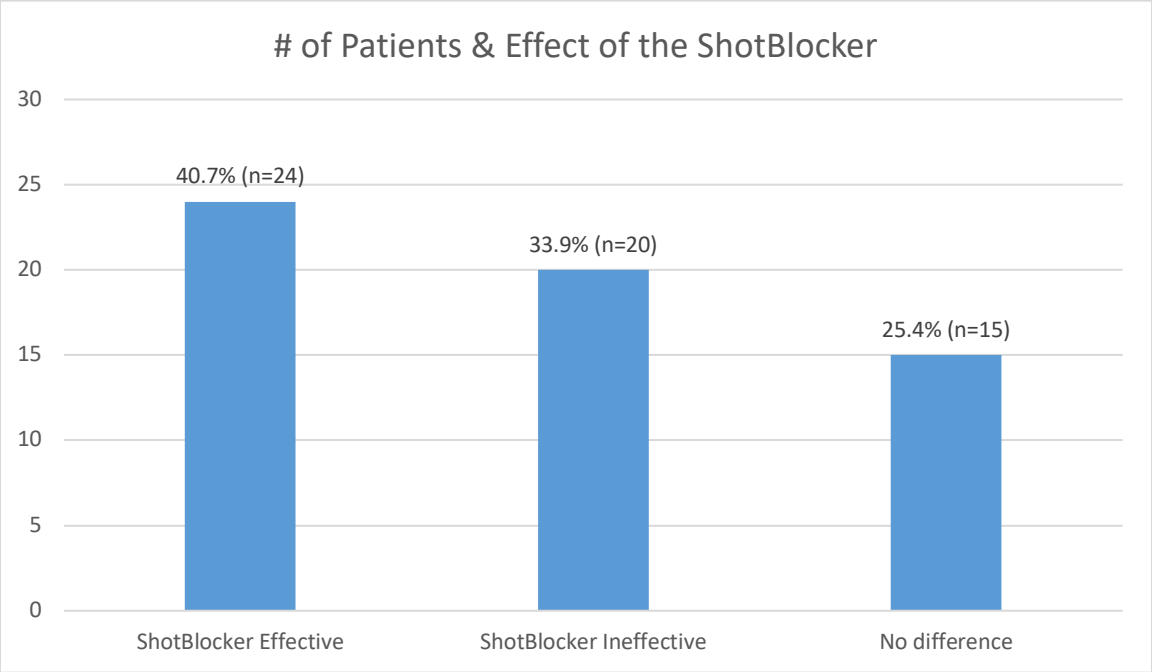

Table 4 Medical Assistant Outcome Survey

	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
Overall, I noticed less crying in children receiving shots with the ShotBlocker®			2	2	
The ShotBlocker was easy to use				4	
It was easy for me to remember to use the ShotBlocker®			1	2	
The ShotBlocker has the potential to improve our immunization procedure.				3	1
I am likely to continue to use the ShotBlocker® in the future.				4	
I think it is realistic to continue to use the ShotBlocker in our clinic setting.				4	

Please select reason(s) why the ShotBlocker® was not always used: (Select all that apply)	**# of times selected**
A) Forgot to use it	4
B) Too difficult to use	0
C) Not enough time to use it	1
D) Parents refused	0
E) Child refused	0
D) Other Comments	2

Appendix G

Meeting the DNP Essentials Criteria

DNP Essential	DNP Student's Activities/Products
Essential I: Scientific Underpinnings for Practice	• Integration of nursing knowledge gained from required DNP program course work, literature search, critique and rating of evidence, used for DNP project.
Essential II: Organizational and Systems Leadership	• In consistency with Essential II, this project worked to promote patient safety by providing pediatric patients a method to prevent vaccination related pain. This was identified as a need due to the suboptimal rates of vaccinations in the clinic.
Essential III: Clinical Scholarship and Analytical Methods for EBP	• Literature critiqued for this EBP project were graded on Mosby's Level of Evidence to determine the most compelling support for a certain method determined to be optimal for vaccination pain mitigation in pediatric patients. Based on the level of evidence, the project design was created. • Data from various studies were presented to the Medical Assistances from the facility in which the project was completed in with hopes of improving healthcare outcomes and understanding of the need for vaccination related pain mitigation methods and techniques.
Essential IV: Information Systems/Technology	• Athenahealth, this facility's online electronic medical record, was used to determine the number of patients who received vaccinations during the time period the project was being implemented. Other forms of technology used were including Microsoft Word, Microsoft Excel and Microsoft PowerPoint.
Essential V: Health Care Policy for Advocacy in Health Care	• This project advocated for the rights of pediatric patients who may not, and much of the time did not, have the voice to advocate for themselves. The pain from vaccinations may not affect all children, however, for the ones who are affected, they may be develop a phobia of needles even into adulthood.
Essential VI: Inter-Professional Collaboration	• Collaboration between the author, facility, providers and various other healthcare liaisons of the facility occurred in order to develop, implement and evaluate the project.
Essential VII: Clinical Prevention and Population Health	• This project focused on reducing vaccination related pain in the pediatric population with hopes of improving vaccination rates and decreasing fear of vaccinations. After review of EBP studies, this method seems most appropriate for the community.
Essential VIII: Advanced Nursing Practice	• Through the use of EBP studies, knowledge gained from DNP courses and a broader understanding for the need of the facility, this DNP project was designed and implemented.