DISTRACTION FOR VACCINE INJECTION PAIN IN PEDIATRICS: REDUCING PAIN AND ENHANCING PATIENT-CENTERED CARE

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Jessica Jean Colombini, titled Distraction for Vaccine Injection Pain in Pediatrics: Reducing Pain and Enhancing Patient-Centered Care and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

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DEDICATION

This project is dedicated to my husband, I couldn’t have done this without his continuous love, words of encouragement, and support.

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ABSTRACT

Purpose: The purpose of the DNP project "Distraction for Vaccine Injection Pain in Pediatrics: Reducing Pain and Enhancing Patient-Centered Care" was to investigate the efficacy of distraction to decrease pain in children requiring vaccines improving the quality of health services. This was accomplished by: 1)the development and deployment of an age-appropriate Distraction Toolkit consisting of toys and books for children ages 4-6 years requiring vaccines; 2) Evaluation of pre and post-vaccination pain scores; and 3) Based on Likert scale survey responses results determined if the use of the distraction intervention is something that can be incorporated into daily practice.

Background: It is not surprising to find that children have inadequate coping skills to manage pain associated with vaccines. Repeated painful experiences can have lasting negative consequences. Locally, in the clinical setting, there are no guidelines in place to manage injection-related pain. Research on the topic highlights the use of psychological interventions such as distraction being efficacious in managing pain associated with vaccines.

Methods: This was a quantitative descriptive study. A pre-intervention educational session was provided to the participating medical assistants about literature that supports the project and the steps involved in the project. Developed based on Ajzen's Theory of Planned Behavior medical assistants evaluated the usefulness of the kit to determine if it promotes patient-centered care. The process involved: 1) The assistant bringing the kit in prior to the vaccines for the child to explore; 2) While the child is distracted the assistant then brings in and delivers the vaccination; 3) Pain scores using the Face, Legs, Activity, Cry, and Consolability scale, post-vaccine survey,

and post-intervention adoption survey were completed by medical assistants to examine perceptions of distraction and its impact on perceived pain and care provided.

Outcome: A total of 24 children were included in the project and six medical assistants. Mean post-vaccine pain scores for the group without the intervention was six and three for those with the intervention. Post-vaccine survey questions were generally agreeable with the child being distracted, and vaccine administration being completed successfully. The adoption survey was generally positive regarding the ease of use of the kit, the use of the kit not impacting workflow, and the kit providing patient-centered care. Additionally, the results of the adoptability survey were in general agreeance of implementing this intervention into daily practice. The results were used to create an executive summary to share with the clinical director to facilitate clinical processes.

Conclusions: The use of the kit can substantially impact the pain children experience during vaccines. Moreover, it is a simple practice that has little impact on workflow. Future directions include replicating this quality improvement project with a larger sample size. Additional interventions identified in the literature to further the understanding of the impact of the kit include the use of a concurrent pre- and post-vaccine anxiety scale, parents and when appropriate children's rating of pain and perception of how well the kit worked, and inclusion of different distractors to expand the age range for children requiring vaccines.

INTRODUCTION

Background Knowledge

Children do not experience pain the same way adults do, with less coping skills children can exhibit a greater emotional and behavioral response to perceived pain experiences (Bahorski et al., 2015). Many misconceptions have been identified related to pediatric procedural pain including: young children do not feel pain due to an underdeveloped nervous system, children do not remember pain experiences, and that pain can never truly be assessed in children (Bice, Gunther, & Wyatt, 2014). Injection-related pain is often underestimated and not fully understood in this population because of difficulties present in evaluating pain and its influencing role in varying ages and development stages (Thrane, Wanless, Cohen, & Danford, 2016). What is known is often medical procedures can be some of the most distressing and influencing healthcare experiences a child experiences (Olsen & Weinberg, 2017). A recent survey of children receiving medical care in a pediatric hospital found patients reported needle sticks during routine procedures as the worst pain experienced (40%) and both children and parents rated nonpharmacological interventions, such as distraction, more effective than medications (Friedrichsdorf et al., 2015).

There are a multitude of clinical guidelines focused upon managing injection-related pain in the pediatric population. However, there is a lack of specific details regarding the implementation of recommended practices in the primary care setting. The Emergency Nurse Association [ENA] (2018) recently updated a clinical practice guideline for needle-related pain focusing on evidence that promotes distraction and incorporates high-quality systematic reviews from the past five years (Birnie et al., 2015; Birnie et al., 2014; Goetterns et al., 2017; Lee et al.,

2014; Rezai, Goudarzian, Jafari-Koulaee, & Bagheri-Nesami, 2016; Riddell et al., 2015; Uman et al., 2018). A total of 30 research articles were analyzed in the development of this CPG however, many did not address distraction directly and of those included many focused primarily on venipuncture in the toddler population (ENA, 2018). Further, this guideline was developed for the inpatient and emergency department setting, not outpatient primary care (ENA, 2018). Another guideline reviewed was the Cincinnati Children's Hospital (2013) guideline for injection-related pain in the pediatric population. This guideline highlights the use of distraction however, it was last updated six years ago, and most of the evidence included for the synthesis and development of the guideline only examined the infant population (Cincinnati Children's, 2013). Additionally, there was limited discussion on how to implement distraction practices in the clinical setting (Cincinnati Children's, 2013). Reviewing these two guidelines reveals a gap in the implementation measures to decrease injection-related pain in the pediatric primary clinical setting. Further, there is a lack of inclusion of all age groups, most notably school-age children.

Using a developmental approach based upon the unique needs of each child can help inform clinicians choice of appropriate interventions for injection-related pain management (Uman et al., 2018). Of available nonpharmacological interventions, distraction has shown to be the most effective method of pain prevention in children and promotes caregiver and clinical staff satisfaction with procedures (Uman et al., 2018). Risaw et al., (2017) showed that children who did not receive distraction for phlebotomy reported severe pain 2.5 times greater than the distraction group. Age-appropriate distractions for 4 to 6-year olds, i.e., blowing bubbles, listening to music, reading a story, playing a game, or utilization of an electronic device are

effective interventions to manage pain with minimal cost and little-associated risk (Taddio & McMurty, 2015).

Local Problem

The clinic of focus for this project is a pediatric primary care clinic that serves children in the Spokane Valley, Washington area from birth up to 18 years of age. Currently, at the clinic there are no clinical guidelines in place to address injection-related pain children feel during immunization. There is evidence that negative experiences related to pain induced by injection-related procedures have a long-term impact on future painful experiences including lasting negative psychosocial consequences (Olsen & Weinberg, 2017).

Medical assistants are responsible for reviewing provider orders for vaccines, drawing up appropriate vaccines, and administering vaccine injections. There are approximately 10 medical assistants that work in the clinic. Challenges identified for managing injection-related pain include lack of resources, lack of knowledge about the subject, and most importantly lack of time to implement this type of care. This challenge underlies the motivation for a quality improvement project in developing an intervention to mitigate injection-related pain experiences by addressing education, resources, and time management.

On average, two to three clinicians are treating about 20 to 25 patients per day. Of those 20 to 25 patients, about 10 to 15 are at the clinic for well-child visits and require the administration of vaccines. Concurrently, throughout the day, many children's appointments are solely for routine vaccination administration. It is logical to conclude there are opportunities present during every clinical day when the use of distraction to mitigate injection-related pain may be employed to decrease pain during vaccine administration.

Key stakeholders in this project include the patients, their parents, the providers, nurses, medical assistants, and administration. The manager of the clinic was consulted and affirmed the benefits of employing distraction to reduce pain children experience during vaccine injections. My quality improvement project has the potential to provide information regarding the effectiveness of distraction in reducing pain and promoting positive patient interactions. It may also provide information regarding which distraction techniques work best for certain children ages 4 to 6 years. Further, it will provide an opportunity to determine if staff readily adopts the utilization of distraction techniques and view it as an opportunity to provide patient-centered care and promote positive experiences.

Needs Assessment

The purpose of this quality improvement project is to determine if the use of distraction is an effective and acceptable intervention to manage vaccine injection pain in children ages 4 to 6 years. Paper surveys were administered to clinical staff that delivers vaccine injections to assess current practices, pain management resources, and to identify staff's baseline knowledge about the use of distraction. Additionally, barriers to implementation and adoption were explored in a staff survey following the intervention. A deidentified summary of the surveys was then shared with the staff and administration to inform them of the results of the project.

Intended Improvement

The purpose of this quality improvement initiative was to develop and implement distraction interventions to decrease pain in children ages 4 to 6 years old requiring routine vaccine injection administration. The rationale for the development of this intervention is that it will lower pain experienced during vaccine injections. This aligns with findings in the literature

that distraction techniques are one of the most effective ways to decrease pain and anxiety in children promoting patient-centered care (Taddio, & McMurty, 2015; Risaw et al., 2017, Uman et al., 2018).

The timing of this quality improvement project aligns with the organization that oversees the clinic plan to expand the "Comfort Promise." The "Comfort Promise," is a national program that focuses on reducing pain and anxiety a child experiences during needle-related procedures (Friedrichsdorf, Eull, & Weidner, 2016). The use of developmentally appropriate strategies are utilized during needle-related procedures to help a child cope with potential anxiety and to minimize pain (Friedrichsdorf et al., 2016). The use of distraction provides a developmentally appropriate approach to managing injection-related pain, a principal value of the "Comfort Promise," (Friedrichsdorf et al., 2016). Barriers identified in developing distraction practices in the clinical setting include lack of awareness about distraction's usefulness, limited resources, conflicting information regarding effectiveness, and a lack of knowledge of how to adequately incorporate distraction into daily clinical operations (Bergomi et al., 2018; Katende & Mugabi, 2015).

The primary aim of this program was to increase age-appropriate distraction usage for children 4 to 6 years old requiring vaccine injections in the primary clinical setting. This quality improvement program was initiated with an educational program directed to staff, with a focus on the medical assistants who are responsible for the administration of vaccines. Outcome measures include: the responses to a Likert scale focused upon effectiveness and adoption of a distraction intervention, as well as Faces, Legs, Activity, Crying, Consolability scale (FLACC) rating children ages 4 to 6 years pain prior to and following the implementation of the distraction

intervention. A Likert scale is a rating system that uses a questionnaire format to measure people's attitudes, opinions, or perceptions (Likert Scale, 2019). Statement responses include words such as agree, strongly agree, neutral, some of the times, and so forth (Likert Scale, 2019). Each response is given a number on a scale from 1-5 (Likert Scale, 2019). This type of scale is ideal to use for both social and educational projects (Likert Scale, 2019).

Study Questions

The study questions for the DNP project are:

1. Does completion of an evidence-based educational presentation on the use of distraction techniques for children ages 4 to 6 years increase medical assistant's knowledge and adoption of a distraction toolkit during vaccination administration in the primary care pediatric setting?
2. Is there a difference between FLACC scale pain scores between children ages 4 to 6 years receiving vaccines prior to and following the introduction of the distraction toolkit intervention?

For this project, the intended practice change was the adoption of distraction during vaccine injection by medical assistants in clinical practice.

Theoretical Framework

Theory of Planned Behavior

The use of a theoretical framework can help the development, assessment, implementation, and evaluation of a quality improvement project creating a conceptual structure that links each step of the project (Moran & Burson, 2017). Concurrently, the use of an appropriate theory can help support practice changes promoting continued excellence in nursing

practice (Moran & Burson, 2017). Often change can be a daunting task as the science of change explores and highlights the use of a structured and strategic program can help decrease resistance the new practices, amplify the growth of change, and also enhance the level of innovation organizations experience from quality improvement project (Levesque et al., 2001).

This project looks to change health care practices already in place in the pediatric primary care setting. The purpose of this project is to enhance pediatric patient experiences through the use of distraction during vaccine injections. The hope is that through the use of developmentally appropriate distraction practices the level of pain a child experiences will be dramatically decreased, thus developing positive patient-centered care. Concepts that are important within the context of this project include vaccine injection-related pain, the patient experience whether positive or negative, and staff's behavior whether choosing to use distraction or not. Another key concept for the construct of this project is a distraction itself which can be defined as the use of nonpharmacological strategies that are comprehensive and developmentally appropriate that promoted procedural comfort that focuses on the reduction of pain and anxiety in children (Leroy et al., 2016).

The Theory of Planned Behavior purports individual's behaviors are guided by three overarching principles, attitude towards behavior, subjective norms, and perceived behaviors that shape an individual's intention and therefore the behavior itself (Ajzen, 2006). Behavioral beliefs include attitudes toward behaviors both favorable and unfavorable (Ajzen, 2006). Subjective norms are defined by social expectations including the pressure of societal norms examining both the perceived desired behaviors of others and what is actually occurring (Ajzen, 2006). Perceived behavioral controls are influencing factors that promote or hamper behavioral

performance, self -efficacy (Ajzen, 2006). The Theory of Planned Behavior has been influential in understanding what factors influence the behavior of health care workers, healthcare systems, and forms of healthcare communication (Ajzen, 2006). This theory postulates that a better understanding of factors influencing individuals' behaviors enables the development of effective interventions that can promote desires behaviors (Ajzen, 1991).

The first assumption of this theory is individuals' attitudes, subjective norms, and perceived control over their behavior influences their choices (Klockner, 2011). The second assumption is what causes individuals to choose desired behavior is the intention (Klockner, 2011). Intention is moving forward from considering alternative behavior to actually performing said behavior (Klockner, 2011). This intention is influenced by attitudes, subjective norms, and behavioral control (Klockner, 2011). The Theory of Planned Behavior can help inform quality improvement projects by defining whether intervention designs need to focus on the content on the intervention or on helping others to act on intentions by addressing situational barriers or lack of necessary skills and resources (Thompson, 2014).

Relevant Constructs

The Theory of Planned Behavior is applicable to this project because it helps define how individual actions can shape whether or not distractions practices are adopted, leading to a change in clinical practice. This theory highlights how certain variables should be considered to reinforce or change particular behaviors (Thompson, 2014). For example, medical assistants may have the intention to use distraction for the administration of vaccines but may lack the necessary skills or not have the appropriate resources to fulfill this intention. Further, if behavior is seen as unfavorable, not an accepted practice by others within the clinic, or a person believes they can't

do it, then behaviors will never change (Thompson, 2014). This points to the need to develop the necessary skills, resources, and situational factors that foster rather than hinder wanted performance (Thompson, 2014). Concurrently, it supports the argument that for change to be successful, it must be shaped and influenced by the attitudes, actions, and intentions of others (Ajzen, 1991; Finkelman, 2018).

Literature Review

Current Topics in Research

Evidence shows that negative healthcare experiences associated with needle-related pain has a long-term impact on future painful experiences and may cause children to develop lasting negative psychosocial consequences (Olsen & Weinberg, 2017). Several federal healthcare organizations propose that pain is often not treated in children undergoing routine procedures such as injections or blood draws and that this must change (Ramira, Instone, & Clark, 2016). The World Health Organization (2012) argues that relief of pain is a basic human right and that in children pain is not only shaped by the physical action but also both the emotional and cognitive response to an event. Negative experiences lead to an amplified behavioral response to medical procedures and have been associated with longer recovery time in children following surgical interventions (Noel, Rabbitts, Fales, Chorney, & Palermo, 2017). Concurrently, positive interactions that address the cognitive and emotional side of a child's pain can help shape both the child and parental attitudes towards healthcare providers promoting trust and quality decision making (Leask et al., 2012). In healthcare, there has been a recent increase in vaccine hesitancy among parents with literature identifying unmanaged injection-related pain as an influencing factor towards parent's decision to not vaccinate (Leask et al., 2012).

Search Strategy

To determine how the utilization of distraction practices impacts pain that children experience and to gain a better understanding of what behaviors, attitudes, and barriers influence the implementation of distraction into the pediatric clinical setting a literature search was conducted. A search was done using PubMed, Cochrane, CINAHL, and Psychinfo. The following keywords were used: pediatrics, procedural pain, distraction, and procedural pain management. Related terms such as children, pain, anxiety, and nonpharmacological interventions were also included to identify other relevant articles. The following limits were applied: English language, full text available, published within the last five years, and human species. A total of 74 articles were found. Articles were excluded if they did not pertain to the pediatric population and procedural pain management exclusively. Further, articles were excluded for only being position statements about the problem. Lastly, some were found to be duplicate from previous searches (Figure 1). Some 23 articles were retained that applied to the purpose of this quality improvement project (Table 1).

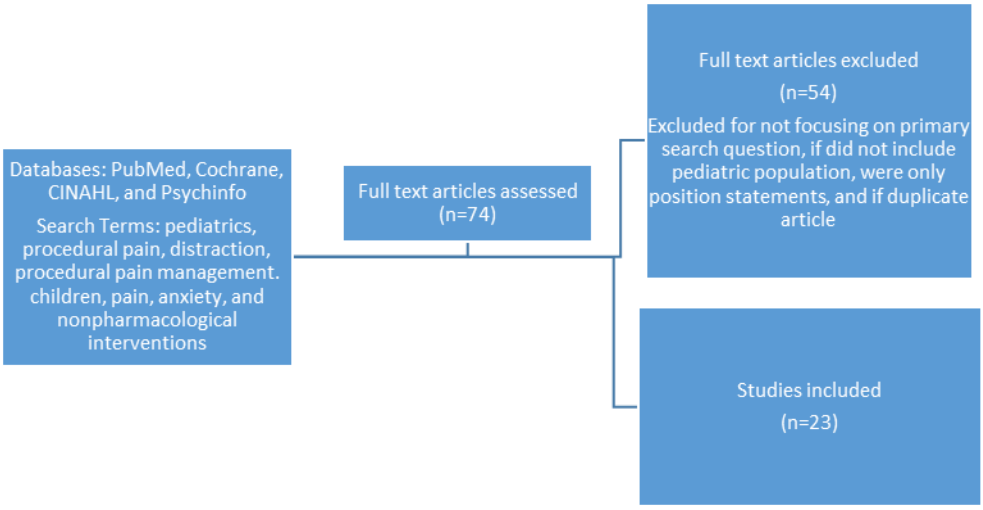

FIGURE 1. Literature retrieval attrition flow diagram.

Defining pain. Pain is an experience that is shaped by both circumstances and the unique background of each experience. Pain is a dynamic process where its ambiguity can make it difficult to quantify (Goldberg & McGee, 2011). Goldberg and McGee (2011) argued that the treatment of pain should become a public health priority globally. Authors argue that pain triggers the fight or flight response in an individual where the persistent accumulation of stress hormones can foster the development of other negative health outcomes (Goldberg & McGee, 2011). Additionally, not only does the influence of pain impact health but it has also shown to influence other parts of an individual's life including mental stability, education, and socioeconomic dynamics (Goldberg & McGee, 2011).

Development plays a crucial role in how pain is experienced in children. Due to the immaturity of a child's development repeated experiences, such as injections, can alter neurobiological process causing a child to become programmed to experience a higher level of pain (Loizzo, A., Loizzo, S., & Capasso, 2009). Pain caused by medical procedures may be brief

but can be some of the most traumatic experiences a child has early on in life (Loizzo et al., 2009). Hence, this supports the argument that preventing or minimizing pain is critical. Not treating pain can cause children to become afraid of future medical treatment causing fear of medical providers (Loizzo et al., 2009). Concurrently, parents may become angered or mistrustful of a healthcare provider when pain is not managed appropriately (Loizzo et al., 2009).

Distraction and pain. Risaw et al. (2017) discovered that the utilization of distraction cards, termed flippits, had a statistically significant effect on the behavioral response to pain of children undergoing venipuncture procedures. Of the children in the intervention group, self-reported pain was significantly lower than those in the control group that only received comfort from a caregiver. Another study looked at the use of video games for distraction during dressing changes for burn care and discovered that children who were in the distraction intervention group had a significant reduction in reported pain, 2.57 versus 8.0 in the control group, pain was measured using the FLACC scale (Kaheni, Rezai, Nesami, & Goudarzian, 2016). This study also found that 70% of children in the control group experienced severe pain whereas 77.5% of children in the intervention group experienced minimal pain, this was found to be statistically significant, $p < 0.01$ (Kaheni et al., 2016).

An interesting pilot study completed by Ballard et al. (2017) looked to see if the use of developmentally appropriate distraction kits was an acceptable practice for managing pain in children undergoing needle-related procedures in an emergency department. Through the use of different questionnaires, researchers found that 100% of parents would want the use of the

distraction kits again and 68.5% of children did not require further comfort measures during procedures (Ballard et al., 2017).

Uman et al. (2018) recently updated an original 2006 review on different interventions for the management of pain and anxiety in children requiring needle-related procedures. Looking at 59 trials, 32 of them focused on the use of distraction with researches finding the use of distraction to have a statistically significant effect at reducing pain in children requiring needle-related procedures (Uman et al., 2018).

TABLE 1. *Evidence appraisal table.*

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
Ali, S., McGrath, T., & Drendel, A. (2016). An evidence-based approach to minimizing acute procedural pain in the emergency department and beyond. *Pediatric Emergency Care, 32(*1), 36-42.	What strategies, as supported by evidence-literature, can be implemented to decrease pain in children undergoing medical procedures?	Systematic review	A total of 57 studies looking at the use of oral sucrose (N = 4730 infants). 6 trials (n = 534 children) of either venipuncture or IV cannulation comparing different numbing mixtures. review of topical anesthetic use for laceration repair in23 randomized controlled trials looked at topical anesthetic for laceration repairs 19 trials looked at effect of music (n = 1513 children) 26 distraction and 7 hypnosis trials for needle related procedures in children aged 2 to 19 years. distraction (n = 2473 children) and hypnosis (n = 176 children)	Data was obtained through multiple Cochrane reviews. Researchers focused in on procedures in the emergency setting: heal sticks, blood draws, IV cannulations, and lacerations repairs. They looked at sucrose, pharmacological measures, distraction, hypnosis, and other behavioral measures to manage pain. Self-reported pain and behavioral responses to procedures were areas of focus.	Sucrose groups had significantly lower pain scores at 30 seconds (weighted mean difference [WMD], −1.76; 95% confidence interval [CI], −2.54 to −0.97) and significantly reduced crying time (WMD, −39 seconds; 95% CI, −44 to −34). Amethocaine significantly reduced pain compared with lidocaine-prilocaine, when all pain data were combined into a common pain score (relative risk, 0.78; 95% CI, 0.62 to 0.98). Children who received music therapy for distraction had a significant reduction in behavioral distress ($p < 0.05$). Distraction or hypnosis shows significantly reduce of

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
					children's self-reported pain and behavioral measures of distress ($p < 0.05$). Concluded lack of knowledge on how to implement treatment modalities for procedural pain in the pediatric setting.
Aydin, D., & Sahiner, N. (2017). Effects of music therapy and distraction cards on pain relief during phlebotomy in children. *Applied Nursing Research*, *33*, 164-168.	To determine if the use of different distraction practices: music therapy, distraction cards, music therapy and distraction cards, versus no intervention effected pain and anxiety in children undergoing venipuncture.	Randomized Control Trial	**Sample:** Children 7-12 undergoing venipuncture mean age 9 years, 42% girls, 58% boys (n=200) **Setting:** Bandirma State Hospital, Turkey	**Intervention:** Participants were divided into 4 groups: Music group (n=50), distraction Card group (n=50), music + Distraction card group (n=50), and control group (n=50). **Data Collection:** After it was determined through physician order that a child required phlebotomy one nurse performed the procedure while another performed distraction method, observed and evaluated pre and post procedural pain using Wong-Baker Faces **(primary measurement)** and anxiety using the Children Fear Scale **(secondary**	Procedural pain was not different among experimental groups ($p=0.72$, $p= 0.23$, and $p = 0.157$). self, parent, and observer reported pain was higher in the control group but not statistically significant ($p> 0.05$). No statistically significant difference between anxiety levels from parent and observer reports in intervention groups ($p = 0.092$, $p = 0.096$). The control groups had higher rated

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
				measurement). Parents also were present and completed the above scales. **Data Analysis:** All scores from the two scales were analyzed using chi-square test and student's t-test. Data on pain and anxiety were compared with a one-way analysis of variance utilizing a statistical significance of $p < 0.05$.	anxiety in both parents and observer reports, but no statistical significance found ($p > 0.05$).
Ballard, A., May, S., Khadra, C., Fiola, J., Charette, S., Charest, M., … & Tsimicalis, A. (2017). Distraction kits for pain management of children undergoing painful procedures in the emergency department: A pilot study. *Pain management nursing*, *18*(6), 418-426.	To determine the feasibility and acceptability of age appropriate distraction kits for procedural pain in children ages 3 months to 5 years undergoing needle-related procedures in the emergency department.	One group pre-experimental design, pilot study	**Sample:** Convenience sample over 6-month period of children ages 3 months to 5 years of age requiring needle-related procedure in the ED who are accompanied by at least one parent and who did not have a known cognitive impairment (n=50). There were 25 infant-toddlers (3months – 2 years) and 25 preschoolers (3-5 years). Most children were awake and calm before procedure (58.9%).	**Intervention:** Distraction kits that were developed by child-life specialists, pain clinic nurse, and child psychologist. Toys, books, and other interactive measures tailored to specific age were included. Parents were given the kit and encouraged to play with contents with child. At the end of the procedure children were allowed to continue to play with kit. **Data Collection:** Nurses filled out demographic questionnaires regarding age, reason for visit, baseline state of child, and	Average length of procedures was 7.3 minutes 68.5% of children did not need other distraction methods then what was in the kit, 31.5% required comfort from own teddy bear or sang during procedure. 100% of parents indicated would use distraction kits again. 70.5% of nurses agreed that the distraction kit was an

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
			Setting: pediatric tertiary university health center in Montreal, Quebec	reason for procedure. Feasibility of the kit was documented by the duration of the procedure, the use of other toys outside of kits, and if pharmacological interventions needed to be used. Likert scale was used to determine usefulness of toys, this was completed by the parent. Acceptability was assessed using a survey of 5 open ended questions given to both parent and nurse. FLACC was used to assess pain in children during the procedure. Data was collected by the same nurse throughout the study, questionnaires were dropped into a clearly identified box which was sealed until completion of the study. **Data Analysis:** Descriptive statistics were used for feasibility, usefulness, acceptability, and satisfaction. Pain was	intervention that needed to be developed There was a signification decrease in pain between procedural and postprocedural pain scored among all groups ($p< 0.001$). No difference in pre and postprocedural pain scores ($p=1.0$).

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
				measured using FLACC before, during, and after being calculated for each group using Friedman's test. P was set to < 0.05, post hoc analysis with Wilcoxon rank was utilized.	
Bice, A., Gunther, M., & Wyatt, T. (2014). Increasing nursing treatment for pediatric procedural pain. Pain *Management Nursing, 15*(1), 365-379.	To examine how quality improvements projects impact nursing utilization of different treatment modalities for pediatric procedural pain.	Systematic review	62 peer reviewed articles were found of those 10 were included since they looked at QI projects for improving pediatric procedural pain management (n=10).	Search of Cinahl, Medline, Web of Science, Google scholar, Psychinfo, and Cochrane from the years 2001-2011. Quality improvement change impacting nursing practice in the management of procedural pain was the primary focus of the search. Key words used were pain, pediatrics, neonatal, nursing, procedures, quality improvements, organizational change, knowledge, and education. Articles were grouped together according to theme identified and agree upon by researchers:	Literature shows that nursing staff thinks the management of pediatric pain is important. The use of quality improvement projects can improve management of pediatric procedural pain and increase the utilization of treatment modalities. Barriers such as time, communication, lack of knowledge, lack of available resources, attitudes towards practices, and lack of autonomy hinder the use of practices. Education, one-on-one coaching, pain

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
				increasing nursing knowledge, empowering nurses, and implementing protocol.	management programs, nursing controlled protocols, and policy changes positively impact the use of protocols to manage procedural pain. Protocols that focus on nursing empowerment and nursing control impact the acceptance of programs and compliance than just education or peer coaching alone.
Bukola, I., & Paula, D. (2017). The effectiveness of distraction as procedural pain management technique in pediatric oncology patients: A meta-analysis and systematic review. *Journal of Pain Symptom Management*, *54*(4), 589-600.	To investigate how effective distraction techniques are at managing procedural pain in oncology pediatric patients.	Meta-analysis	299 articles found, 7 randomized control trials were evaluated. Researchers looked at any distraction techniques in comparison to control intervention. Total of 312 participants, age 2-19, pediatric oncology patients undergoing cancer related treatment, a majority were diagnosed with leukemia.	**Data Collection/Analysis:** Searches were conducted on 8 databases. Data extraction done by 2 reviewers using JBI form. Cochrane collaborative used for risk of bias, Stata used for data analysis ($p < 0.05$). Flow diagrams and adequate description of why certain articles were kept. Measurements included self-reported pain, observer reported pain, physiologic measures.	Forest plot of RCT's for self-reported pain showed statistically significant impact of procedural distraction ($p = 0.007$). Children who received distraction had lower pulse rate than control ($p < 0.001$).

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
Burns-Nader, S., Joe, L., & Pinion, K. (2017). Computer tablet distraction reduces pain and anxiety in pediatric burn patients undergoing hydrotherapy: A randomized control trial. *Burns, 43*(6), 1203-1211.	To determine the effectiveness of the use of a tablet for distraction in managing procedural pain children receiving hydrotherapy for burn care.	Randomized Control Trial	**Sample:** 30 children ages 7-12 years undergoing hydrotherapy for burn care (n=30). Average age was 7 years sample was 63.3% male and 36.7% female. **Setting:** Children's of Alabama Burn Center, Birmingham, Alabama	**Intervention:** Tablet distraction given via child life specialist during hydrotherapy procedure. The child life specialist assessed needs of child and engaged them with table activities (n=15). The control group received support from the child life specialist without added (n=15). distraction tools. **Data Collection:** FACES scale was used for self-reported pain after procedure **(primary measure).** Nurses were asked using a Likert scale for overall observation of child's pain during procedure **(primary measure)**. Children's emotional manifestation scale (CEMS) was used by child life specialist to determine emotional response to hydrotherapy **(secondary measure).** Lastly length of time was looked at to see if distraction altered length of procedure. **Data analysis:** Independent sample t-test	Nurse report of pain was lower in distraction group compared to control (p=0.03) CEMS during procedure was lower in the tablet group (p = 0.001). CEMS was lower post procedure in the tablet group (p = 0.002). FACES score was lower in tablet group (2.53 vs 3.20) but not significant (p=0.29). There was no significant difference in length of procedure time between two groups (p=0.66).

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				and chi square tests were completed to determine significance of differences between groups, p was set at < 0.05. ANOVA was used on CEMS for pre, procedural, and post procedure.	
Cristal, N., Staab, N., Chatham, R., Ryan, S., Mcnair, B., & Grubenhoff, J. (2018). Child life reduces distress and pain and improves family satisfaction in the pediatric emergency department. *Clinical Pediatrics*, *57*(13), 1567-1575.	To see the effectiveness of the use of a child life specialist for distraction intervention on pediatric distress and pain during intravenous cannulation in the emergency department.	Non-randomized control trial	**Sample:** Convenience sample of 78 patients ages 3-13 years old requiring IV for treatment in an emergency department (n=78). **Setting:** Level one pediatric trauma center in the United States.	**Intervention:** Received coping support and distraction from child life specialist (n=39) Control group received standard clinical care including nursing communication and numbing medication when indicated for IV (n=39). **Data Collection:** Key things looked at were patient distress and pain (primary measure). As well as effectiveness of procedure and family satisfaction (secondary measures). CEMS tool was used to measure distress response, Wong-Baker faces for self-reported pain, Likert scale for efficacy (completed by nursing staff), and a Likert scale	CEMS scores were lower in intervention group compared to control (9.9 vs 13.5; p = 0.002) Wong Baker score was higher in intervention group than control (2.18 vs 1.92' p = 0.002), researchers contributed this to lack of experience for nursing in intervention group. Family rated overall satisfaction higher in intervention group vs control (26 vs 15; p = 0.007).

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				survey for parents regarding satisfaction with care. **Data Analysis:** Descriptive statistics were used to summarize experimental data. Means and SD were used for continuous data. Linear regression models were used to compare results between groups. P was set to < 0.05.	
Cummings, J. (2015). Pediatric procedural pain: How far have we come? An ethnographic account. *Pain Management Nursing, 16*(3), 233-241.	To review and explore the management of procedural pain in the pediatric population in a mixed (adult and pediatric) emergency setting.	Qualitative ethnography study	100 hours of observation over a 5-month period, hours varied for about 4-hour intervals 3 times weekly at different points in time. It totals about 44 pediatric procedural interactions with 27 health care providers. Children ranged in ages from 2-8 years. 6 individuals were interviewed, 5 nurses and 1 emergency technician. 5 were women and 1 was a man, ages ranged	**Data Collection:** 100 hours of observation was conducted in the pediatric care area in emergency department. Field notes were written within 24 hours of observation. Data collection was over 5 months to achieve repetition and to ensure a full, accurate description of procedural pain management. Observations were centered on needle related procedures conducted by health care providers.	Physical restraint was one of the most used measures for procedures. Most staff believed in efficiency being the best way to manage procedural pain "gone in 60 seconds rule." There is lack of use of standardized protocols for managing procedural pain. Even though caregivers admit to knowing procedures can cause pain this did not alter how care was

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			from 31-55 years old. **Setting:** Suburban based emergency department in New Jersey	Observations and interviews looked at practice issues that impact management of procedural pain, the use of physical restraints, nonuse of non-pharmacological measures, actual treatment of pain, and the use of pharmacological measures such as sedation. **Data Analysis:** occurred continuously while data was being collected. Process followed 1 4 sequence phase of ethnographic analysis, focusing on building on ideas through entirety of the study. A coding system was used to analyze behaviors of both providers and children Interviews were audio recorded and transcribed verbatim. Ethnographic database software was used to develop themes throughout interviews.	delivered. There is lack of knowledge among healthcare providers on how to provide age appropriate, nonpharmacological intervention for management of procedural pain.
Inan, G., & Inal, S. (2019). The impact of 3 different distraction techniques on the pain and anxiety levels of children	To evaluate the effectiveness of 3 types of distraction	Randomized control trial	Sample: Children ages 6-10 presenting for phlebotomy as	Intervention: Video game group (n=45), cartoon movie (n=45), parent	There were statistical differences in both child, parent, and

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during venipuncture: A clinical trial. *Clinical Journal of Pain, 35*(2), 140-147.	techniques on pain and anxiety in children undergoing venipuncture procedures.		ordered by a physician (n=180). 50.6% were female and 49.4% male. Mean age was 7.7 years. Setting: Training and Research Hospital in Istanbul	supported distraction (n=45), and control group that received no intervention (n=45). All interventions started 3 minutes prior to procedure and ended when procedure was completed. Data Collection: Children's Fear Scale (CFS) was used to determine anxiety during procedure. Wong-Baker Faces for pain during procedure. Both were gathered from self-report and parent and nursing observations. Data Analysis: means and SD for descriptive statistics. Kruskal Wallis and chi square for comparing scores and differences in groups, $p < 0.05$.	observer reporting of anxiety ($p<0.001$). Video game group had least amount of anxiety and control group had the highest (0.27 vs 2.22 $p < 0.001$). Child, parent, and observer report pain was least in video game group ($p < 0.001$) Of the intervention groups pain scored highest in parent led distraction ($p <0.001$) All interventions scored less for all three levels of pain as compared to control group ($p<0.001$).
Goldberg, D. S., & McGee, S. J. (2011). Pain as a global public health priority. *BMC Public Health, 11*, 770. doi:10.1186/1471-2458-11-770	To determine if pain is a symptom of a disease or a disease state itself	Allostatic load theoretical framework, persistent exposure to certain conditions	Not applicable	Not included	Pain is a dynamic ambiguous phenomenon difficult to quantify Pain is often accompanied with

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		activates the fight-or-flight response, the persistent stress response has been linked to negative disease states.			other comorbidities. Chronic pain has been linked with physical, mental, and work stress. And has also shown to impact socioeconomic dynamics and education. Since pain can impact so many levels of an individual's life management of pain should become a public health priority.
Jeffs, D., Dorman, D., Brown, S., Files, A., Graves, T., Kirk, E., … & Swearingen, C. (2014). Effect of virtual reality on adolescent pain during wound care. *Journal of Burn Care and Research*, *35*(5), 395-408.	To compare the effectiveness of the use of virtual reality as compared to passive distraction in management of pain during burn care treatments.	Randomized Control Trial	**Sample:** 30 adolescents age 10-17 years requiring burn care, 2 withdrew prior to completion of study (n=28). Mean age was 13 and 68% were male 32% female. 44% of burns caused by fires, 30% scalds, and 26% a hot object. **Setting:** Outpatient burn clinic in children's hospital	**Intervention**: participants were randomly assigned to 3 groups: interactive virtual reality (n=8), passive distraction like watching a movie (n=10), and no form of distraction just talking with nurse (n=10). **Data Collection**: The Adolescent Pediatric Pain Tool was used to measure baseline preprocedural pain and pain intensity associated with would care during procedure and	Adolescents pretreated with opioid reported more pain than those who did not have pretreatment (95% CI: 7.0–37.1, P = .004). No difference in anxiety was between those who received or did not receive preprocedural opioids (P = .18 and P = .81). Virtual reality group reported less pain than passive distraction

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			located in mid-south United States.	post procedure **(primary measure)**. The Speilberger State Trait anxiety inventory for children was used to assess participants level of distress **(secondary measure).** A post procedure survey was used to determine desire for distraction, belief in how distraction work, and perceived level of engagement with the distraction during procedure. **Data Analysis**: 2 researchers collected all data. Demographic, anxiety, type of injury, if analgesia was used, treatment length, pain ratings, and engagement was summarized for each group. Continuous measures were summarized as means and standardized deviations. Categorical was utilized via percentages. Fisher exact test was used for nominal categorical data. P was set at <0.05. Multiple linear regression	group (95% CI: 2.4–45.0, *P* = .029) Virtual reality reported less pain than communication group but not significant (95% CI: −9.5 to 28.9, *P* = .32). Researchers concluded that interactive distraction practices, such as virtual reality, are more effective at managing procedural pain than passive distraction methods.

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				models were utilized. Stata was used for all statistical analysis.	
Kaheni, S., Rezai, M., Nesami, M., & Goudarzian, A. (2016). The effect of distraction technique on the pain of dressing change among 3-6-year-old children. International *Journal of Pediatrics*, *4*(4), 1603-1610.	To determine the effect distraction has on pain during dressing changes of second degree burn victims ages 3-6 years old.	Randomized Control Trial	**Sample:** 80 children ages 3-6 years requiring burn care for second degree burns (n=80) 56% were males 44% females and the average age was3 years old. **Setting:** Burn ward of Zareh Hospital	**Intervention:** There are 3 stages of dressing changes: removing clothes, wound debridement and placement of new dressing. The intervention group was allowed to play a video game starting 3 minutes prior to care and played until end of care. The control group had dressing changes done without any intervention. 1 parent was present for each group member. **Data Collection:** demographic information and the use of FLACC to assess pain during dressing changes **(primary measure),** data was observed and collected by same researcher. **Data Analysis:** means and SD were used to evaluate quantitative variables and absolute and	Age, gender, weight, and type of burn were not significantly different between groups ($p>0.05$) There was a significant difference in pain between intervention and control group (2.57 vs 8.0; $p < 0.001$) 70% of children in control group experienced severe pain while 77.5% of children in intervention group had little pain ($p < 0.001$).

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				relative frequency for quantitative. Independent t-tests were performed to assess changes between groups. Chi-square was used to compare pain intensity. P was set to < 0.05.	
Kuo, H., Pan, H., Creedy, D., & Tsao, Y. (2016). Distraction-based interventions for children undergoing venipuncture procedures: A randomized control study. *Clinical Nursing Research*, *27*(4).	To examine how the use of distraction impacts behavioral distress associated with venipuncture in children ages 3-7 years.	Randomized control trial.	**Sample:** 276 children ages 3 to 7, 49% males, 51% females, the mean age was 6 (n=276). **Setting:** Children hospital in Taiwan.	**Intervention:** Distraction A involved a storybook reading about a bear going to the doctor and getting better (n=92). Intervention B was cartoon viewing about a tiger going to the doctor (n=92). The control group received oral instructions regarding the procedure. All had a physician order for venipuncture. **Data Collection:** The Observational Scale of Behavioral Distress was used to calculate total distress score during procedure (primary measure). All venipunctures were performed by a nurse with at least 3 years experiences. 6 pediatric	Children experienced less distress in both intervention group a and b as compared to the control group. Group A: 27.4 Group B: 28.9 Control: 38.5 (P < 0.05)

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				staff members were trained on observational tool, 2 were randomly selected based on rotation and arranged to attend procedure to only assess not assist. **<u>Data Analysis:</u>** Demographic information was summarized using descriptive statistics with SD. Differences between groups used a chi-square and one-way ANOVA to analyze variables. A two-factor ANOVA was used for behavioral scores with a p value of < 0.05.	
Lee, G., Yamada, J, Kyololo, O., Shorkey, A., & Stevens, B. (2014). Pediatric clinical practice guidelines for acute procedural pain: A systematic review. *Pediatrics, 133*(3), 500-515.	To review the level of evidence available in existing practice guidelines for acute procedural pain in children, determining if recommendations are appropriate for use.	Systematic review of clinical practice guidelines from 2000-2013	18 guidelines included, 4 were tools to help clinicians apply recommendations into practice, 5 were for use in clinical setting, and final 13 were recommended for hospital setting with modifications (n=18). 7 were focused on neonates/infants.	Search was conducted on Medline, Embase, CINAHL, PsycINFO, and Scopus from 2000-2013. Four reviewers rated guidelines using AGREE II framework. 2 other researchers screened guidelines, assessment of methodological quality, and data abstraction.	Four major categories for pain management are environmental (minimizing number of procedures), physical (holding), pharmacological (sucrose, topical anesthesia, opioids), and psychological (distraction and breathing exercises). Of the 18 reviewed

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			11 were infants and children 0-18 years of age.	Disagreements were figure out via group consensus. Key variables looked at were pediatrics, pain assessment tools, management recommendations, and healthcare setting.	guidelines only 5 met AGREE II evaluation recommendations and only 1 met all criteria in the AGREE II domains. Of all domains reviewed the applicability domain scored the lowest, there was lack of intention on implementing guidelines, most were unclear and not developed in this section.
Loizzo, A., Loizzo, S., & Capasso, A. (2009). Neurobiology of pain in children: an overview. *The open biochemistry journal*, *3*, 18–25. doi:10.2174/1874091X00903010018	To describe different theories on the development of pain in children.	Grounded Theory	52 peer reviewed articles from 1973-2004	Not included.	Neurobiology of pain in pediatrics is influenced by development stages of a child where repeated stress response caused by pain can alter neurobiology pathways that can last into adulthood. Pain from routine medical procedures though brief can be some of the most traumatic experiences

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					a child has. The use of guided imagery or distraction have shown to be effective methods at minimizing pain and trauma. Not treating pain can cause children to become afraid of future medical treatment causing fear of medical providers. Parents can become angry/mistrustful when pain is poorly managed.
Miller, K., Tan, X., Hons, B., Hobson, A., Khan, A., Ziviani, J., … & Kimble, R. (2016). A prospective randomized control trial of nonpharmacological pain management during intravenous cannulation in a pediatric emergency department. *Pediatric Emergency Care 32*(7). 444-451.	To investigate if the use of diversional technology intervention provides intravenous cannulation preparation and distraction in order to manage pain in pediatric patients	Randomized control trial	**Sample:** children ages 3-12 years requiring an IV procedure in the emergency department, mean age 7, 49% male 51% female (n=99) **Setting:** Royal Children's Hospital, Australia	**Intervention**: Diversion Therapy Technology distraction (n=59) Control groups: Standard distraction (toys, parental interaction; n=20) PlayStation distraction group (n=20) **Data Collection**: Recruitment of children was during a 10-month period, those included required an IV, had the	Experienced pain was significantly lower in individuals receiving diversion therapy technology as compared to standard distraction or use of play station ($p < 0.001$). Parents reported significantly less pain in diversion therapy technology group then PlayStation ($p <$

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				cognitive abilities to report pain, could speak English, and had no visual/hearing impairments. Pain was reported for both pre, procedural, and post procedure. Children self-reported using the Wong-Baker face scale, parents reported perceived pain using visual analog scale, and nursing staff scored pain using FLACC scale. **Data Analysis**: Descriptive statistics were used to describe demographic information. Kruskal-Wallis test was used to ensure homogeneity among participations. Chi square was used to detect differences among groups. Pain at 3 points in time was compared among the groups using regression model and generalized estimating equations. P value was set to < 0.05.	0.001) and standard distraction practices ($p < 0.001$). Nursing staff reported less observed pain in both PlayStation and diversion therapy group versus standard distraction ($p < 0.001$).
Postier, A., Eull, D., Schulz, C., Fitzgerald, M., Symalla, B., Watson, D., … & Friedrichsdorf, S. (2018). Pain	To describe children's procedural pain in	Cross-sectional analysis	**Sample:** 194 children and parents (n=194). Included those in	**Data Collection**: A hospital wide survey was given that used both open	A higher percentage of children reported having no pain

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experience in a US children's hospital: A point prevalence survey undertaken after implementation of a system-wide protocol to eliminate or decrease pain caused by needles. *Hospital Pediatrics, 8*(9), 515-523.	the hospital and determine if it is adequately managed after a hospital wide QI project to reduce pain during needle related procedures.		inpatient setting, emergency room, and day surgery.	and closed ended questions to determine if the implementation of comfort promise for needle related pain was beneficial **(primary measure).** To see if the use of pain management strategies has increased since program was implemented **(secondary measure).** **Data Analysis**: survey answers were compared to survey from 2 year previous before program was implemented.	compared with survey from 2 years previous (33% vs 24%) but is was not significant (p=0.07). Less children identified pain caused by needles as the worst pain (21% vs 30%). The number of pain management strategies used and offered to children increased ($p < 0.05$).
Risaw, L., Narang, K., Ghai, T., Kaur, S., & Bharti, B. (2017). Efficacy of flippits to reduce pain in children venipuncture: A randomized control trial. *Indian Journal of Pediatrics 84*(8). 597-600.	To test the effectiveness of the utilization of flippit distraction cards at reducing pain in children undergoing venipuncture.	Randomized Control Trials	**Sample**: Children ages 4 to 6 undergoing phlebotomy, mean age 5, gender distribution not given (n=210) **Setting**: Pediatric outpatient hospital, India	**Intervention**: Use of distraction cards during venipuncture (n=105). Control Group: no distraction (n=105). **Data Collection**: All children underwent blood sampling, parents were present but instructed not to engage with children. 22 different cards were used in	Distraction card use had a significant effect on behavioral response to pain (2.75) as compared to control group (3.24) ($p < 0.001$) Parents and self-reported pain scale were lower in intervention group than control ($p < 0.001$)

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				intervention group. All procedures were videotaped. Children and parents reported pain experienced using Wong Baker Face scale. An observer also reported pain using FLACC scale. **Data Analysis**: Univariant odds ratios were used for outcome pain measures using a linear aggression analysis for confounding variables of gender, age, and past experiences. All tests were two tailed with a p value of < 0.05.	Severe pain was reported to be 2.5 times higher in control group vs. distraction card group (p = 0.002)
Sahiner, N., Bal, M. (2016). The effects of three different distraction methods on pain and anxiety in children. *Journal of Child Health Care, 20*(3), 277-285.	To review the impact of different distraction methods (distraction cards, balloons, and music) on pain and anxiety in children undergoing phlebotomy. To review if intervention is an effective way to reduce pain/anxiety compared to no intervention.	Randomized control trial	**Sample:** Children ages 6-12 requiring phlebotomy, mean age 9, 47% female, 53% male (n=120) **Setting:** Maternity and Children Hospital, Lab	**Intervention**: Distraction card group (n=30) Balloon inflation group (n=30) Music (n=30) Control Group: No distraction, family presence (n=30). **Data Collection**: Two nurses were trained by the research team to collect data. One performed venipuncture,	No significant difference of pre-procedural anxiety among all 4 groups (p=0.811). Self-reported procedural pain significantly different among groups (p=0.040). Distraction card group had the lowest pain level (2.33) compared

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				the other observed and evaluated pre-procedural and procedural anxiety as well as procedural pain. This nurse was also responsible for initiating distraction. The children's fear scale was used for anxiety **(secondary measure)** and Wong Baker Faces scale for pain **(primary measure)**. The observer, parent, and child were responsible for reporting pain. Parent and observer reported on anxiety. **Data Analysis**: Data was analyzed using chi-square and student's t test. Statistical significance was set a $p < 0.05$ and pain was compared using a one-way analysis of variance.	to control group (4.53) but not significant ($p = 0.057$). Parental reported pain was lower in all intervention groups compared to control group but not significant (cards 1.87 $p = 0.057$, music 3.13 $p = 0.108$, and balloons 2.51 $p = 0.410$). Balloon inflation showed significantly lower anxiety levels than all other groups ($p = 0.049$). Anxiety levels experienced by children were statistically less in intervention groups ($p = 0.032$)
Sundar, S., Ramesh, B., Dixit, P. B., Venkatesh, S., Das, P., & Gunasekaran, D. (2016). Live Music Therapy as an Active Focus of Attention for Pain and Behavioral Symptoms of Distress During Pediatric Immunization. *Clin Pediatric (Phila), 55*(8), 745-748.	To determine if the use of music therapy during routine childhood immunization reduces discomfort	Randomized Control Trial	**Sample:** 100 children 18 months and younger requiring routine childhood vaccinations (n=100)	**Intervention**: Experiment group received live music therapy during immunization procedure (n=50). Control group received no intervention (n=50).	All 3 domains of the MBPS showed significant improvement in the experiment group versus control ($P < .05$).

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doi:10.1177/0009922815610613			**Setting**: pediatric outpatient department at Mahatma Gandhi Medical College & Research Institute Puducherry, India	**Data Collection**: The Modified Behavior Pain Scale (MBPS), 10-point pain levels, and 10-point distress levels were documented by parents. Duration of crying was recorded by investigators. Pre- and postimmunization blood pressures and heart rates of parents holding the children were recorded by investigators. **Data Analysis**: Independent and paired t tests were used for analysis. P<0.05	Pain levels and distress levels also showed improvement in the experiment group but were not significant. Mean (±SD) duration of crying spells was 25.02 (±13.98) seconds in the experiment group and 41.66 (±17.29) seconds in the control group (p<0.05). The experiment group, systolic blood pressure and heart rates showed improvement after music therapy intervention (p>0.05
Thrane, S., Wanless, S., Cohen, S., & Danford, C. (2016). The assessment and non-pharmacologic treatment of procedural pain from infancy to school age through a developmental lens: A synthesis of evidence with recommendations. *Journal of Pediatric Nursing, 31*(1), 23-32.	To determine the best developmental approach for assessing and treating pain for varying age groups.	Systematic review	118 articles were found during a search of PubMed and non-identified library from the years 1980 to 2014 of those 54 were found to address purpose of search (n=54). A majority of literature focused on interventional studies (42).	Information was extracted based on specific age groups (infant, toddler, preschooler, or school age children), and the use of non-pharmacologic interventions to address pain. Additional information was extracted related to developmental issues, assessment tool validation, and position statements from experts	Infants: FLACC scale and CRIES observational tool show most consistent measurements in studies, swaddling, sucking, and attachment especially in combination have the best overall effect in reduction of procedural pain.

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				and organizations such as the World Health Organization and the International Association for the Study of Pain. One author conducted the search while other authors evaluated studies for inclusion and synthesis. No clear information on how this was done and how data was specifically analyzed.	Toddlers: FLACC and CHIPPPS are best homogenous evaluation tools for pain. Due to cognitive advances distraction is the most effective technique at treating procedural pain. Preschoolers: FLACC and BOPS observational tool most effective at assessing pain. Distraction is the most effective technique in decreasing perception of pain and helping with coping during procedure. School Age: Faces pain scale is most effective in this age group. Distraction that promotes positivity and a calming environment is the best intervention that lower pain and alters reactions to painful procedures.

Author/Article	Research Question/ Hypothesis	Design	Sample (N)	Data Collection/ Instrument/Tools	Findings/ Conclusion
					(A note on this study is there is lack of explanation on how conclusions were reached)
Uman, L., Birnie, K., Noel, M., Parker, J., Chambers, C., McGrath, P., Kisely, S. (2018). Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database of Systematic Reviews, 10,* 1-111	Update on original 2006 review looking at effect of psychological interventions on procedural pain in children related to needle procedures, specifically distraction and other cognitive interventions.	Meta-analysis	59 trials with 5550 participants. Studies included children aged 2 to 19 years, a majority from 4 to 6 years old. The most common intervention was distraction (n = 32). Most common procedures were venipuncture, IV, or vaccines.	**Data Collection/Analysis**: Cochrane risk of bias tool used 5 databases utilized, detailed appendices listed search terms Review Manager software used from computed analyses 2 authors assessed articles for inclusion criteria, 2 performed data extraction Data looked at included demographics, type of procedure, type of intervention, controls, and outcome variables. Measures of treatment effect included: self-report pain, observer report of pain, behavioral measures, physiological measures.	Strong evidence to support use of distraction for self-reported and observed procedural pain in children ($p < 0.0001$). Evidence that supports the use of distraction for procedural distress ($p < 0.0001$). Cognitive behavioral therapy did not have a significant impact on pain ($p = 0.08$). Hypnosis did have a significant impact on pain ($p=0.03$)
Yinger, O. S. (2016). Music Therapy as Procedural Support for Young Children Undergoing Immunizations: A Randomized Controlled Study. *Journal*	To determine the effects music therapy has on the behaviors of	Randomized Control Trial	**Sample**: Children ages 4 to 6 years undergoing immunizations (n=58)	**Intervention**: experimental group received music therapy during injections (n=29)	Children in the music therapy group showed better coping behaviors during

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of Music Therapy, 53(4), 336-363. doi:10.1093/jmt/thw010r	children, their parents, and their nurses during childhood immunizations.		Parents of the children (n=62) Nurses administering immunizations (n=19). **Setting**: 2 sites both family medical centers	control group did not (n=29). **Data Collection**: The Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) was used to measure child distress and coping behaviors and adult distress- and coping behaviors The University of California at Los Angeles Universal Pain Assessment Tool was used to measure parents' ratings of their child's pain Upon completion of the procedure, all parents were asked to complete a researcher-created questionnaire comparing their child's present level of distress to previous medical experiences using a 7-point Likert-type format **Data Analysis**: Videos of procedures were transcribed by three research assistants who transcribed videos coding	preparation phase (p=0.01). Intervention group had significantly lower rates of distress behaviors during the procedure phase (p =0.001) Parents of children in the intervention group showed lower rates of distress-promoting behaviors during the preparation phase and recovery phase (p=0.005, 0.001). Parents of children in the intervention group rated their child's level of distress lower than previous experiences (p < .001). There was no significant difference between groups in parents' ratings of their children's pain (p>0.05) . No significant

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				them using the CAMPIS-R. Distributions for rates of distress, coping, distress-promoting, and coping-promoting behaviors were examined. A series of Mann–Whitney U-tests were used. Effect sizes (r) were calculated based on the z-scores associated with the Mann–Whitney U values.	differences between groups in the rates of nurse coping- or distress-promoting behaviors ($p > .05$).

Inan and Inal (2019) investigated different distraction methods and their impact on a child's pain during venipuncture. All interventions, video game, watching a movie, and parent support, had statistically lower Wong-Baker Faces scores as compared to the control group, $p < 0.001$ (Inan & Inal, 2019). Something of interest to focus on in this study is in comparing the intervention groups active distraction from the video game had the lowest score of pain in comparison to the passive methods of watching a movie (Inan & Inal, 2019).

Music therapy was another form of distraction used in some of the articles analyzed for this project. Sundar et al. (2016) utilized music therapy for the management of discomfort in children younger than 18 months undergoing routine childhood vaccinations. Though pain levels and discomfort were not statistically significant between the intervention and control group, the mean duration of crying was shorter in the intervention group (Sundar et al., 2016). Yinger (2016) utilized music therapy to determine its effectiveness on distress and coping behaviors in children ages 4 to 6 undergoing immunizations. What is unique about this study is it not only looked at the child's and parent's response but also nursing staff (Yinger, 2016). Children in the intervention group had significantly lower rates of distress and overall better coping behaviors (Yinger, 2016). Parents of the children in the intervention group rated their child's overall distress level as lower than previous healthcare experiences (Yinger, 2016). Yinger (2016) also cited that many of the nursing staff requested the continued use of music therapy even for children who did not meet the criteria of the study.

Barriers and facilitators to use of distraction. Two of the 19 articles reviewed examined the management of pain caused by routine medical procedures in the pediatric population. Cumming (2015) conducted a study that used both interviews and direct observation

of healthcare providers performing procedures on children in an emergency department that cares for adults and children. A startling finding from this study is that though the staff believed that pain from medical procedures should be managed, efficiency was deemed the best management option (Cummings, 2015). Often efficiency meant physically restraining a child to get a procedure done as quickly as possible, gone in 60 seconds rule (Cumming, 2015). Cumming (2015) concluded that there is a lack of knowledge and standardization of protocols to not only manage pain, but that also focus on patient-centered interventions.

Bice, Gunther, and Wyatt (2014) conducted a systematic review to determine what is known about different practices used for the treatment of pain caused by routine medical procedures. Authors further went to identify barriers that impact utilization of pain management (Bice et al., 2014). 10 articles were included in the review, barriers that were identified included communication, lack of knowledge regarding practices, lack of available resources, negative attitudes towards practices, and lack of autonomy (Bice et al., 2014). Reviewers concluded that to support the use of nonpharmacological methods to manage pain in the pediatric population education, one-on-one coaching, nursing controlled protocols, empowerment of nursing staff, and the development of organizational policy needs to occur in order to encourage initiation of quality improvement projects and the transformation of organizational practices (Bice et al., 2014).

Strengths, Weaknesses and Gaps

The review of the literature shows the vast availability of evidence that supports the idea that distraction practices can effectively manage pain children experience during vaccine injections. A strength of this literature review is that many of the articles were either a

randomized control trial or systematic review which is considered a higher level of evidence as compared to other designs (Greenhalgh, 2014). Additionally, many of the studies found similar results when looking at the statistical significance distractions usage had on pain in the children studied. The studies reviewed highlight practices that can help researchers develop a better understanding of influencing roles on behavioral responses to pain in children.

Primarily the articles reviewed focused on procedures of phlebotomy and burn care, which can impact the generalizability of findings to other procedures such as vaccine injections. There was also a lack of development on how previous painful experiences influenced study outcomes. The studies also focused on varying age groups ranging from the infant population to adolescents. This is important to note since the behavioral response a child has to a painful procedure is heavily influenced by developmental and coping skills available to that child (Lynch, Zuck, Goldschneider, & Jones, 2007).

The literature predominantly examined either the emergency setting or inpatient hospital setting, not primary care. Unfortunately, despite the multitude of studies that point to distractions usefulness, there is a large gap in the current literature of how to apply and implement practices into the primary care setting. Lee et al., (2014) conducted a systematic review examining available clinical practice guidelines on managing acute procedural pain in children. Of the 18 guidelines reviewed, none had an appropriately developed applicability or implementation section (Lee et al., 2014). These findings were consistent in the literature review for this project. This gap points to the reason further research needs to be done to help providers not only understand why the use of distraction is important but also how to implement its use into the primary care setting. Further, this information can help cultivate developmentally appropriate

distraction interventions that will provide the tools, knowledge, and resources needed to impact the problem of poorly managed vaccine injection pain in the primary pediatric clinic.

METHODS

Project Design

This quality improvement project used a quantitative descriptive research design. Participants evaluated the usefulness of a Distraction Toolkit and determined whether its use promoted patient-centered care. Data was gathered to examine participants' perceptions of the distraction and its overall impact on perceived pain and care provided. This type of design allows descriptive data to be quantified to predict and explain the barriers, facilitators, and other influences on the intervention of study (Atiqi, Ieresel, & Cleophas, 2009). Institutional review board approval was obtained from the University of Arizona.

Setting and Participants

The project setting took place at a pediatric primary care clinic located in Spokane Valley, Washington. The practice has approximately 10 primary pediatric care providers, three registered nurses, and 10 medical assistants. The practice sees children ages birth to 18 years, managing wellness visits, sick visits, behavioral concerns, and mental health medications. The clinic is part of a larger healthcare organization, Providence, which is the primary source for pediatric specialty care in the Inland Northwest. A Distraction Toolkit was provided to two medical assistants in the clinic that agree to participate in the project.

Intervention and Data Collection

The study occurred in two parts. The first stage included the recruitment of potential participant, medical assistants, being informed of the purpose of the project via email from the

Clinical Director. The project investigator (PI) conducted an education session for those interested in participating in the study.

During the educational session, the project investigator further explained the purpose of the project and introduced the use of the Distraction Toolkit. The Distraction Toolkit was developed by the project investigator using evidence-based age-appropriate distractors. Two kits were developed with each kit including a book, two light-up toys, two toy cars, and one magnetic drawing board. A PowerPoint format was employed for this 20-minute educational session emphasizing rationale to promote stakeholder buy-in. Additionally, specific information on how to assess a child's pain using the Face, Legs, Activity, Cry, Consolability (FLACC) scale was provided in this educational session via PowerPoint. Following the educational session, medical assistants utilized the (FLACC) assessment tool to rate a PowerPoint exemplar patient. The survey included a disclosure statement that by completing the FLACC assessment tool medical assistant consented to participate in this project.

All children ages 4-6 years receiving vaccines during the project were evaluated using the FLACC scale immediately prior to and 1-minute following vaccination administration. Prior to implementing the Distraction Toolkit, the Project Investigator functioned as an inter-rater, also rating the pain scores to promote reliability. A total of at least six children requiring vaccines were evaluated via this method before implementing the Distraction Toolkit.

The second stage of the project included the developmentally appropriate Distraction Toolkit comprised of books and toys. The process involved the medical assistants making two trips. First, the assistant brought the kit into the room. The medical assistant explained the purpose of the project and allowed the parent or child to decide if they would like to use the

Toolkit (Appendix A). The child then explored the toolkit and chose a toy or book. Second, while the child was distracted with the materials in the toolkit, the medical assistant then brought in and delivered the vaccination. Once the vaccine was administered, the toolkit was returned to the medical assistant, and the visit completed.

Data collection was done via paper surveys using a Likert scale format (Appendix B). This type of survey is beneficial for evaluating attitudes, beliefs, and behaviors regarding practices within a healthcare organization (Centers for Disease Control [CDC], 2012). A Likert scale format aligns with elements of the Theory of Planned Behavior since it is designed to determine attitudes, behaviors, and possible barriers present to the adoption of distraction practices. This instrument was developed using Likert scale guidelines published by the CDC (2012). The tool provides the opportunity to assess whether the use of distraction is an acceptable practice for managing vaccine injection pain.

Pain assessment for each child was evaluated using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale (Appendix C). Pain was measured no more than one minute following a vaccine injection. The FLACC scale is a valid and reliable tool for calculating observed pediatric pain (Crellin et al., 2017). Findings in the literature show that the FLACC scale has been positively correlated to self-reported pain in children ages 5 to 7 (Willis, Merkel, Voepel, & Malviya, 2003). Each of the five items is scored on a 0-2 scale, with a maximum total score of 10 (Crellin et al., 2017). This validated scale was initially created to measure postoperative pain in children 2 months to 7 years but has since been used routinely in a variety of pediatric clinical settings (Crellin et al., 2017).

Data collection took place over four days. Inclusion criteria included children ages 4 to 6 requiring routine vaccination administration. Medical assistants were responsible for providing the child with the Distraction Toolkit and completing each paper Likert survey and FLACC assessment after the visit, which was returned to the designated folder. Demographic information was collected for each child including age, gender, and caregiver present with the child. Demographic information was also collected for each medical assistant (Appendix D). After the four-day trial of the use of the Distraction Toolkit, a post-test design, Likert scale survey was administered to the medical assistant staff that participated to measure the intervention's usefulness and potential for adoption as a routine protocol. An additional survey item measured the medical assistant's perception of the distraction practice promoting patient-centered care which could impact adoption (Appendix E). Once surveys were completed results were tallied and individual sheets destroyed. Cumulative data from surveys were shared with administration and staff via executive summary.

Since the questions on the Likert scale have not been previously evaluated two experienced Pediatric Nurse Practitioners reviewed items for clarity and content. During the educational session with clinical assistant staff, the procedure was reviewed including specific content of the scales to ensure information was clear and to allow an opportunity to give feedback on any parts of the scale and surveys that appeared unclear.

Data Analysis

Microsoft Excel and Stata were used to analyze data that was collected from the Likert surveys and FLACC scale including means, standard deviations, and statistical significance. Pain scores of each child using the Distraction Toolkit wee compared to the children that did not

receive this intervention. The mean score of the adoption survey given to the medical assistants after the study helped to determine the effectiveness of the intended improvement of the project.

Budget and Timeline

The only cost associated with this project is the development of the Distraction Toolkit. The kits include three look and find books, two light up toys, two toy trucks, and a small magnetic drawing board (Figure 2). The total cost for developing these kits was about $35. Once the staff was given education on how to use the kit medical assistants collected daily data using the Likert scale and FLACC provided and at the end of the 4-day period a follow-up Likert scale was completed.

FIGURE 2. Distraction toolkit.

Ethical Consideration

The population of the study included two groups medical assistants, a non-vulnerable population, and children ages 4 to 6 years old, a vulnerable population. Respect for the medical assistant staff was demonstrated by making participation voluntary and making both surveys as brief and easy to complete as possible. Respect for children participating in the study was shown by making both the child and caregiver present fully aware of the study and the option to refuse the Distraction Toolkit if wanted. Privacy was ensured for each child where no identifiable data was collected that could be linked back to each child.

No incentives were given for participation. Medical assistant staff was advised that employment would not be affected by participation. Beneficence was further demonstrated by the possibility that participants may gain the satisfaction that their involvement in the project contributes to the efforts of the clinic to promote patient-centered care encouraging better patient outcomes.

There are minimal associated risks with this study. There is a potential for children participating in the project to experience increased anxiety related to unknown people present in the room, stranger danger. There are no other known risks. The design of this project ensures a child's safety while obtaining positive outcomes and minimize negative consequences. Benefits include the promotion of patient-centered care, potentially decreasing pain, and overall making vaccine injections a better experience for children, families, and medical staff. This leads to improved quality and value of healthcare services delivered.

Justice is demonstrated in the study by the inclusion of all children requiring vaccine injections ages 4 to 6 years old without any further demographic limitations. Allowing the child

to choose what distraction item they want from the kit promotes equality, decreasing the chance of favoritism by the medical assistant picking an item that has shown to be more effective than another.

RESULTS

Demographics

A total of 24 children participated in the project, 19 children used the Distraction Toolkit intervention, and five did not. 58.3% were male, and 41.7% were female. The mean age for participants was 4.4 years. Mothers were the caregiver most often present during vaccine administration. Demographics of patients are presented in Table 2. A total of six medical assistants participated in the project; this was more than the original expected two. 100% were female. 100% were medical assistants. Years of experience ranged from one year up to 12 years, with the average being five years. Demographics of medical assistant staff are presented in Table 3.

TABLE 2. *Patient demographics.*

Children Participating (N)	**# of Participants**	**Percentage**
Intervention		
No Distraction	5	20.8%
Distraction Toolkit	19	79.2%
Age		
4	15	62.5%
5	9	37.5%
6	0	0.0%
Gender		
Female	10	41.7%
Male	14	58.3%
Prefer Not to Say	0	0.0%
Other	0	0.0%
Caregiver Present		
Mom	14	58.3%
Dad	3	12.7%
Mom & Dad	6	25.0%
Grandparent	1	4.2%
Other	0	0.0%

TABLE 3. *Medical assistant demographics.*

Total Staff Participants (N)	**# of Participants**	**Percentage**
Profession		
M.A.	6	100%
Nurses	0	0.0%
Other	0	0.0%
# Years Practicing		
0-5	4	66.6%
6-10	1	16.6%
11-20	1	16.6%
21-30	0	0.0%
Gender		
Female	6	100%
Male	0	0.0%
Prefer Not to Say	0	0.0%
Other	0	0.0%

Pain Scores

The pre-vaccine pain scores for those children in the Distraction Toolkit group (mean 0.4, min 0, max 3) was slightly lower than the group without the intervention (mean 1, min 0, max 5). The post-vaccine pain scores for those children in the Distraction Toolkit group (mean 3.1, min 0, max 6) were significantly lower than the group without the toolkit (mean 6, min 1, max 9). Pain scores for those children that did not receive the Distraction Toolkit intervention are presented in Table 4; pain scores were on a scale of 0 to 10 with 0 pain being no pain and 10 being the most pain. Pain scores for those that received the distraction Toolkit intervention are presented in Table 5, these scores follow the same scale as above. Mean score comparison for both groups is depicted in Figure 3.

TABLE 4. *Pain scores without intervention.*

Patient #	**Pre-vaccine**	**Post-vaccine**
1	0	6
2	0	1
3	0	9
4	0	7
5	5	8
Mean	*1*	*6*

TABLE 5. *Pain scores with distraction toolkit.*

Patient #	**Pre-Vaccine**	**Post-Vaccine**
6	0	1
7	0	5
8	0	5
9	2	5
10	0	5
11	0	5
12	1	3
13	3	1
14	1	6
15	0	4
16	1	5
17	0	1
18	0	0
19	0	2
20	0	3
21	0	3
22	0	1
23	0	2
24	0	2
Mean	*0.4*	*3.1*

Post Distraction Intervention Survey

The mean score for all three questions on the post distraction intervention Likert survey was four and above. This signifies that the overall use of the kit did not impact vaccine delivery. Also, with responses being mostly agreeable in regards to the child actively engaging with either a toy or book in the kit this points to the use of these distractors being appropriate for both the age of the population and vaccine intervention. Post distraction intervention survey question

answers are presented in Table 6; answer choices were on a scale of 1 to 5 with 1 representing strongly disagree, 2 disagree, 3 neutral, 4 agree, and 5 strongly agree.

TABLE 6. *Post distraction intervention survey.*

Patient #	**Question 1** The child was actively engaged….	**Question 2** Vaccines were completed in a timely manner	**Question 3** Vaccine administration was successful
6	4	5	5
7	4	5	5
8	5	5	5
9	2	5	5
10	4	4	5
11	4	5	5
12	3	4	5
13	4	4	5
14	4	5	4
15	5	5	5
16	4	5	5
17	5	5	5
18	5	5	5
19	4	5	5
20	4	5	5
21	5	5	5
22	5	5	5
23	5	5	5
24	4	4	4
Mean	***4.2***	***4.8***	***4.9***

Note: Score represents a value from 1 to 5 (Appendix B for each question's corresponding scale).

Post Quality Improvement Adoptability Survey

Individual and mean scores for the post quality improvement adoptability survey is presented in Table 7. The lowest mean score on the questions about potential adoptability of the Distraction Toolkit was for the question about whether or not the use of the kit reduced pain for children during vaccines. Interestingly though in looking at pain scores it was found mean pain scores were much lower during vaccines for the distraction group than the group without distraction. Another question with a lower mean score, though still rated as agreeing according to the Likert format, was whether or not this was an intervention that medical assistants would incorporate into their everyday practice. Higher mean scores were recorded for questions

regarding ease of use, lack of impact of job requirements, and overall benefits of the kit providing patient-centered care. Individual and mean score comparisons for all questions are demonstrated in Figure 7; answer choices were on a scale of 1 to 5 with 1 representing strongly disagree, 2 disagree, 3 neutral, 4 agree, and 5 strongly agree.

TABLE 7. *Adoptability survey.*

Question	MA 1	MA 2	MA 3	MA 4	MA 5	MA 6	Mean
The Distraction Toolkit is easy to use	5	5	5	4	5	5	4.8
The Distraction Toolkit helped reduce pain a child feels during vaccine injections	4	5	5	3	4	2	3.8
The use of the Distraction Toolkit did not impact my ability to perform vaccine administration	5	5	5	4	5	5	4.8
Using the Distraction Toolkit did not interfere with my daily workflow	5	5	5	3	5	3	4.3
The Distraction Toolkit helps to provide patient center care	5	5	5	4	4	3	4.3
The Distraction Toolkit is something I will use in my daily practice at the clinic	4	5	5	3	4	3	4

Note: Score represents a value from 1 to 5 (Appendix C for each question's corresponding scale).

DISCUSSION

Results versus Expectations

Though the sample size of this quality improvement project was small, making it difficult to determine statistical significance the results of the project are not surprisingly consistent with findings in the literature. The lower pre and post-vaccine pain scores in the Distraction Toolkit intervention group (Figure 3) are consistent with results found in the literature review regarding the use of distraction for pain management (Aydin & Sahiner, 2017; Ballard et al., 2017; Bukola & Paula, 2017; Burns-Nader et al., 2017; Cristal et al., 2018; Inan & Inal, 2019; Jeffs et al., 2014; Kaheni et al., 2016; Kuo et al., 2016; Miller et al., 2016; Risaw et al., 2017; Sahiner & Bal,

2016; Uman et al., 2018). As can be seen in Figure 4 and 5 MA's had an overall positive opinion of the Distraction Toolkit with many of them either agreeing or strongly agreeing with the intervention being easy to use. Additionally, MA's generally agreed that the intervention aligned with one of the primary aims of the study the provision of patient-centered care. Lastly, of the MA's in the project many agreed that this was an intervention that they would incorporate into their daily practice.

Question two and three of the first Likert survey and questions three and four of the second Likert survey looked at the overall impact the use of the kit had on workflow. As was expected, the MA's were consistent in agreement with the use of the kit not impeding workflow. By providing the needed education and resources this helped to minimize barriers to the use of distraction as highlighted in the literature review (Bice et al., 2014; Cummings, 2015).

In looking at question two of the adoptability survey, whether the kit reduced pain, answers ranged from strongly agree to disagree. This is interesting since pain scores on average post-vaccine were half of what the post-vaccine pain scores were for the group without the intervention. It would be interesting to see if this project were to be done over a longer period, one to two months, if answers to question two of the adoptability survey would be more consistent with pain scores. Of note the MA with the most pediatric clinical experience, 12 years, answered neutral on the last three questions of the adoptability survey. However, the individual with the second greatest amount of years of experiences, eight years, strongly agreed with the last three questions of the adoptability survey questioning whether years of experience impacts attitudes towards the use of distraction. In future studies it may be of benefit to also include how

many children each MA uses the Distraction Toolkit intervention to see if the attitudes toward the intervention vary among those that use the kit more than others.

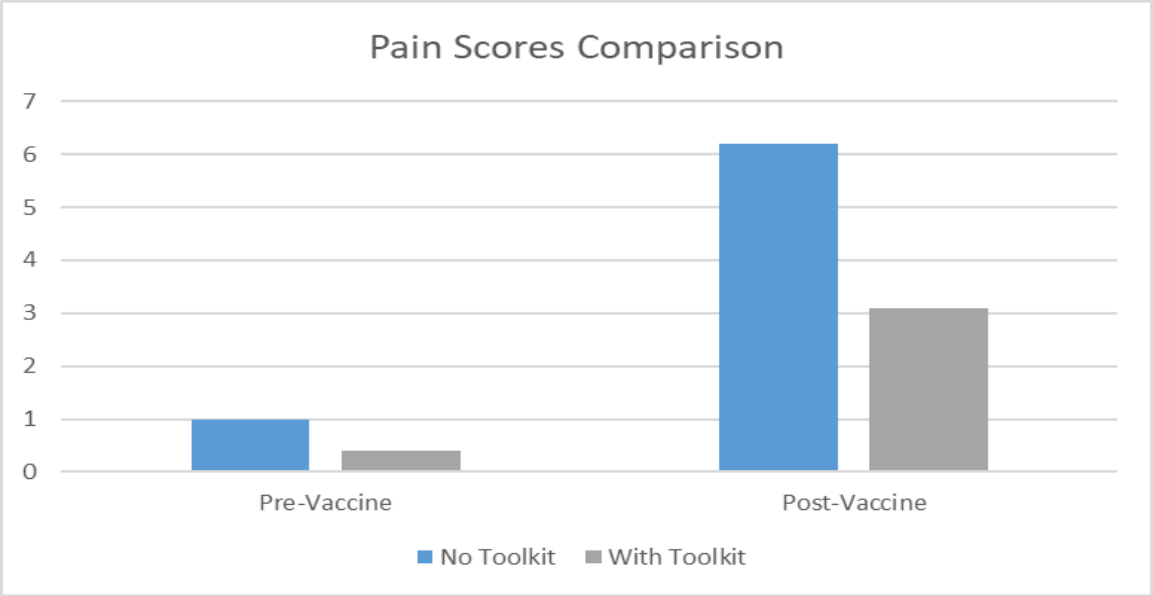

FIGURE 3. Mean pain scores. (Comparison of pre and post-vaccine pain scores between the group without the kit and with the kit).

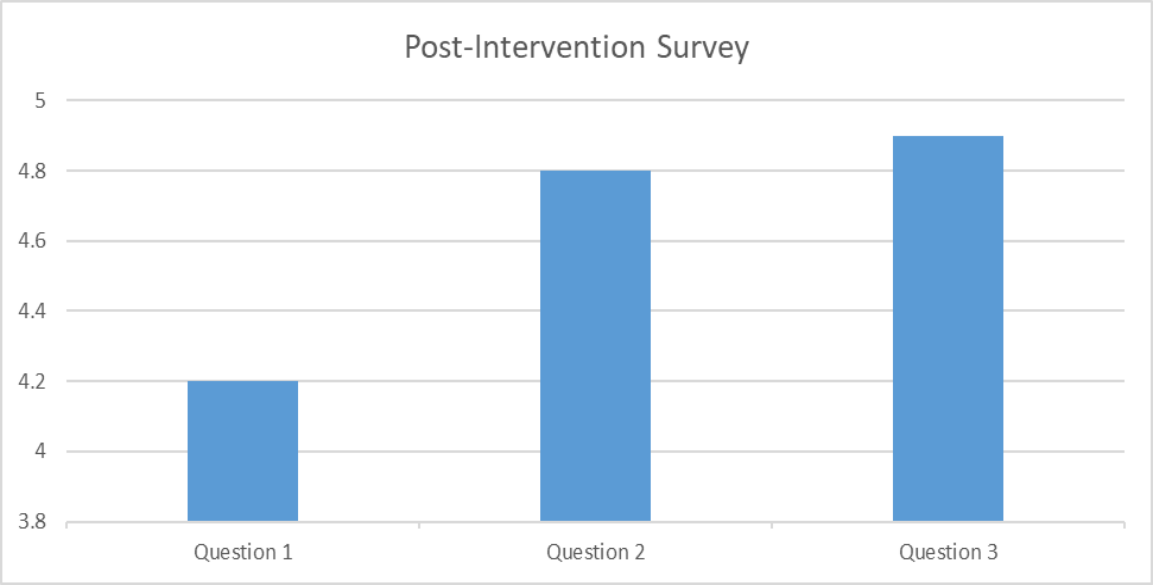

FIGURE 4. Mean post distraction survey scores. (Mean scores of post intervention survey with '5' indicating *strongly agree* and '1' indicating *strongly disagree*).

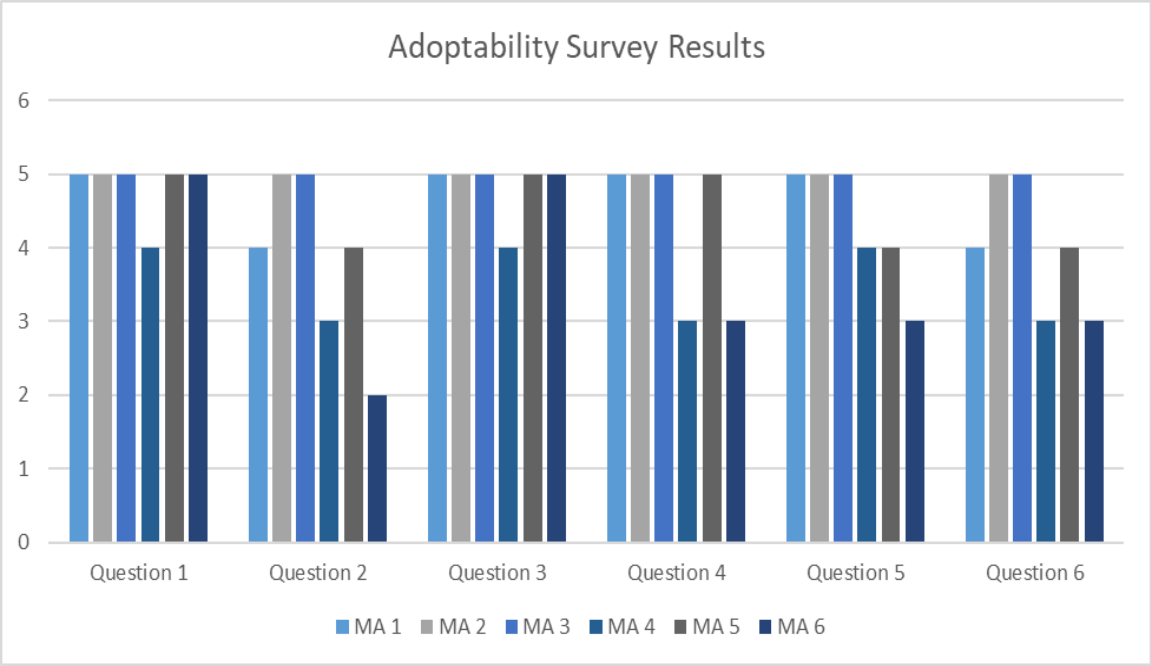

FIGURE 5. Individual adoptability survey scores. (Comparison of individual scores for the second Likert survey; '5' indicating *strongly agree* and '1' indicating *strongly disagree*).

Challenges and Limitations

The main limitation of this quality improvement project is the small sample size. The small sample size makes it difficult to construct conclusions about whether the kit decreased pain with the group that did not receive the intervention having five children and the group that received the intervention having 19. The small sample size concurrently makes it difficult to conclude if the use of the kit is an effective and accepted intervention to use in daily clinical practice. Additionally, sample bias is present in that not all medical assistants evaluated the same number of patients with some evaluating a handful while others evaluated more. The small sample size is not aimed to be representative of the clinic population or staff; however, it does offer a functional illustration of the perceived effectiveness of the kit and feasible future

interventions to decrease pain and promote comfort in the pediatric population. If future studies were to be conducted

Another limitation of the study includes that though the FLACC scale has a high sensitivity for rating pain, there are still questions of whether it can distinguish pain versus distress behaviors associated with anxiety and fear a child may have over vaccinations (Crellin et al., 2018). These phenomena are identified in the study where some patients had a pre-vaccination pain score above zero. Additionally, some pain scores were higher pre-vaccine than post-vaccine injection. This finding does beg the question of whether the distraction helped these children with any anxiety or fears associated with vaccines. If this project were repeated, the use of a pre-vaccine injection and post-vaccine injection anxiety scale would be a useful tool in determining if the kit decreases anxiety concurrently, helping to validate pain scores.

One important challenge faced during the data collection phase was that the original project site did not have the expected patient numbers. Lower than expected patient volumes led to data collection dates being extended over two weeks versus four days. Further, data collection occurred at a second clinic site. This clinic is operated by the same organization as the original clinic and is overseen by the same medical and clinical director, the original project site approval letter included the added site (Appendix G). Additionally, due to low volumes, interrater reliability was achieved by either the medical assistants and project investigator concurrently evaluating FLACC scores on three patients, medical assistants and the project investigator evaluating FLACC scores on three virtual patients, or a combination of the two. This was different from the expected pre-intervention FLACC scoring of six patients where the first day of data collection prior to the kit intervention only four patients met the criteria of children ages 4 to

6 requiring vaccines with one MA being assigned to three of the children and another having the other. Furthermore, the number of MA's participating in the study was higher than originally expected, six versus two. As with any quality improvement project efforts, this highlights the importance of being flexible. Transformational change occurs when one is willing to change behaviors based on the information available to develop successful improvements in the care process (Kouzes & Posner, 2017).

Another challenged that occurred during this project was the MA's not bringing in the kit before vaccine administration. This led to the project investigator being the one to bring the kit in and introduce it to parents. This did not occur with all the children included in the project. The fact that the project investigator was the one to bring the kit into the room for a majority of the participating children does impact whether or not the medical assistants agree or disagree with how the use of the kit impacts workflow and whether it is something they would feel comfortable using. If this project was to be completed again, it might be beneficial to do a two-week session with the project investigator working side by side with the medical assistants in deploying the kit followed by an additional one to two-week session of the MA's deploying the intervention independently.

An additional challenge that was encountered involved whether or not the caregiver present participated in the distraction process. Some caregivers helped to actively engage the child with the distractor during the vaccine administration process. Other caregivers were more focused on holding the child during vaccines to prevent the child from moving or reaching for the needle. Some caregivers were holding siblings, making it difficult to help hold the child and encourage engagement with the distractor. Future consideration should include assessing

whether or not the additional staff could be available in helping with distraction, such as a child life specialist.

Future Directions

The results of this quality improvement project suggest that the use of developmentally-appropriate toys and books can effectively reduce pain and promote patient-centered care. The next step for this quality improvement project would be to repeat it but with a larger sample size over a longer period to further evaluate the pain-reducing effect of this intervention. Also, an added anxiety scale would be a useful data collection tool to determine if the use of the kit influences the anxiety response in a child thus influencing pain scores. Further interventions could look at including other developmentally appropriate distractors for both older and younger children to expand the use of the kit for all children requiring vaccines.

Another possibility to explore with this project, as done in some of the previously reviewed literature, is to incorporate both parents and if appropriate the child's perspective on how well the kit worked (Aydin & Sahiner, 2017; Ballard et al., 2017l Burns-Nader et al., 2014; Cristal et al., 2018; Jeffs et al., 2014; Miller et al., 2016; Risaw et al., 2017; Sahiner & Bal, 2016). This would provide further information on the impact of the kit on pain and help to correlate and validate FLACC scores. Furthermore, this information would provide an individualized perspective on how well the kit worked to promote patient-centered care.

APPENDIX A:

MEDICAL ASSISTANT SCRIPT

We are offering a Distraction Toolkit to our children receiving vaccines today so they can choose a toy or book to play with during the vaccine. This distraction may help with the discomfort of the vaccine. We are evaluating the effectiveness of the Distraction Toolkit. No patient identifying information will be gathered. May I bring the Distraction Toolkit to your child?

APPENDIX B:

POST DISTRACTION INTERVENTION SURVEY

Age of Child:
Gender:
Caregiver accompanying child at office visit:

DISCLOSURE STATEMENT

By completing this survey, you are indicating that you are willing to participate in this DNP project, it will take approximately 8 minutes to complete the survey.

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
The child was actively engaged using a toy/book from the distraction kit during vaccine injections	1	2	3	4	5
Vaccine administration was completed in a timely manner	1	2	3	4	5
Vaccine administration was completed successfully	1	2	3	4	5

APPENDIX C:

FLACC SCALE

Faces, Legs, Activity, Consolabilty and Cry Scale (Crellin et al., 2017)

Total pain score prior to vaccine:

Total pain Score 1-minute post-vaccine injection:

Categories	Scoring		
	0	1	2
Faces	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

APPENDIX D:

MEDICAL ASSISTANT DEMOGRAPHICS

MEDICAL ASSISTANT DEMOGRAPHICS
Job title:
Gender:
Years employed in pediatrics:

APPENDIX E:

POST QUALITY IMPROVEMENT PROJECT SURVEY

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
The Distraction Toolkit is easy to use	1	2	3	4	5
The Distraction Toolkit helped reduce pain a child feels during vaccine injections	1	2	3	4	5
The use of the Distraction Toolkit did not impact my ability to perform vaccine administration	1	2	3	4	5
Using the Distraction Toolkit did not interfere with my daily workflow	1	2	3	4	5
The Distraction Toolkit helps to provide patient center care	1	2	3	4	5
The Distraction Toolkit is something I will use in my daily practice at the clinic	1	2	3	4	5

APPENDIX F:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	June 28, 2019
Principal Investigator:	Jessica Jean Colombini
Protocol Number:	1906746396
Protocol Title:	Distraction for Vaccine Injection Pain in Pediatrics: Reducing Pain and Enhancing Patient-Centered Care
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *Colombini IRB form.pdf*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(l): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX G:

PROJECT SITE APPROVAL LETTER

Providence Valley Young People's Clinic
1414 N. Vercler, Building 1
Spokane Valley, WA 99216
tel: 509.928.6383
fax: 509.926.9420

PROVIDENCE
Medical Group

May 24, 2019

Re: DNP Project approval

To Whom It May Concern,

I am the practice manager for Providence Valley Young People's Clinic in the Spokane Valley and Liberty Lake. I am approving Jessica Colombini to complete her DNP project on comfort care in our clinics.

If you need further information or have questions regarding this letter please feel free to contact me at 509-321-3681.

Sincerely,

Ronda Martin

Ronda Martin

Practice Manager

REFERENCES

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