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Implementation of Interventions to Reduce Pediatric Pain Associated with Vaccination: A Quality Improvement Initiative

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Abstract

Background: Routine vaccination is an important component of pediatric preventative care but for many children, the experience can be painful and anxiety provoking, potentially leading to a cascade of negative events. ***Problem:*** Under-recognition of the pain that children experience during vaccination leads to an under management of such pain in ambulatory care settings. ***Methods:*** The Face, Activity, Legs, Cry, Consolability (FLACC) scores of a convenience sample of children ages 2 months to 7 years at a small, rural family practice clinic were evaluated throughout the vaccination process over a three-month time period. ***Intervention***: Two evidence-based interventions - distraction techniques and comfort positioning, including breastfeeding - were implemented by clinicians in an attempt to decrease the patients' pain perceived during the vaccination procedure. FLACC scores were evaluated one minute before vaccination, during vaccination, and one minute after to investigate the effectiveness of such interventions. ***Results***: Statistical analysis of pre-intervention difference scores compared with those observed during the intervention period demonstrate a beneficial relationship between the use of distraction and comfort positioning and a decrease in pediatric pain experience. ***Conclusion:*** The use of evidence-based distraction techniques and comfort positioning offers an easily implemented, cost-effective solution to the problem of under managed pediatric procedural pain.

Keywords: pediatric, pain, vaccination, immunization, comfort positioning, distraction techniques, FLACC, breastfeeding

Title of Project

The title of this project is, "Implementation of Interventions to Reduce Pediatric Pain Associated with Vaccination: A Quality Improvement Initiative."

Background

In the United States, it is estimated that vaccines save 42,000 lives every year, three times more than the use of seatbelts and child restraints (The Immunization Partnership, 2019). For this reason, routine childhood vaccination is recognized as an important component of preventative care. There is a parallel under-recognition of pediatric pain and its management in the ambulatory care setting (The Joint Commission, 2018). For many children, the painful experience of receiving vaccinations provokes increased anxiety, which can lead to a cascade of negative impacts. These repercussions include long-term consequences, such as the avoidance of healthcare into adulthood, leading to higher morbidity and mortality risks (Friedrichsdorf, Eull, Weidner & Postier, 2018).

Though there has been much attention paid to the reduction of pediatric procedural pain within Emergency Departments (ED) and perioperative arenas, routine well-child visits are not often perceived as anxiety provoking for children. While a child may visit the ED once, they will have 27 well-child checks in their first 18 years, and will receive about 29 immunizations by age six (American Academy of Pediatrics [AAP], 2019; Cwynar & Osborne, 2019). Therefore, a child's positive perception of healthcare must be formed on the forefront: within the walls of the primary care office. The introduction of non-pharmacological pain management strategies provides an opportunity for quality improvement (QI) in this instance.

Problem Statement

The negative repercussions associated with mismanaged vaccination procedures can be avoided through proper pain recognition and management. Interventions, such as distraction and comfort positioning, with the inclusion of breastfeeding, demonstrate potential benefits across a variety of settings, but the application of these findings into clinical practice is lacking. This project sought to answer the following question: In pediatric patients ages 2 months to 7 years receiving an immunization in the primary care setting, does the use of comfort positioning and distraction techniques reduce pain as measured by the Face, Legs, Activity, Cry, Consolability (FLACC) scale during immunization administration when compared to standard administration?

Needs Assessment

This project took place at Penn State Health St. Joseph Strausstown Family Practice (SFP). The rural setting of this practice attracts an underserved group of patients who often struggle to maintain routine, preventative medical care. When the importance of regular well-child visits goes unrecognized, it raises the concern that children negatively affected by the fear of vaccination pain will be at even higher risk for compromised adherence to future preventative care. The culture prior to project implementation was to console the patient after vaccination with a sticker or a lollipop, rather than proactively intervening before and during the procedure itself. Assessment of pain related to vaccination was not a part of the standard of care. The Agency for Healthcare Research and Quality (AHRQ, 2019) recognized that a culture of safety is more than just reducing errors, but also focused on improving the overall quality of the health care provided to patients. When vaccination is viewed as a routine procedure, the potential traumatic impact can be underestimated and opportunity to improve the care provided to children is negatively affected. In terms of quality care, there is evidence supporting the use of

nonpharmacological interventions to reduce needle-related procedural pain, and these, "best available techniques," should be applied (Institute for Healthcare Improvement, 2019, para. 4). Additionally, patient-centered care requires respect for the patient's specific needs, which should include pain management efforts during any procedure.

In order to further understand the different attributes and threats to the project phenomenon of interest, a strengths, weaknesses, opportunities, and threats (SWOT) analysis was performed. Results from this analysis can be located in Appendix A. Likewise, Appendix B shows a root cause analysis completed to investigate the underlying problem surrounding insufficient pain control during vaccination procedures.

Aims, Objectives, Purpose Statement

The aim of this QI project was to determine whether standard comfort positioning and distraction methods reduce the perception of pain during immunization administration. The outcomes for this project focused on three main objectives, which were accomplished in chronological order as they are presented below:

1. In the 3 weeks prior to project implementation, 100% of patients who received an immunization had a FLACC score obtained by the providers during vaccine administration.
2. The week before intervention implementation, all providers at the primary care office were educated by the DNP student about the initiation of age-appropriate comfort positions and distraction methods that should be used during vaccine administration, measured by verbalization of understanding of the benefits of such interventions.
3. At least 80% of patients who present to the primary care office for routine childhood vaccinations between the ages of 2 months and 7 years received provider-initiated, age-

appropriate comfort positioning interventions or distraction techniques during their vaccination procedure during the project implementation period.

Overall, the purpose of this project was to introduce the use of age-appropriate comfort positioning, including breastfeeding, and distraction techniques to aid in the reduction of overall procedural pain experienced by children receiving routine childhood vaccinations in the primary care office.

Review of Literature

In order to investigate the efficacy and practicality of such interventions, a thorough exploration of the best evidence-based practice options was completed. To ensure that the literature included was current, only articles published within five to seven years were included. A PRISMA table (see Appendix C) describes the search strategy, notes the databases queried, and demonstrates the number of articles yielded and eliminated throughout this search process. A total of 21 articles were then formally critiqued, using the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) appraisal tool to evaluate the strength and quality of the evidence as well as to identify major patterns, trends, and gaps in the literature (Dang & Dearholt, 2017). Articles that were determined to have a quality rating of C were eliminated from inclusion as their results are not reliable and cannot be applied to future studies. The final set of evidence was comprised of 17 articles, all with quality ratings of A (high quality) or B (good quality) (Dang & Dearholt, 2017). The majority of the articles reviewed were Level I (systematic reviews of randomized controlled trials), or Level V (literature reviews or QI). An evidence matrix evaluating the included articles can be found in Appendix D.

This review allowed for further understanding of the current state of knowledge about the use of interventions to decrease pediatric procedural pain and presented a few approaches for

alleviating the problem. To begin, there is a body of evidence that describes the negative psychological impact of improperly managed childhood procedural pain. Children that experience ineffective pain management may develop needle phobias, avoid future preventative or diagnostic care, require increased referrals to child psychologists, increased complications associated with future medical visits, and chronic pain in adulthood (Birnie et al., 2014; Boerner, Gilespie, McLaughlin, Kuttner, & Chambers, 2014; Thrane, Wanless, Cohen, & Danford, 2016).

A recent Cochrane Review (Birnie et al., 2018) supported the efficacy of distraction as a non-pharmacological intervention for the reduction of needle related procedural pain. Presently, there seems to be no significant difference between different types of distraction, but when choosing a method, the child's developmental stage should be considered (Boerner et al., 2014). Cwynar and Osborne (2019) found that FLACC scores during vaccination decreased with the use of interventions such as holding/positioning, breastfeeding, or distraction with lights/bubbles. Though the evidence quality of much of the research is low, the potential benefits of reducing distress and long-term detrimental outcomes supports the use of this intervention in the clinical setting (Birnie et al., 2018). Likewise, comfort positioning methods, such as swaddling and the use of skin-to-skin contact for infants, as well as sitting in an upright position on a parent's lap, or with a parental figure next to a child, have demonstrated success (Friedrichsdorf et al., 2018; Schurman et al., 2017). Included in comfort positioning is the act of breastfeeding. A Cochrane Review by Harrison et al. (2016) concluded that breastfeeding may help to reduce behavioral responses to pain during vaccination for infants up to 12 months of age.

While there is a wide research foundation for this problem, and needle-related pain management is well reviewed, there is a lack of discussion surrounding the delivery of these evidence-based interventions into the clinical context, especially in ambulatory care areas

(Boerner et al., 2014). Thus, the application of these findings into primary care practice is lacking and should be further targeted, as reflected in the aims of this project.

Theoretical Model

Kolcaba's (2004) theory of comfort was used as the theoretical model to frame this project. Kolcaba (2004) describes comfort as something that exists in three different forms: relief, ease, and transcendence, and she believes that a person experiences comfort in four different contexts: physical, psychospiritual, environmental, and sociocultural (Utley, Henry, & Smith, 2018). This nursing theory provides a comprehensive perspective that makes it easily applicable to patients with diverse health conditions and varying comfort needs, likely representing most of what is seen the pediatric primary care (Utley et al., 2018). Implementation of interventions such as comfort positioning and distraction allow the providers in this setting to offer enhanced comfort using the framework provided by Kolcaba (see Appendix E).

Translation Model

The JHNEBP model (see Appendix F) was used to fill the gap between research findings and clinical application as its goal aims to ensure that best practices are appropriately and quickly incorporated into the patient care setting (Dang & Dearholt, 2017). The JHEBP model seeks to facilitate evidence translation into aspects of administrative, clinical, and educational practice ensuring that all practice gaps, both internal and external, are recognized and addressed (Dang & Dearholt, 2017). Specifically, the Practice question, Evidence, Translation (PET) process was selected to guide the application of the best evidence into bedside practice. This stepwise approach was used to identify a problem, develop a PICO question, review the current literature, and evaluate the application of interventions into clinical practice (Dang & Dearholt, 2017). The breadth of potential application for this model makes it fitting for the wide variety of

patients seen in pediatric primary care. Likewise, the JHNEBP approach to evidence translation was ideal given the QI nature of this project.

Methodology

Participants

A convenience sample of children between 2 months and 7 years old presenting to the primary care office were evaluated for enrollment into the project. To be included, the child needed to fall within the specified age range and must have presented to the project site for the receipt of one or more vaccinations accompanied by a parent or legal guardian that was willing to provide verbal consent. The parent or guardian needed to be fluent in written/spoken English and when appropriate, the child must have been able to communicate in English to provide assent. This project was unable to include children with identified developmental delays as the reliability and validity of the FLACC pain scale for this patient population was not evaluated.

A total of 17 patients were evaluated for eligibility in March of 2020. Of these, 16 patients met eligibility criteria and all parents/guardians agreed to participation in the project. The final sample consisted of 11 patients in the baseline group, and five in the intervention group.

Setting

SFP is located in Berks County, and is a rural community with a median household income lower than the state average, and 96.5% Caucasian residents (Onboard Informatics, 2019). This clinic provides primary care services for episodic illnesses, as well as preventative care for patients from across the lifespan. During project implementation, there were two providers (one medical doctor [MD] and one nurse practitioner [NP]) at this practice, as well as

four medical assistants (MAs). The limited number of staff at this practice allowed for more personal oversight of the interventions.

Tools

The standardized method for pain assessment in most ages is self-report, but this is unreliable in young children, so an observer-reported approach was used (Crellin, Harrison, Santamaria, Huque & Babl, 2018). The FLACC scale (see Appendix G) provides a total pain rating of 0-10 based upon observation of the child's facial expression, leg positioning, overall activity, cry, and ability to be consoled. A score of 0 would suggest that the child experienced no pain, while a score of 10 would be indicative of severe pain. The validity, reliability, and feasibility of this tool have been demonstrated in a variety of areas (Crellin et al., 2018; Gomez et al., 2013). Specifically, Crellin et al. (2018) reported high interrater and intrarater reliability coefficients of .92 and .87 respectively. When tested at a cutoff of 2, sensitivity was 94.9%, and specificity was 73.5% (Crellin et al., 2018). The FLACC score was especially beneficial to this project because of its simplicity and applicability to a busy clinical setting.

Intervention

All staff were educated by the Doctor of Nursing Practice (DNP) student about eligibility criteria and how to identify potential participants, as well as the application of evidence-based distraction and comfort positioning. The NP and physician were specifically trained regarding proper selection of age-appropriate distraction tools and comfort positions as well as proper data collection. A collection tool, developed by the DNP student, was used to ensure standardized collection of information.

To begin, participants were recruited upon presentation for a well-child check or vaccine visit, and those who met inclusion criteria were provided an informational handout (see

Appendix H). For those interested, the clinician provided a further description of the project, including its purpose, expectations for the participant, potential risks/benefits regarding the interventions, and privacy measures through the Summary Explanation of Research (see Appendix I). Verbal consent was obtained by the parent/guardian once all questions were answered.

The clinician then chose a developmentally appropriate distraction tool and/or comfort position. Items in the distraction tool kit included: bubbles, I Spy (Seek and Find bottle), a light globe, glitter wand, mindful kids card deck, stories about relaxation, pinwheels, and a rainmaker. For infection control purposes, some items such as bubbles and pinwheels were designed to be one-time use only. Once a distraction tool was selected and introduced, the child was placed into a position of comfort with the parent. Age appropriate comfort positions included: swaddling, chest-to-chest, or back-to-chest.

Two MAs were present during each vaccination procedure. One MA administered the vaccination, and the other assisted the parent with providing distraction while the DNP student or provider observed the process for data collection purposes. A process map outlining the described process can be located in Appendix J.

Data Collection

Observer-reported FLACC pain scores were used to assess the impact of the interventions. The provider or DNP student recorded participant FLACC scores at three defined points during the immunization procedure: 1 minute before vaccination, during vaccination, and one minute after vaccination. Pre-intervention, baseline data was collected for three weeks and observed a total of 11 participants comprising the control group. These participants were

provided usual care, which did not include distraction or comfort positioning during immunization.

During the intervention period, the evidence-based, age-appropriate distraction tools and comfort positions were selected and applied by the provider/DNP student and clinic staff. Data points were recorded by the provider/DNP student in the same manner as described above. For all participants, demographic data, including participant age, sex, race/ethnicity, religion, and number of vaccines received were collected to describe the sample. Data collection of the intervention group occurred over a two-week period and evaluated 100% of vaccination encounters during this timeframe. A total of 5 participants made up the intervention group. Unfortunately, due to COVID-19, the intervention implementation had to be ceased and further data was unable to be obtained.

Cost Analysis

The costs for this project were minimal in comparison to the potential savings that could ultimately occur. Fortunately, comfort positioning comes with no monetary cost, and the assembly of a distraction toolkit is minimally expensive. Tools for this kit were selected from recommendations by the American Pain Society (2018) and the majority of items were purchased by the DNP student through a play therapy supply company. For infection control purposes, some items such as bubbles and pinwheels were designated to be one-time use only. Ongoing use of the distraction toolkit would incur very minimal cost for the clinic, limited to the additional purchase of one-time use items, should they choose to utilize these interventions in the future.

Implementation of the interventions did require the clinical staff to be educated about the proper use of comfort positioning and utilization of the distraction tools included in the kit. This

education was completed during a 1-hour training performed by the DNP student, that took take place during a regularly scheduled monthly staff meeting. Further project costs, which were absorbed by the clinic, included the cost of paper to print worksheets to record procedural FLACC scores, as well as educational handouts and summary explanation of research forms that were provided to each parent/legal guardian. Specific information about costs can be found in the overall budget (see Appendix K).

Positive association with routine well-checks and preventative care begins in the pediatrician's office. Distraction and comfort positioning are interventions that require little time in the office setting, and can be integrated into the daily workflow, thus having positive implications for population health when applied to a broader perspective. The CDC (as cited in American Academy of Family Physicians [AAFP], 2016), estimated that vaccinations among children that are born between 1994 and 2013 will prevent 21 million hospitalizations, 322 million illnesses, and 732,000 deaths. An overall decrease in needle-related phobias therefore may contribute to improved compliance with preventative care as the patient ages, leading to a decrease in future disease, potentially impacting families, employers, insurance companies, local hospitals, and the community at large.

Timeline

Actualization of this project began with a successful proposal defense, followed by Institutional Review Board (IRB) submission and approval. Implementation and data collection occurred over a one month period at SFP. The implementation period was shortened by restrictions related to COVID-19. The collected data was then compiled and analyzed by the DNP student. Findings were summarized into a manuscript for journal publication and poster presentation. The manuscript was prepared specifically for submission to the Journal of Nursing

Care Quality. Specific details of the timeline are outlined through a GANTT chart (see Appendix L).

Ethics and Human Subject Protection

IRB approval was obtained through the Penn State Health IRB, as well as the Messiah University (formerly Messiah College) IRB prior to initiating the DNP project. The approval letters from the above agencies can be found in Appendix M. Because the project presented no more than minimal risk of harm to the subjects involved, approval for implied/verbal consent was also obtained. The principal investigator ensured that all participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protects patients' identifiable health information (Modifications to HIPPA, 2013). As this was a QI project, the risk to patients participating remained unchanged from the risks of patients receiving standard, routine vaccination care. The DNP student and clinical practice staff who conducted the project carefully followed the scope and standards for practice in a primary care office as outlines by the American Nurses Association (ANA, 2015). This was a de-identified study, and all information was aggregated data from the project participants, without patient identifiers. The list of participants, as well as their assigned identification numbers, were kept in a locked box within a locked office, only accessible to project coordinators. Furthermore, the electronic data associated with this project were stored on the Penn State Health Information Technology provided data base application, REDCap. Only the principal investigator maintained authorized assess to this online database.

Results: Analysis and Evaluation

Data were maintained and analyzed with IBM SSPS Statistics for Mac, Version 26.0 (Armonk, NY: IBM Corp). Prior to the commencement of data analysis, the data was cleaned,

coded, and compiled into an SSPS codebook. No missing data was present, and no outliers were noted. The demographic variables were evaluated based upon their level of measurement. Gender, ethnicity, and religion were identified as nominal data while patient age (in years) and number of vaccines received was considered interval/ratio level data. Measures of central tendency for the interval/ratio variables were analyzed.

In order to evaluate for differences between the control group and the intervention group for demographics (gender, ethnicity, and religious affiliation), a Pearson's chi-square test or was used. Because this data set was comprised of a small sample, the assumptions of the chi-square test were violated. Therefore, Fischer's exact test was interpreted. The differences in age (measured in years), and number of vaccines administered among the two groups were evaluated with a Levene's Test for Equality of Variances. In order for the data analysis to make clinical sense and to control for the pre-score confounder, the "during" FLACC score was compared to the "before" FLACC score for each participant, and a "difference score" was calculated. This measure then became the outcome variable that was analyzed. The difference score was examined to assess assumptions for parametric testing. The data violated the assumptions of normality (Kurtosis -1.322, Shapiro Wilk .192), so nonparametric analyses were pursued. The Mann-Whitney U Test was used to evaluate for a significant relationship between the difference FLACC score and the independent variables (distraction/comfort intervention). Statistical significance was established as $p < .05$. A significance level of .10 may also be appropriate as this is a very low risk study. However, to demonstrate rigor in this instance and present more applicable data, .05 was chosen.

The final sample of 16 eligible pediatric patients presenting for vaccination (11 in the control group, 5 in the intervention group), had a mean age of 2.5 years (SD 2.13), with a median

age of 2.00 years, and a mode of 1.00 years. The majority of the subjects were male (62.5%, n=10), Caucasian (93.8%, n=10), and parents/caregivers reported their religious affiliation to be unknown or unspecified (81.3%, n=13), while the remaining three participants were Christian, Evangelical, or Mennonite. Participants received a mean of 2.1 (SD .72) vaccines, with a median of 2.00, and a mode of 2.00 vaccines per encounter. The maximum number vaccines received by any participant was 3.00. There were no statically significant differences in the control or intervention group for age [*t(14) = .705, p* = .492.), gender [$\chi^2(1) = .95$, *p* = .588], ethnicity [$\chi^2(1) = .485$, *p* = 1.000], religious affiliation [$\chi^2(1) = .2.156$, *p* = .214], or number of shots received per encounter [*t* (14) = 1.241, *p* = .235] (Appendix N).

Overall, there was a decrease in the mean FLACC pain scores when the control group was compared to the intervention group (*M* = 5.36, *SD* = 3.50 vs *M* = 3.80, *SD* = 3.1) when the difference score was evaluated. Evaluation of the outcome measure demonstrated no statistically significant difference among the difference FLACC scores between the intervention and control groups (*U = 21.50, Z= -.685, p* = .49). In regards to clinical significance of the results, effect size was calculated using Cohen's *d* and found to be small (*d= 0.19),* indicating little application to individual patients (Kim & Mallory, 2017).

Discussion

The purpose of this QI project was to evaluate the impact of distraction techniques and comfort positioning on pediatric pain experienced during routine vaccination. In order to obtain data for comparison, all children who presented to the office for immunization three weeks prior to implementation of the intervention were observed and had FLACC scores recorded throughout the process. Moving forward, all clinical staff at the practice received education regarding the proper use of distraction and comfort positioning we well as the benefits of using such

interventions. During project implementation, each child receiving an immunization was offered a comfort position and distraction object once agreed upon by the parent/guardian.

The data suggested that immunization is a procedure that can cause pain among pediatric patients, and the introduction of distraction tools and comfort positioning may help to reduce the overall pain experienced. The patients who received the intervention did not show statistically significant decreases in pain scores, but a decrease in mean FLACC scores among the intervention group represents a positive impact of the interventions and suggests a potential benefit when compared to usual care. As mentioned in the literature review, a recent article by Cwynar and Osborne (2019) published in the Journal of Pediatric Health Care showed similar results as it sought to decrease the impact of the number one cause of pain in pediatric settings: immunization. The project, implemented in a pediatric primary care clinic, found that non-pharmacological pain prevention interventions, including distraction and comfort positioning, decreased mean pain scores during immunization 4.7 points on the FLACC scale for children ages 2 months to 7 years (Cwynar & Osborne, 2019). Cwynar & Osborne's (2019) data also had a small sample size of 29 participants.

One anecdotally identified strength of this project was that staff felt that the intervention was easily incorporated into their workflow and made a positive impact on the care that the patient and family experienced while in the clinic. Though the research evidence quality related to comfort positioning and distraction is low, the opportunity to reduce distress and improve long-term outcomes among pediatric patients should not be undermined (Birnie et al., 2018). This intervention takes little time or effort to implement, is cost-effective, supported by parents and staff, and provides increased comfort during a very common pediatric procedure. Therefore, its implementation into practice should be further considered.

Though the outcome measure for this project was not statically significant, and there was a small effect size, the initial results suggest that this intervention could be effective in the ambulatory care setting. An additional pilot project is recommended. To aid with planning for a future QI project, a power analysis was completed to determine the sample size required for adequate power. The calculated required sample size would be 79 participants per group (N=158) for a power of 80% and an alpha 0.05. To account for attrition, an additional 10% should be added, requiring a total sample of N=174.

By their nature, QI projects often aim to systematically translate evidence-based data into a local setting in order to advance care more quickly. Because of the single-site nature of this project, it may be difficult to generalize the results to broader patient populations or settings. Recommendations for future implementation include multiple study sites, or a non-rural setting that would evaluate a larger variety of children from different ethnic and religious backgrounds.

Due to DNP course layout, this project took place between the months of January and May. Delayed due to prolonged time for IRB approval, implementation of study interventions was unable to begin until early March. This timeline likely led to a decrease in the number of available study subjects as the clinic sees a rise in vaccinations at the beginning of flu season and just prior to school starting. Future research may focus on gathering data during August-January in order to overlap with peak immunization times.

In order to address potential observer bias, both providers at the project site were added to the study team and approved to collect data alongside of the DNP student. Unfortunately, due to the presence of COVID-19, the organization made the decision to limit clinic time to essential personnel only. Additionally, the clinic cancelled or moved all well-child visits to a virtual format and vaccination was scheduled for a later date. This restricted the opportunity for data

collection and led to less participants than intended and ultimately a small sample size of 16 participants. The unprecedented nature of this worldwide pandemic was unanticipated and should not have an impact on future studies of this type. However, it is important to note that the limited number of participants increased the risk for a Type II error, which may have contributed to the non-statically significant results.

Because of the defined age range for this project, the review of the literature investigated breastfeeding as a beneficial comfort position. A Cochrane Review concluded that breastfeeding may help to reduce behavioral responses to pain during vaccination for infants up to 12 months of age (Harrison et al., 2016). None of the 16 participants in this study were breastfeeding infants but this should be considered for use in future research.

This project was widely supported by clinical site management and staff as they were eager to provide improved care to their pediatric patients. The ease of project implementation and limited interruption to daily workflow provided more motivation to apply the evidence-based interventions. Parents, guardians, and participants were receptive to the changes, and anecdotally appreciated the efforts being made to improve the patient experience and decrease trauma associated with painful, but necessary procedures. After the initiation of interventions, the site manager expressed interest in making these changes a standard of practice at her three other sites as well. Overall, these small changes may potentially improve patient experience and, when applied in a broader perspective, improve long-term outcomes.

Conclusion

Comfort positioning and distraction techniques are well supported by the literature, and provide many potential benefits to our smallest patients. However, the application to these interventions in the outpatient setting are limited and there is further need for translation of the

delivery of these evidence-based interventions into clinical context. The interventions in this project demonstrated promising clinical application that would be substantiated by an additional pilot project with a larger sample size.

From a provider perspective, the American Association of Nurse Practitioners (n.d.) describe NPs as being in a unique leadership role to assist in the coordination of patient care for optimal outcomes. Likewise, it has been estimated that the United States would save an estimated $67 billion every year if everyone saw a primary care provider for his or her first visit (Primary Care Progress [PCP], 2019). The barriers surrounding preventative care can be overwhelming to providers, but there are small changes that can easily be enacted in every office, which may ultimately lead to improved outcomes and decreased disease. It is the hope that through this project, reducing perceived pain during vaccination will also reduce anxiety associated with future medical visits, and in turn, lead to increased preventative compliance in the years to come offering increased job security and healthier communities for primary providers.

Negative psychological experiences during routine childhood vaccination have implications that linger throughout the lifespan. The management of procedural distress through evidence-based distraction and comfort positioning is simple, cost-effective, and can provide both short and long-term benefits. Active participation and advocacy by the advanced practice provider can help to encourage the use of these small changes that can be easily integrated into the daily workflow and are widely accepted by parents and children. This population health focused initiative uses an interdisciplinary approach to influence practice change and achieve positive health outcomes potentially impacting young patients now, and for many years to come.

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Appendix A

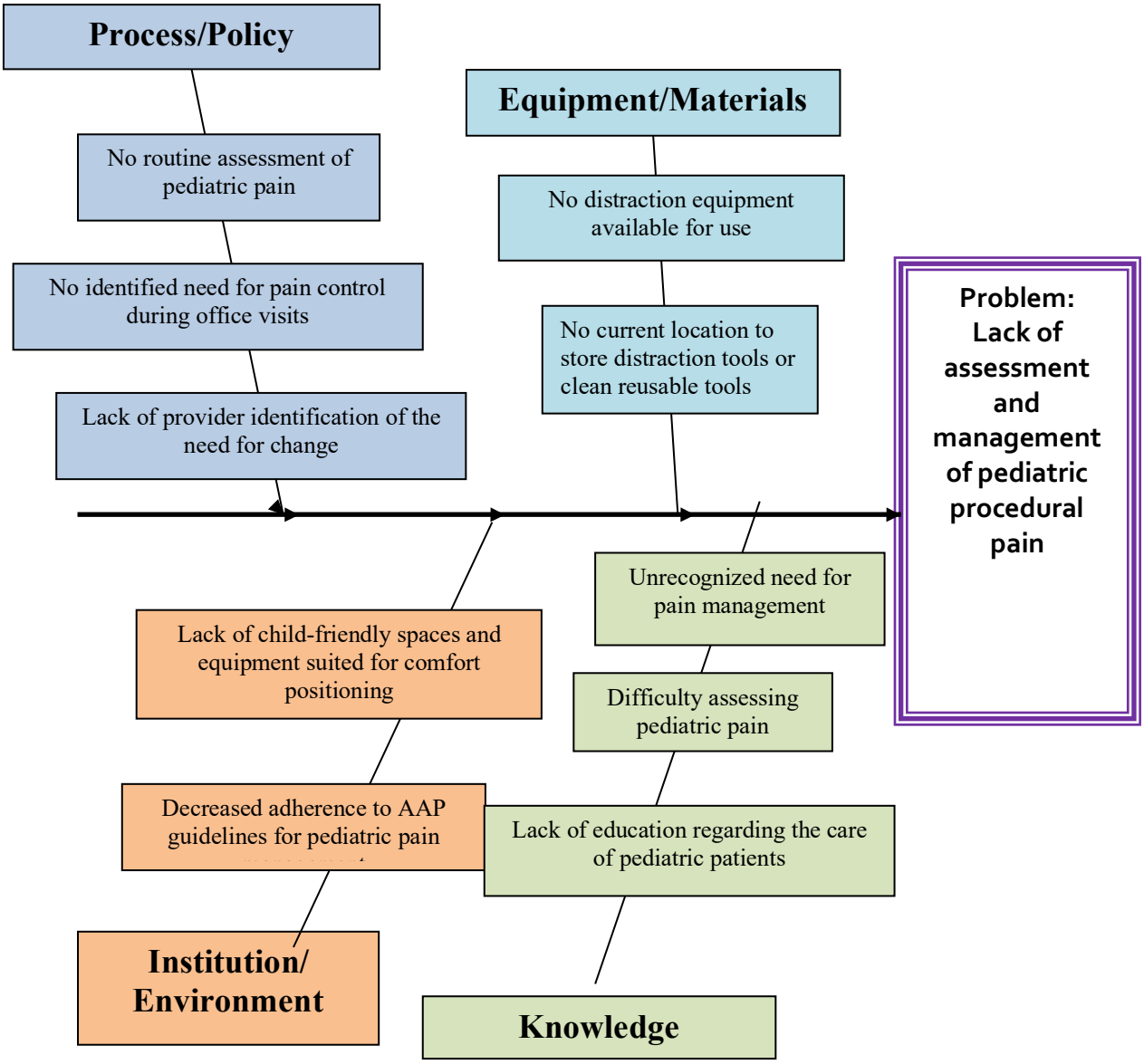
SWOT Analysis

INTERNAL FACTORS	
STRENGTHS (+)	**WEAKNESSES (-)**
-Staff already has experience caring for pediatric patients within the age range specified in PICO question -The staff has already established a positive relationship with many patients that will participate -Currently, there are no interventions in place prior to procedures. This intervention would be a new and innovative -Only two providers in the practice- patients will likely see someone that they already know and are familiar with as opposed to larger practices where there may be numerous providers	-Staff requires education about proper word choice, comfort positioning, and further interventions to reduce procedural anxiety -Tangible asset needs- supplies for distraction -Gaps in educational level among providers- will be working with medical assistants, nurse practitioners, and physicians -Location is not a pediatric practice but it a family practice so does see a large number of pediatric patients

EXTERNAL FACTORS	
OPPORTUNITIES (+)	**THREATS (-)**
-Practice is relatively new and expanding rapidly- new processes like this may help further improve reputation and acquire more patients -Specific practice is part of a network, success at this practice could allow for interventions to be implemented at other practice sites. -Will enhance overall provider education and promote improved patient well-being	-Parents may not be willing to engage in comfort positioning or other efforts to decreased patient anxiety -Parental anxiety is not accounted for -Previous negative experiences may affect the child's ability to properly receive and cope with interventions -Staff turnover may not allow for equal training for all staff

Appendix B

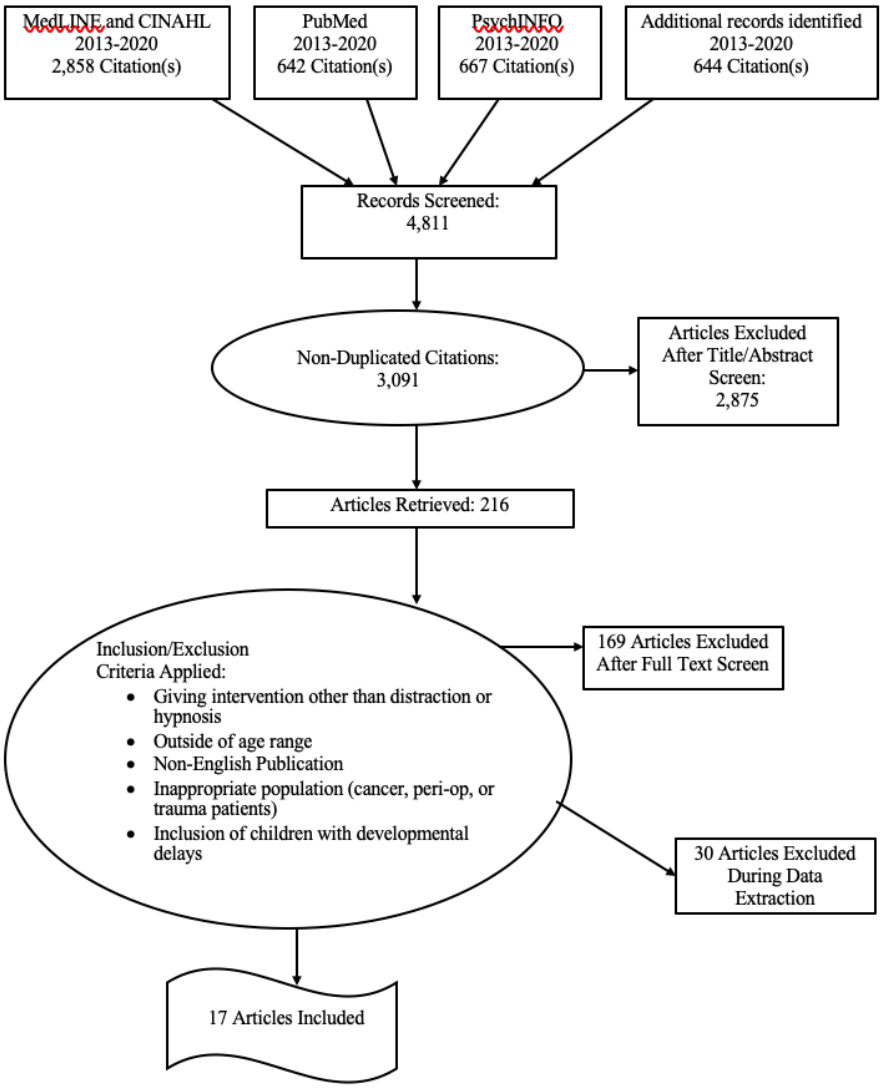
Root Cause Analysis



Appendix C

PRISMA Table

There were five electronic databases searched for relevant studies: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, PubMed, Google Scholar, and PsychINFO. All reference lists were also manually searched for additional articles. The search terms used for this review included MeSH terms such as pediatric, needle-related pain, procedural pain and distress, pain reduction, FLACC pain scale, distraction, comfort positioning, and breastfeeding. This diagram demonstrates identification, screening, eligibility, and inclusion process:



Appendix D

Literature Review Evidence Matrix Table

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
1	Ballard et al. *Pain Management Nursing* 2017	Quasi experimental (Pre-experimental pilot) in which there was manipulation of an independent variable but no control group and no randomization. Purpose: "Assess the feasibility, usefulness, and acceptability of distraction kits, tailored to age, for procedural pain management of young children visiting the ED and requiring a needle related procedure" (Ballard et al., 2017, p. 419)	Sample type & Size: n=50, convenience sample of children ranging from 3 months to 5 years old, visiting the emergency department, requiring a needle-related procedure. Setting: The Emergency Department of a pediatric tertiary university health center in Quebec.	Bubble blowing was found to be the most useful distraction toy by both parents and nurses. 100% of parents reported that they would use the distraction kit again for future painful procedures. 70.5% of nurses agreed that the use of distraction kits were an intervention that should be developed, and 65.9% reported that such kits were easy to use. Procedural pain scores (measured using the FLACC score) significantly increased from pre- procedure to peri-procedure. They did however decrease	Generalizability- this study only evaluated patients in the emergency department setting; a place that can be highly anxiety provoking for parents as well as patients. Likewise, the demographics for the sample were not discussed so it is difficult to determine if this sample was representative of the population in question. The study design was the biggest weakness present. The lack of a control group in this study made it difficult to make conclusions about the effect of distraction kits on	II	B The researchers recognized this as a pilot study, the reasoning for determining this type of study, and the limitations that were associated. They made conclusions only based on the information gathered, and introduced some great ideas for future research. Their literature review was one of the only up to date reviews with most articles being published within 5 years. There were some concerns for generalizability as well as a weak study design with no control group.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				from peri- procedure to post procedure.	lowering pain scores following painful procedures. However, the researchers recognized this limitation and made several good suggestions for future research. The researchers used the pre-experimental design because they could not identify a comparator to the distraction kits and were simply seeking to examine their usefulness and feasibility rather than their efficacy. Threat to testing- the toys in the kits were administered by the parents of the children rather than a trained professional, such as a nurse or child life specialist, introducing some potential variability as to the administration of		

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					the intervention and potentially introducing a confounding variable.		
2	Birnie, Noel, Chambers, Uman, Parker *Cochrane Database of Systematic Reviews* 2018	Systematic Review with meta-analysis (included only peer-reviewed published randomized controlled trials) Purpose: Provide an update to the 2006, and 2013 Cochrane Reviews; "assessing the efficacy of psychological interventions for needle-related procedural pain and distress in children and adolescents" (Birnie et al., 2018, para 2).	Sample type & Size: n= 59 trials evaluating 5,550 participants in total. All trials included had at least five participants per study arm, and compared psychological interventions with a control group. All trials included evaluated children aged two-19 years undergoing needle related procedures Setting: various settings where needle-related procedures took place	The most commonly used psychological intervention was distraction including a variety of methods such as distraction cards, TV, blowing bubble, puppet shows, stress balls, and music. Newer literature also introduced the use of combined cognitive behavioral therapy and hypnosis. Almost all trials introduced risk of bias and there were study limitations often including inconsistency, self-reporting, and imprecision. The quality of overall evidence and completed trials in this area of study remains low. This underscores	Because of the quality of evidence reviewed, many of the interventions could not have complete meta-analysis with all six primary pain and distress outcomes. There were also 24 studies excluded because they did not provide enough data within their published reports or through attempts for further correspondence. The exclusion of trials that have not yet been published may introduce some bias. Assessments of reported pain or distress at various times were	I	A This review was the most up-to-date, and represents the largest, most-rigorous review of this topic to date. It provides consistent and generalizable results from a large number of studies selected from a comprehensive, reproducible literature review

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				the need for improved trial reporting and study rigor. Even though the quality of most studies are low, there are enough potential benefits to reducing pain and distress to support the evidence in favor of using such interventions in the clinical practice setting. Recognizes that much of the evidence in this area speaks more to experienced/observed pain intensity and less to procedural related distress. Most clinical practice guidelines promote a multimodal approach to pain reduction and recommend the use of pharmacological, physiological, procedural, and psychological strategies.	combined, and there was some pooling of studies with variability in the types of distractors, study participant age, and healthcare setting- these factors potentially introduced some bias and variability in the outcome assessments.		

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				In future studies, it may be difficult for randomized controlled trials using psychological interventions to reach the highest quality of evidence because there are challenges related to the blinding of study participants and providers. However, quality of evidence can potentially be improved with better study designs and implementation.			
3	Birnie et al. *Journal of Pediatric Psychology* 2014	Systematic Review and Meta-Analysis (all studies included were randomized controlled trials) Purpose: "In-depth examination of the evidence for distraction and hypnosis as psychological interventions for needle-related procedural pain and distress in children and adolescents"	Sample type, Size & Setting: n=32 studies included in the meta-analysis. Inclusion criteria: -Randomized controlled trials with 5 participants per group (at minimum) -Children ages 2-19 receiving needle-related procedures -Published in peer-reviewed journal -One arm studied a psychological intervention while	A variety of pain scales were used in the studies included. These included self-report scales (visual analogue, numeric caring, FACES), observer report (self-reports measures above completed by a parent or provider), and behavioral rating scales (FLACC) completed by trained health professionals. 26 of the 37 articles that examined the	There were 12 studies excluded because the data provided was insufficient for the meta-analysis, potentially introducing a source of potential bias. This article also presented several subgroup analyses which are only observational, not based on randomized comparisons, and	I	A Though there are some limitations to this study, the results were consistent and generalizable. The literature search was clearly reported and reproducible with quality identification of studies to be included and excluded. As with Taddio, Birnie is also referenced throughout the

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		(Birnie et al., 2014, p. 785).	the other arm was a control -Assessed pain and/or distress using measurements that were valid and reliable Exclusion Criteria: -Quasi-experimental projects that lacked randomization -Inclusion of children with known needle phobias -Studies involving surgical procedures -Unavailable information needed for meta-analysis	effects of distraction on needle-related pain provided the necessary data to be included in a Meta-analysis. In regards to pain intensity, there was a significant effect of distraction on *self-reported* pain ((SMD = −0.44 [−0.67, −0.21], Z = 3.72, p < .01, I^2 = 86%) but not on observer reported pain. For distress, there was also a significant effect of distraction on self-reported scores (SMD = −0.63 [−1.09, −0.17], Z = 2.70, p < .01, I^2 = 66%) but not observer reported scores. There was a significant effect of distraction on the behavioral measures of distress (SMD = −0.32 [−0.63, −0.02], Z = 2.06, p < .05, I^2 = 71%) according to the meta-analysis.	should only be viewed as tentative. Variability in outcome measures: the meta-analytic approach increases validity but using multiple studies can result in increased variability. Researcher bias: In order to conduct the subanalyses, the interventions were placed in different categories based on the distraction method and the mean age of the sample. This allowed for maximum inclusion of the studies but causes the misclassification of a portion of the study subjects.		literature regarding this phenomenon and puts forth quality work.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				Distraction has been highly used and wifely investigated for a variety of painful procedures, across many different health care settings. Because of the variety of distraction subtypes, further research is recommended to compare the efficacy of different techniques with the assessment of the degree of child engagement necessary to reach efficacy in pain relief. There are concerns surrounding the quality of evidence supporting distraction for the reduction of needle-related pain as most evidence was of very low or low quality and the researchers indicated that further research in this area was warranted.			

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				Most evidence has been downgraded in its appraisal because of the lack of quality in the study design, small sample sizes, generally poor reporting methods, and high risk of bias.			
4	Boerner, Gillespie, McLaughlin, Kuttner, & Chambers *Clinical Practice in Pediatric Psychology* 2014	Literature Review Purpose: "To review the application of evidence-based psychological needle pain management in clinical situations, address practical issues that a pediatric psychologist may face in implementing interventions in various complex clinical service delivery settings, and briefly describe strategies when implementing such interventions in unique populations"	Sample type, & Size: Number of articles used in literature review not explicitly noted. Based on review of the references, the literature, various different settings were represented within a variety of studied.	Distraction has a strong evidence base and is a flexible strategy requiring little provider and patient education. The selection of a distraction tool used should take into consideration the developmental stage of the child as well as their preferences. There are a variety of healthcare providers that may be involved in procedures involving needles. "Increasing assess to evidence-based pain management starts with education" (Boerner et al., 2014, p.227)	Researcher bias- The authors did not discuss the process used to search the literature so there is little information about what types of articles were used, inclusion/exclusion criteria, and what method was used to appraise the literature.	V	A There were very few concerns with this review. The articles included were appropriate and applicable to a variety of different patient groups in a variety of settings. The literature reviewed was the most up to date and relevant in comparison to all other studies in this matrix. The researchers seem to be well-versed in what is known about the topic as well as the indications for future research.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		(Boerner et al., 2014, p. 225).		Pediatric psychologists can be used as a tool to educate staff about evidence-based pain management. This may also help decrease their number of referrals as many of them are the result of a challenging medical procedure which results in anxiety or behavioral changes. Increased research is needed in the following areas: -Decreasing barriers to the application of pain reduction strategies -Appropriate length of time needed to prepare children for painful procedures. -Degree of clinical expertise needed to adapt, such as evidence-based education			
5	Crellin, Harrison, Santamaria, Huque, & Babi	Non-Experimental comparative study	Sample type & Size: n= 100 previously video-recorded procedures taken	Demonstrated that the reliability of the FLACC scores was good, and the scale is	Generalizability: This again, was an international study,	III	B The sample size is mentioned to be sufficient though no

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
	The Journal of Pain 2018	Purpose: "Assess the psychometric performance of this (FLACC) scale used to assess several commonly performed procedures in the ED setting" (Crellin et al., 2018, p. 863.	from a convenience sample of children ages 6-42 months undergoing both painful and non-painful procedures Exclusion criteria: Children with cognitive delays, those who required immediate medical treatment, altered level of consciousness, significant comorbid disease, parent that did not speak English, or the video recording did now show the child adequately. Setting: Emergency Department of a tertiary pediatric hospital in Melbourne, Australia.	sensitive to procedural pain with 94.9% sensitivity. However, results only demonstrated 72.5% specificity. The researchers reported that the feasibility of scoring pain during such procedures was impaired by circumstances. The FLACC scale has the capacity to detect pain undergoing painful procedures and can differentiate between children undergoing painful vs. non-painful procedures. There remains some question about the capacity of this scale to distinguish between the distress behaviors caused by pain and those that are associated with other motions such as fear and anxiety that are commonly connected	using a younger age group. Cultural influences could limit the application to all populations. This was also a single-center study and may not have included a representative sample. Threat of testing: The researchers reported that it was not possible to determine an appropriate sample size because "the true variation in the population" was unknown (Crellin et al., 2018, p. 863 Internal threat (researcher bias): the 26 doctors and nurses that evaluated the videos were *recruited* into the study. Perhaps if this study had been completed in real-time, a more accurate assessment		statistical data is provided to support this statement. The results are consistent and the recommendations are based on a good literature review. There are some concerns for the study design and generalizability

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				with painful procedures. This is evidenced by the fact that infants and children did not consistently score a "0" during non-painful phases of procedures, or during non-painful procedures.	could have been completed. Threat to external validity (situational): FLACC scores for ALL procedures were not found to be normally distributed. Threat of testing: As with many of the other studies, the performance of measurement scales such as the FLACC scale is often contingent on different circumstances and populations which can cause variability in the outcome measures.		
6	Cwynar & Osborne *Journal of Pediatric Health Care* 2019	Quality Improvement Project Purpose: "to implement a	Sample Type & Setting: children ages 2 months-"adolescence" receiving routine immunization in a	For the children aged 2 months-7 years old, mean pain scores measured during vaccination decreased by 4.7, and the post-	Selection (threat to internal validity): Rather than excluding patients that were non-verbal or non-	V	B This was a good QI study. The implementation was based upon the best evidence, the tools

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		sustainable immunization-associated pain management program for pediatric patients at a primary care clinic located in the rural midwestern region of the United States" (Cwynar & Osborne, 2019, p. 448).	primary care clinic located in the rural Midwest. N= 52	immunization scored decreased by 2.68 (FLACC scale used). Interventions used were sorted into three categories including: pharmaceutical, psychological and physical. Physical interventions included the positioning of the child, breastfeeding, and pain prevention techniques chosen from a "comfort menu". Items such as bubbles, distraction cards, music, and books were included on this menu. Pre-implementation pain scores during vaccination for this age group were significantly higher than post implementation scores (p-value of .0000224). The older children (ages 7 and older) pain during immunization decreased by 1.76, and	English speaking, perceived pain scores were documented despite the fact that research offers conflicting results regarding the agreement between self-reported pain scores and perceived pain ratings. Potential sources bias: the majority of the pain scores were completed by a single evaluator. Likewise, blinding was not an option for this study because of its design. However, the researcher did attempt to decrease potential bias by using the NIPS, FLACC and visual analog scales which had been established as valid and reliable.		used were valid and reliable, data collection methods were clearly described and the results were consistent. However, the study only evaluated a single setting, and there is some concern for bias.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				by 1.94 after (visual analog scale used). Pre-implementation pain scores for this age group during immunization were also significantly higher than post implementation scores (p-value of .043). Anecdotal comments that were provided by the nursing staff during the project implementation period suggested that they were satisfied with the changes made to the vaccination practices.	Concern for small sample size which can potentially limit the reliability and transferability of the results. However, since this is a QI project, a power analysis is not required.		
7	Friedrichsdorf, Eull, Weidner, & Postier *Innovations in Pediatric Pain Research and Care* 2018	Quality Improvement Project Purpose: To implement a system-wide multi-layer process called, "Children's Comfort Promise" to reduce needle	Sample type & Size, Setting: The authors did not provide an exact "sample size" but all patients cared for at the Children's Hospitals and Clinics of Minnesota were engaged. Patient types included those seen in: inpatient	Interventions consisted of four approaches: numbing the skin, sucrose or breastfeeding, comfort positioning, and age-appropriate distraction such as bubbles, books, stress balls or electronic devices.	Instrumentation was a threat to internal validity- data was obtained from process audits with a variety of collection methods creating variability, and increased time to providing staff feedback.	V	A This was a well-designed implementation. The researchers recognized their own limitations and made an attempt to address them. The methods used for implementation were described

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		related pain, using Lean methodology	admissions, surgical cases, home visits, emergency department visits, and clinic visits. The authors did also estimate that about 200,000 children currently benefit from this quality improvement initiative.	During the implementation period, the percentage of staff offering the bundled service increased. Likewise, patient satisfaction with pain management was improved, the filing of safety learning reports (to measure adverse effects) decreased, and patient wait times decreased. Note: this was a quality-initiative and no statistical analysis of improvements was performed. Very few patients declined any of the strategies when offered as long as education was provided by the nursing staff. Families who reported that the, “Hospital staff did everything they could to help with pain” on patient satisfaction surveys	The nurses performed self-audits which can introduce some bias. However, the researchers attempted to verify such results with observations from core team members (these audit results were closely aligned).		adequately, process measures were stated clearly, and the results were interpreted appropriately.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				increased from 78.3% to 85.3%. Likewise, families who stated that their, "Child's pain was always well controlled" increased from 59.6% to 72.1%. Causation in these instances can't be assumed but the authors clarified that this was the only pain-directed initiative implemented during the time period reviewed. Some resistance to the new program was met but overcome by providing resources, support and training to the staff.			
8	Gomez, Barrowman, Elia, Manias, Royle, and Harrison *Pain Research & Management* 2013	Correlational study evaluating intra and inter-rater agreement of FLACC scores utilizing video files from a larger randomized controlled trial of sucrose use with a placebo in toddlers	Sample type & Size: 29 video recordings of toddlers between 12 and 18 months of age receiving 1-4 injections Setting: The overarching RCT took place at the Immunization Service Drop-in	The FLACC scale demonstrated acceptable intra and inter-rater agreement to be used with toddlers receiving immunization. The highest agreement was found to occur when high FLACC scores were present, seemingly at the time	The majority of literature cited in this study were not published within 5 years. In fact, only 7/32 articles were current. Though the sample size was sufficient to reject the hypothesis that the	III	B The results gathered are consistent and acceptable for the recommendation given. There are some concerns that a larger sample size may be more proficient and provide improved confident.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		receiving immunization Purpose: "The objective of this study was to establish interrater and intra-rater agreement of the FLACC scale for measuring pain during immunization in toddlers 12 to 18 months of age" (Gomez et al., 2013, p.125).	Center at the Royal Children's Hospital, video footage was evaluated at the Children's Hospital of Eastern Ontario Research Institute	of needle insertion and injection. "Intrarater agreement coefficients were 0.88 at baseline, 0.97 at insertion of first needle, and 0.80 and 0.81 at 15 s and 30 s following the final injection, respectively. Inter-rater coefficients were 0.40 at baseline, 0.95 at insertion of first needle, and 0.81 and 0.78 at 15 s and 30 s following the final injection, respectively" (Gomez et al., 2013, p.124). Identified the FLACC scale as a reliable tool to be used as an, "outcome measure in future intervention studies of pain management during short-lasting acute procedural pain in toddlers" (Gomez et al., 2013, p. 128).	reliability is 0.4 if the population reliability was above 0.8, a larger sample size of 40 was needed to reject the hypothesis of reliability of 0.6. The authors report that the sample size used was sufficient for study purpose. Internal threat of testing- there were some cases in which not all five of the FLACC items were able to be evaluated so the mean value of the other items were imputed instead of eliminating that specific case. Threat of researcher bias- before the video recordings were viewed, raters received training which was conducted by the studies principle investigator (PI).		Though the literature review was out of date, the information seemed to come from applicable, peer reviewed sources. This study identified the FLACC score as a reliable tool for use- which played an important role in the selection for utilizing this scale in the PICO question.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					During this training, the PI showed example videos and subsequently discussed his interpretation of scoring techniques. Concern for generalizability- because this study was not performed in the United States, there are some generalizability concerns surrounding differences in vaccination administration techniques and cultural influences.		
9	Harrison et al. *Cochrane Database of Systematic Reviews* 2016	Systematic review with meta-analysis of RCT's and quasi-RCT's Purpose: "To determine the effect of breastfeeding on procedural pain in infants beyond the neonatal period up to one year of age compared to no	Sample type: infants aged 28 days post-natal to 12 months and receiving breastfeeding while undergoing a painful procedure (vaccination) (convenience sample) N= 10 studies with 1,066 infants	Found that breastfeeding did reduce the infants behavioral pain response (as measured through cry time and pain scores) during vaccination when compared to alternate methods of pain control. Specifically, breastfeeding decreased cry time by	Risk for bias: Overall, breastfeeding is an intervention that cannot be blinded. Nine of the 10 studies that were included were considered to be at high risk for bias because they had fewer than 50	I	A This study was comprehensive, the methods were reproducible, the literature was clearly critiqued and those methods were published in the review, risk for bias was thoroughly evaluated and

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		intervention, placebo, parental holding, skin-to-skin contact, expressed breast milk, formula milk, bottle feeding, sweet-tasting solutions, distraction, or other interventions" (Harrison et al., 2016, p.6).	Setting: various settings where needle-related procedures took place	38 seconds when compared to infants that were provided no intervention, and pain scores decreased by 1.7 points (*moderate quality of evidence per GRADE critique)*. It was also noted that breastfeeding did not consistently decrease physiological indicators of pain such as heart rate (*low quality evidence per GRADE critique)* None of the included studies reported any adverse advents associated with breastfeeding during vaccination.	infants enrolled in each study arm. One of the studies included used the Wong-Baker FACES scale (as self-report scale) that was reported by nursing staff. Likewise, this tool is not validated for the specified age group, introducing a high risk for bias. Other studies measured cry duration or used validated pain scales such as NIPS, NFCS, MFCS, or MBPS. However, none of these studies used FLACC. Concern for generalizability: The majority of the studies (8/10) included evaluated infants that were between 1 month and 6 months. There was limited data to		documented, and the results were mostly generalizable and based on the data gathered.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					evaluate the 6-12 month age range. Additional research to include this age range may impact the confidence of the researchers in the estimate of effect.		
10	Matziou, Chrysostomou, Vlahioti, & Perdikaris *British Journal of Nursing* 2013	Randomized Controlled Trial (two experimental groups and a control group) Purpose: "To investigate the effect of parental presence and distraction in children who are having a painful procedure" (Matziou et al., 2013, para 5).	Sample type, Size, & Setting: n=130 Children aged 7-10 years who were admitted to the pediatric clinics at a Children's Hospital in Athens, Greece and required venipuncture for their diagnosis/treatment. Exclusion criteria: No cancer or chronic illnesses no previous experiences with venipuncture other than vaccination.	The scores on the pain scales were the lowest in the parental presence group (2.00), followed by the toy group (3.09), and the control group (5.53) with a $p<0.001$). Multiple linear regression showed significant negative correlation within the intervention groups as compared to the control group -Children with parental presence had reduced breaths per minute, decreased blood pressures, and decreased heart rate. -The same occurred for children who used a kaleido-scope when	The study mentions that the sample size was calculated by a statistician but none of the statistics are provided within the article. It is unknown if a proper power analysis was completed. Threat to internal validity (Instrumentation): A verbal pain rating scale was used and the children rated their pain 0-10, as well as the State-Trait Anxiety Inventory for Children was used but there was no discussion of the validity or	I	B The results for this study were statistically significant and demonstrated correlations that were used to make practice recommendations. There was adequate control demonstrated with demographically similar intervention and control groups. There is some concern for the sample size as a power analysis was not demonstrated, and the literature review for this article, like many of its kind, was outdated. Likewise,

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				compared to those in the control group. -The intensity of the pain that the child perceived was lower in both intervention groups -Negative correlation found between the age, as well as the anxiety score and the pain that the child reported ($p<0.001$).	reliability of these tools. The use of vital sign measurements was also included to evaluate distress. However, these physiological parameters can be affected by other variables such as fever- potential introduction of confounding variable.		the validity and reliability of the tools used was not discussed.
11	Risaw, Narang, Thakur, Ghai, Kaur, Bharti *Indian Journal of Pediatrics* 2017	Randomized Controlled Trial (intervention group received distraction with Flippits and control group received standard care) Purpose: "To investigate the efficacy of flippits/distractions cards in ebbing pain related to venous blood letting among children aged 4-6	Sample type & Size: n=210; children enrolled were ages 4-6 years. Exclusion criteria included those with visual and auditory impairment, disability and cognitive impairment. Setting: "sampling room" at the Advanced Pediatric Center outpatient department in India	The children in the intervention group had statistically significant lower mean pain scores than the control group when both the FLACC and Wong-Baker pain scales were used. There was a statically significant difference in children's behavioral response to pain between the two groups ($p<.0001$).	The literature review for this article only included 4/13 articles published within the 5 previous years. Threat of testing: Within the intervention group, the participants were given the choice (22 options) of a variety of Flippits introducing potential variability	I	B This study had a properly calculated, sufficient sample size with proper demographic evaluation of the intervention and control groups for generalizability. The literature review was lacking, and there were some study flaws making this only of good quality.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		years of age" (Risaw et al.., 2017, p. 597).		Agreement between the two assessment scales was found: -Spearman Coefficient, r=0.80 was noted between the *parents* report of the Wong-Baker scale and the FLACC scale -r=0.78 between the *patient* report of the Wong-Baker scale and the FLACC scale. -The Interclass Correlation Coefficient between parent and child reporting was 0.93 with a confidence interval of 0.91-0.95 with a $p < 0.001$. The calculated odds ratio between the groups demonstrated that the odds of severe pain (a score of 7-10 on the scales) was 2.5 times higher in the control group with 95% confidence. FLACC scale demonstrated high reliability (Cronbach	within the outcome measures. Threat to external validity (experimenter effects): the patients and parents completed the Wong-Baker scale but per the article, the "researcher" scored the pain objectively using the FLACC score. There is no discussion of how many researchers were used, or the training they received. This could be a potential area for bias or variability. Study design: as with many randomized controlled trials on this topic, there was a lack of blinding which could introduce some researcher bias.		

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				alpha 0.85) and validity.			
12	Schurman et al. *World Journal of Clinical Pediatrics* 2017	Quality Improvement Purpose: "To increase, in a sustainable way, the use of pain prevention techniques for children vaccinated in our ambulatory primary care clinic to greater than 80% and thus close the observed practice gap" (Schurman et al., 2017, p. 82. The focus was not to evaluate the effectiveness of interventions, but to focus on the changes in provider behavior thus reflecting the uptake of pain prevention strategies.	Sample type & Size: n= 101; convenience sample of patients aged 0-5 years over a 4-week period. Setting: Pediatric care clinic at a large academic medical center, in an urban setting. The team of providers at this practice included 41 physicians, 18 nurse practitioners, and 45 nurses who conduct about 45,000 patient visits each year.	Nursing self-report suggested that 99% of patient visits were offered one or more evidence-based pain prevention interventions. The most commonly used strategies were comfort positioning and distraction which were offered 57% and 54% of the time. Parents/caregivers reported greater agreement during the post-intervention phase that their child's pain was eased, they were satisfied with the technique used, and they were willing to use the same intervention again during future visits. Time was reported as the most common barrier to the use of pain-prevention	Instrumentation could have been a threat to internal validity as self-report prevented the analysis of pre- and post-changes in the rate of interventions being offered- the researchers recognized this threat and did have some informal observations take place during clinic-visits post-intervention. There was no discordance detected. Likewise, the primary outcome measure was rated using a subset of 3 items from the Pain Treatment Satisfaction Scale. Validity and reliability of this tool was not discussed by the researchers, and manipulation of the	V	B This was a well-designed QI study. There are generalizability concerns, recommendations made in the discussion were not always consistent with the findings, and there were several potential threats to internal validity. It is helpful to know that comfort positioning and distraction are strategies that are widely accepted and offered by providers.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				strategies amongst staff. Area for improvement- 7% of families offered comfort positioning declined suggesting an need for further assessment of this intervention and its implementation.	scale (using only a few items) could introduce increased threat. Though providers reported that time was their most common, the researchers stated, "Nurses do not possess the skills and knowledge to incorporate these practices effectively in their daily patient care" (Schurman, et al., 2017, p. 87). There was little to no mention of lack of skills or knowledge among nursing staff, so this conclusion does not seem consistent with the findings, suggesting a potential researcher bias. The researchers also identified this practice as one, "That did not understand or		

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					promote evidence-based pain prevention" (Schurman et al., 2017, p. 82). Again, this seems like an assumption. Informal pre-intervention observation suggested that nurses were not delivering consistent interventions but mentions nothing of their knowledge of such interventions. There are some concerns for the generalizability of this project because of the urban setting and patient population of mostly underserved, uninsured patients. Only 6/17 of the articles included in the literature review were published within 5 years of the quality		

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					improvement project.		
13	Stevens & Marvicsin *Pediatric Nursing* 2016	Literature Review: Including guidelines, reviews, meta-analyses, and RCT's Purpose: "Summarizing evidence –based findings according to patient age-groups--- recommend behavioral strategies for use in the primary care setting during routine vaccinations, with a goal of decreasing patient distress before, during, and after administration" (Stevens & Marvicsin, 2016 p. 267).	Sample type & Size: 41 clinical guidelines reviews, and randomized controlled trials with study populations ranging from newborn to 18 years of age Setting: Not specifically mentioned however, the authors do state, "Articles were selected from vaccine-specific literature by relevance and practicality for primary care" (Stevens & Marvicsin, 2016, p. 267).	There are several interventions identified in the literature that may be helpful in reducing pain and anxiety associated with vaccinations. These include: the use of local anesthetics and sucrose, comfort positioning, and verbal scripting for staff. Frequent, consistent implementation of such recommendations is a challenge in primary care offices. Patient education material, in the form of a printed handout, may help to empower families to become more involved in these stressful events.	This study is only considered a literature review because it did not systematically appraise the evidence quality or strength of the studies reviewed. The majority of the literature used in the review were published within 7 years, rather than 5. Handouts were formulated based on research but no evidence was presented to evaluate their effectiveness when implemented (could be indication for future research). When speaking about the scripting used on the handouts, the authors do mention	V	A There are a few concerns with this study, as listed in the limitations section. The authors do provide clear aims and study objectives but are unable to provide a specific setting, making transferability within the primary care setting a slight concern. However, primary care is an area in which patients receive vaccinations. Therefore, I do not believe this concern severely alters the quality of the study. The authors are able to make reasonable and consistent recommendations based on the literature reviewed, and the articles

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
					that they gleaned some recommendations from, "personal interactions with peer experts" (Stevens & Marvicsin, 2016, p. 273). This could cause some concern for researcher bias. The authors did not specify which settings were included in the literature review, and therefore could not specifically demonstrate consistent results across multiple settings.		cited are from peer reviewed journals.
14	Taddio et al. *Canadian Medical Association Journal* 2015	Clinical Practice Guideline published by an independent cross-Canada multidisciplinary team Purpose: The update the 2010 guideline for reducing pain during childhood vaccination	Sample type & Size, Setting: Not applicable for clinical practice guidelines It is important to note that the 18 members that formed the guideline panel practiced in a variety of clinical settings with a breadth of	This study identified several procedural, physical, pharmacologic, and process interventions. (However, many have low confidence in estimates of effect.) -Recommendation to not utilize aspiration during vaccine injections	The authors did not discuss the elimination of bias within these guidelines. It is difficult to know if there were any external influences (i.e. funding) that may have had an impact on the recommendations.	V	B- This was a good quality study. There are generalizable recommendations as the researchers applied the guidelines to all ages ranging from infant to adult in a variety of clinical settings. The recommendations,

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
			expertise, and studies were evaluated from several different clinical practice settings	-Inject the most painful vaccination last -Breastfeeding can be used during vaccination for children two years and younger -Holding be utilized for children three years and younger -Children aged three years and older should be sitting upright rather than supine during administration -Sucrose given to children two years and younger -Topical anesthetics be applied before injections for children younger than 12 years -Pain management education for clinicians, parents, and children three years or older	All of the recommendations provided were based on very-low or low confidence which makes it difficult to support the implementation of such recommendations The literature search utilized was not listed in a reproducible manner, and the reader is not informed of inclusion/exclusion criteria, making selection bias and internal as well as external validity a concern.		though they are not based on high confidence, are based on the literature and the authors did recognize the strength of the evidence that they were appraising. Though the authors did not provide a reproducible approach to the literature review, they did provide a clear summary of the approach to the guideline development.
15	Taddio et al. *Clinical Journal of Pain* 2015	Systematic Review (randomized and quasi-randomized controlled trials)	Sample type, Size & Setting: n=31 total studies (experimental and quasi-experimental)	There was some evidence which supported the following interventions:	The limitations of individual studies were recognized by the researcher and are cited in the	II	A This was a fantastic literature review, and Taddio's work seems to be well

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
		Purpose: "Update and expand the knowledge synthesis" on the effectiveness of different physician and procedural interventions in reducing pain and other related outcomes during vaccination (Taddio et al., 2015, p. 21.	included in the systematic review which studies individuals of all ages (including some trials with adults), undergoing vaccination in any setting	-No aspiration for IM injections -Injecting the post powerful vaccine last -Simultaneous, rather than sequential injections -IM injections into the vastus lateralis rather than deltoid -Multiple positioning interventions such as skin-to-skin holding -Non-nutritive sucking -Tactile stimulation (external vibrating devices or vapocoolant) -Caution should be taken when performing positioning techniques as this can lead to an increased fall risk Overall, the evidence base that exists for these interventions is scant, and the overall quality of such evidence is either low or very low. All included trials had a high risk of bias and	study findings. This literature review however, was fantastic with little to no flaws in its approach. The literature review was current and generalizable to many ages and areas of practice. It was quite difficult to find any limitations to this review that were within the control of the researchers.		respected and referenced in the literature on this phenomenon.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				uncertain internal validity, mostly because it is difficult to blind the person giving the immunization. Most studies also limited age ranges, making it unclear if the results are generalizable to other ages			
16	Thrane, Wanless, Cohen, & Danford *Journal of Pediatric Nursing* 2016	Literature review (evaluating a variety of research studies, informational articles, and review articles) Purpose: "bring a developmental lens to the challenges of assessing and treating pain in young children" (Thrane et al., 2016, p.24).	Sample type & Size: no applicable for literature reviews but the researchers included a total 54 articles Setting: various settings where needle-related procedures took place	Though self-report is used as the gold standard for pain evaluation of older children, when toddlers and preschoolers are being evaluated, it is helpful to include an observational assessment such as the FLACC score. Pain expression in infancy is a bidirectional process between the baby and the parent so treatment of this age group should include the parent's role in the	The researchers identify that this was not intended to be an exhaustive review, rather a narrative approach and only well-designed studies were included. This could introduce some bias. There was no formal quality rating of the studies or their designs. Threat to internal validity/ concern for generalizability (selection bias):	V	B The expertise appears to be credible, the literature search was easy to follow with a flow-diagram included, the recommendations were based on findings from the articles but there was some concern for lack of quality rating and appraisal of the articles included.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				management of the child's pain. Developmentally, toddlers also rely on their parents, so they should be incorporated into distraction methods. Under treatment and poor assessment of infant and child pain is still a challenge for both caregivers as well as healthcare providers. Use of different non-pharmacological methods to reduce pain have demonstrated effectiveness in infants and children, and can also serve to increase coping. "Educational awareness coupled with institutional changes resulting in system-wide cultural transformation could lead to a significant	only sources published in English were included Only 9/47 of the articles were published within 5 years of this review so the information may be out of date and irrelevant. The researchers did not speak to the gaps in the literature, but did include recommendations for future research.		

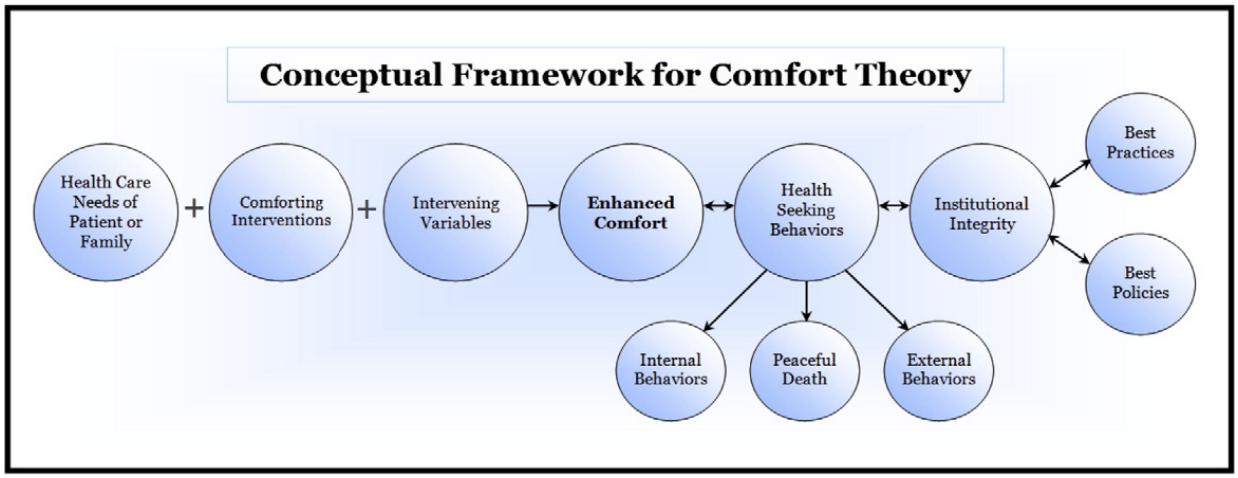
Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				reduction in childhood suffering from pain" (Thrane et al., 2016, p.29).			
17	Uman, Birnie, Noel, Parker, Chambers, McGrath, & Kisely *Cochrane Database of Systematic Reviews* 2013	Systematic Review with Meta-Analysis- Only RCT's which had at least 5 participants within each study arm were included in the review Purpose: "Assess the efficacy of psychological interventions for needle-related procedural pain and distress in children and adolescents" (Uman et al., 2013, p. 1).	Sample Type: Children and adolescents ages 2-19 years undergoing needle-related procedures N= 39 trials with 3,394 participants Setting: various settings where needle-related procedures took place	There is strong evidence to support the efficacy of distraction for reducing pain during needle sticks, and hypnosis to reduce pain as well as distress. These interventions also help to empower patients and parents as being active agents in their own pain management. Since the original review was published in 2006, there has been a decrease in the use of the classic, "no-treatment" approach, and an increase in the use of topical anesthetics as part of standard care. Presently, there is no evidence for the efficacy of different interventions such as	There were 21 studies excluded because the data provided was insufficient for the meta-analysis thus introducing a source of potential bias. Since the researchers wanted to limit the exclusion of trials, some studies that provided full data for only one outcome measure were included potentially posing an additional source of bias. The timing of pain and distress assessments varied across studies which produces concern for variability in the outcome assessments.	1	A This one was a tough one to critique. These reviews are so well done; it really served as a barometer for critiquing the other articles in this matrix. The limitations were few, and the researchers were aware of all of them. It is also important to note that many of these limitations were created when creating inclusion/exclusion criteria to formulate a quality meta-analysis. Adjustments for these limitations could have placed the reliability of the analysis at risk.

Article #	Author, Publication Source, & Date of Publication	Evidence Type and Purpose	Sample Type, Size, Setting	Study Findings	Limitations	Evidence Level	Quality Rating
				preparation, parental coaching and distraction or virtual reality. Further research: -Should compare different types of distractors and assess develop-mental appropriateness -There is overall limited evidence related to a variety of different psychological interventions and further studies will need to be completed to determine efficacy. There is a gap in their understanding of efficacy among different age ranges, as well as children with developmental differences.			This study was comprehensive, the methods were reproducible, the literature was clearly critiqued and those methods were published in the review, and the results were generalizable and based on the data gathered.

Appendix E

Kolcaba's Theory of Comfort

The use of this diagram, as well as the theory of comfort as it applies to this DNP Project implementation, has been granted permission by personal communication with Dr. Kolcaba.

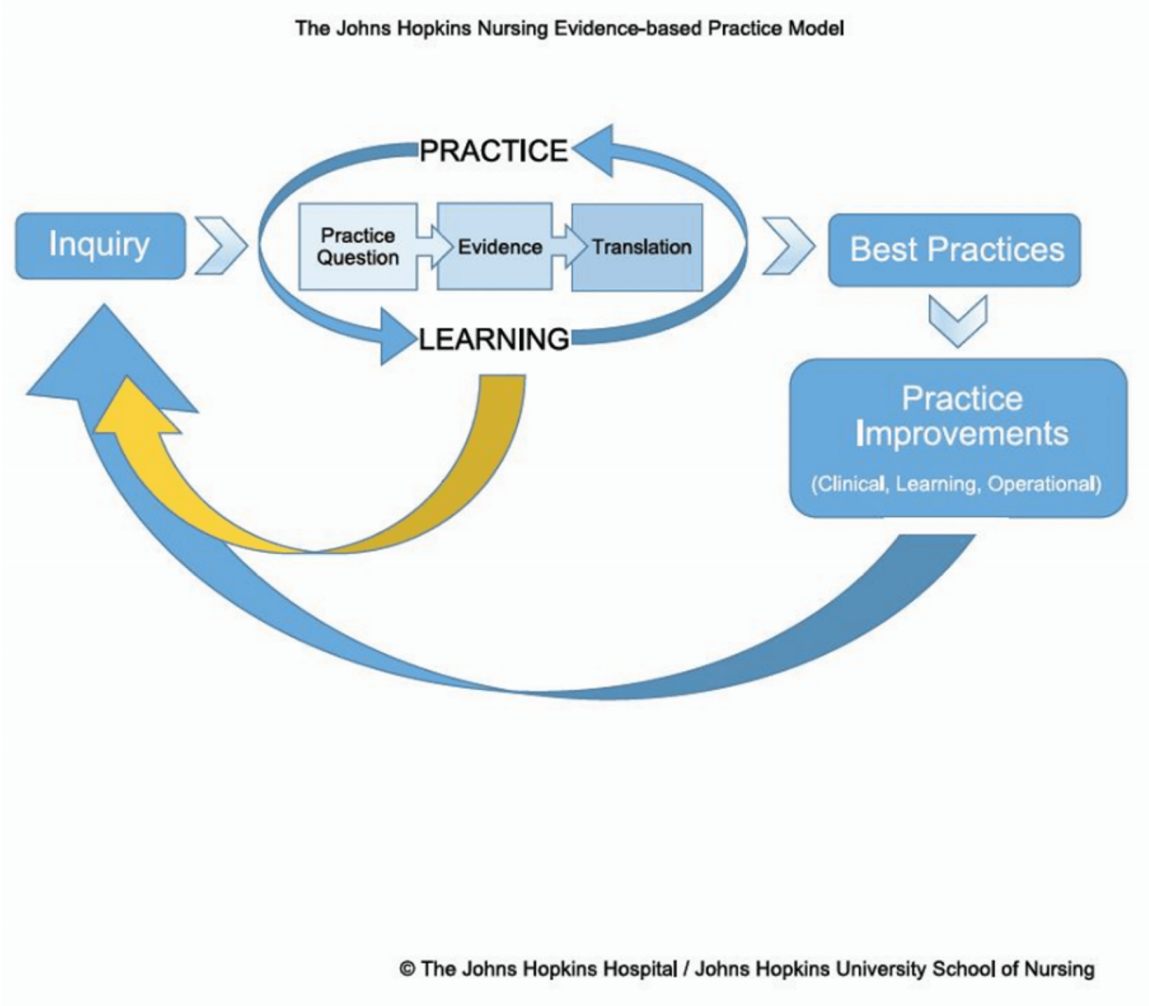


From "The Comfort Line", by K. Kolcaba, 2019, https://www.thecomfortline.com. Copyright [2019] by Kathy Kolcaba. Adapted with permission.

Appendix F

Johns Hopkins Nursing Evidence Based Practice Model

The use of this diagram, as well as the Johns Hopkins Nursing Evidence Based Practice Model as it applies to this DNP Project implementation, has been granted permission by personal communication with Johns Hopkins University.



From *Johns Hopkins nursing evidence-based practice: Model and guidelines* by D. Dang & D. Dearholt, 2017, Indinapolis, IN: Sigma Theta Tau International. Copyright [2017] by The Johns Hopkins University. Adapted with permission.

Appendix G

FLACC Tool

The FLACC tool was used to evaluate observer-reported pain scores one minute prior to immunization, during immunization, and after immunization, and was an integral part in data collection for this project.

FLACC scale (Face, Legs, Cry, Activity, Consolability scale)	Score
FACE 0- No particular expression or smile 1- Occasional grimace or frown, withdrawn, disinterested 2- Frequent to constant frown, quivering chin, clenched jaw	
LEGS 0- Normal position or relaxed 1- Uneasy, restless, tense 2- Kicking, or legs drawn up	
ACTIVITY 0- Lying quietly, normal position, moves easily 1- Squirming, shifting back and forth, tense 2- Arches, rigid, jerking	
CRY 0- No cry (awake or asleep) 1- Moans or whimpers; occasional complaint 2- Crying steadily, screams or sobs, frequent complaints	
CONSOLABILITY 0- Content, relaxed 1- Reassured by occasional touching, hugging, or being talked to; distractible 2- Difficult to console or comfort	
Total score (0-10)	

From "The FLACC: A behavorial scale for scoring postoperative pain in young children," by S. I. Merkel, T. Voepel-Lewis, J. R. Shavevitz, and S. Malviya, 1997, *Pediatric Nursing, 23,* p. 293-297. Copyright [2002] by The Regents of The University of Michigan. Reprinted with permission.

Appendix H

Educational Handout

Distraction and Comfort Positions to Reduce Pain During Vaccination

What is the project?

The purpose of this project is to determine if the use of distraction techniques and comfort positioning can help to decrease the pain and anxiety that children between the ages of 2 months and 7 years old feel during routine childhood vaccinations.

In this project, the person receiving vaccines will be placed in a comfort position, or provided a distraction tool (such as bubbles, or a book) to evaluate the usefulness of these interventions in reducing pain scores.

Overall, this project will seek to improve the quality of care provided to all patients. Approximately 300 children at this site will take a part in this research.

Distraction Tools

Distraction tools are chosen based on patient preference as well as age. Some of the tools that may be used include:

- Bubbles,
- I Spy (Seek and Find) bottle,
- A pinwheel
- A light globe
- Glitter wand,
- Stories about relaxation
- Mindful kids card deck
- A rainmaker

Comfort Positions

Comfort positioning may be used for younger children to help ease pain and anxiety, making them feel more secure in their parent's arms.

Principal Investigator: Kelly Snyder

Email: Kthomas9@pennstatehealth.psu.edu

Study ID: STUDY00013704

Appendix I

Summary Explanation of Research

SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine
Penn State Health

Title of Project: Implementation of Interventions to Reduce Pediatric Pain Associated with Vaccination: A Quality Improvement Initiative

Principal Investigator: Kelly Snyder

Address: Strausstown Family Practice
Attn: Kelly Snyder
44 East Ave.
Strausstown, PA 19559

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (610) 488-7080

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains key information about this research. You are urged to ask questions about anything that is unclear to you.

- The negative effects that result from anxiety related to vaccination procedures can be avoided through proper pain recognition and management. Interventions, such as distraction and comfort positioning, demonstrate potential benefits across a variety of settings. However, these interventions have not been well studied in the primary care setting. Overall, the purpose of this project is to introduce the use of age-appropriate comfort positioning and distraction techniques to help reduce the pain experienced by children receiving routine childhood vaccinations in the primary care office.

- During this study, the provider will choose a developmentally appropriate distraction tool (such as bubbles or a book) and/or a comfort position. There will be two medical assistants in the room while the child receives the vaccination. One medical assistant will give the shot, and the other will assist the parent or guardian with providing distraction. While this is happening, the provider will observe the process and record a standardized pain assessment score, called a FLACC score, one minute before, during, and one minute after the child receives their vaccination.

- You will only be asked to participate in this study during your time in the office today. Once the vaccination is completed, your participation in the study will be completed.

- You may choose not to take part in this research study.

- There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.
- The possible benefit to you from participating is that your child may experience reduced pain and anxiety associated with the vaccination procedure. This may also help to reduce anxiety associated with future office visits, or appointments with other medical providers. The results of this research may guide the future treatment of pediatric patients receiving vaccinations in other primary care offices
- There will not be any confidential information about the study subject maintained. The clinician will obtain some demographic information about the patient, and this information will be identified by a de-identified Subject I.D. number, rather than personal identifier.
- Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.
- There is no cost associated with participation in this study. This will not be reported to your insurance or billed as a part of your office visit today.
- The Principal Investigator does not identify any consultative or financial relationships the related to the research.
- This section is about your identifiable health information that will be collected for this research study as explained above.
    - We will use and disclose your information only as described in this summary and in the HMC privacy Notice.
    - If you do not want us to use your identifiable health information, you should not be in this research.
    - Your permission for the use and sharing of your identifiable health information will continue indefinitely.
    - You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form.
    - The PSU Institutional Review Board, the Human Subjects Protection Office and the Research Quality Assurance Office at HMC/PSU, the sponsor (if applicable), FDA (if applicable), and Office for Human Research Protections (if applicable) in the Department of Health and Human Services may need to read your medical and research records if they need to review this study as part of their duties.

- In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

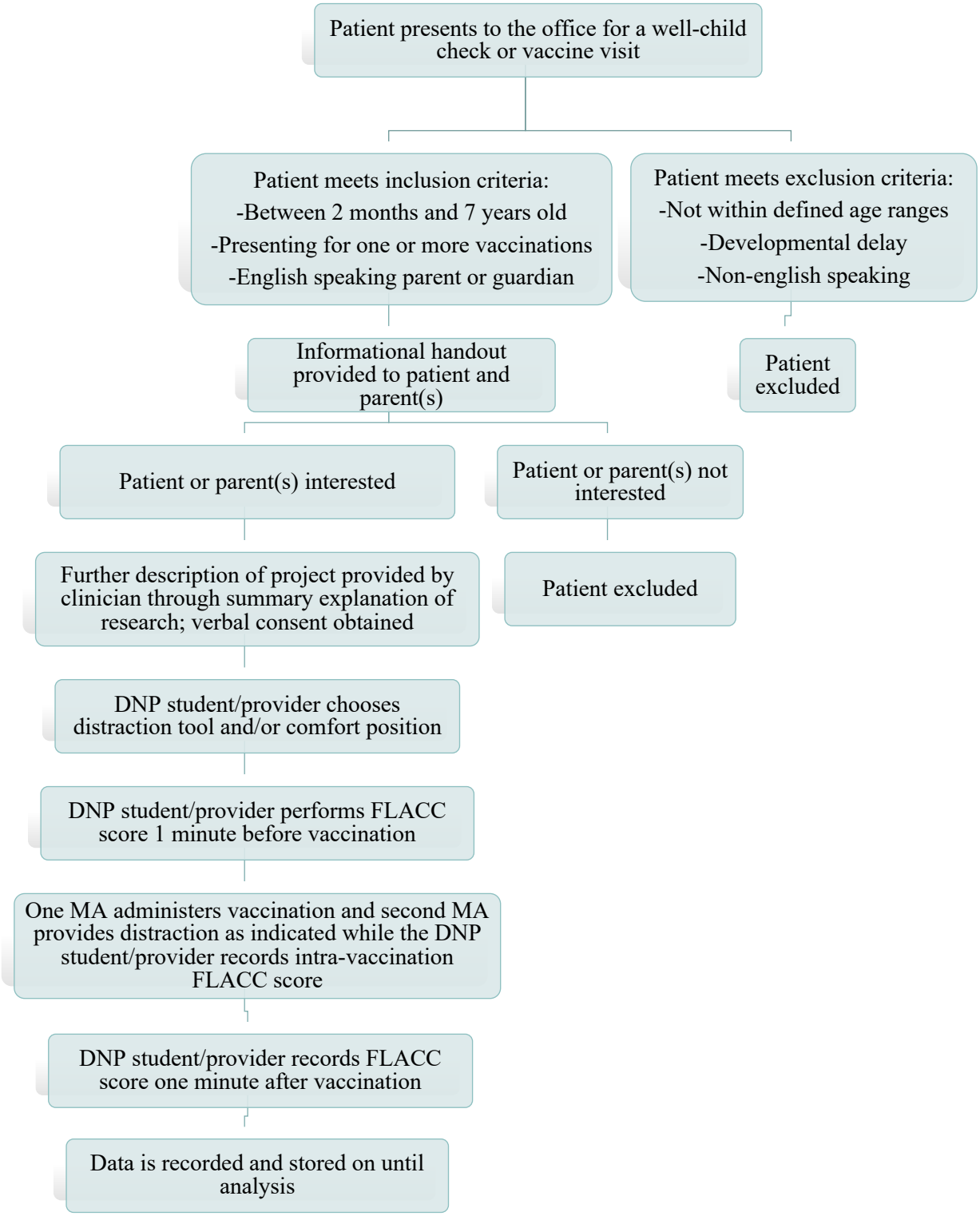
You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Kelly Snyder at (443) 504-8123. If you have questions regarding your rights as a research subject or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

You do not have to participate in this research. Taking part in the research study is voluntary. Your decision to participate or to decline the research will not result in any penalty or loss of benefits to which you are entitled.

Tell the researcher your decision regarding whether or not to participate in the research and to allow your information to be used and shared as described above.

Appendix J

Process Map



Appendix K

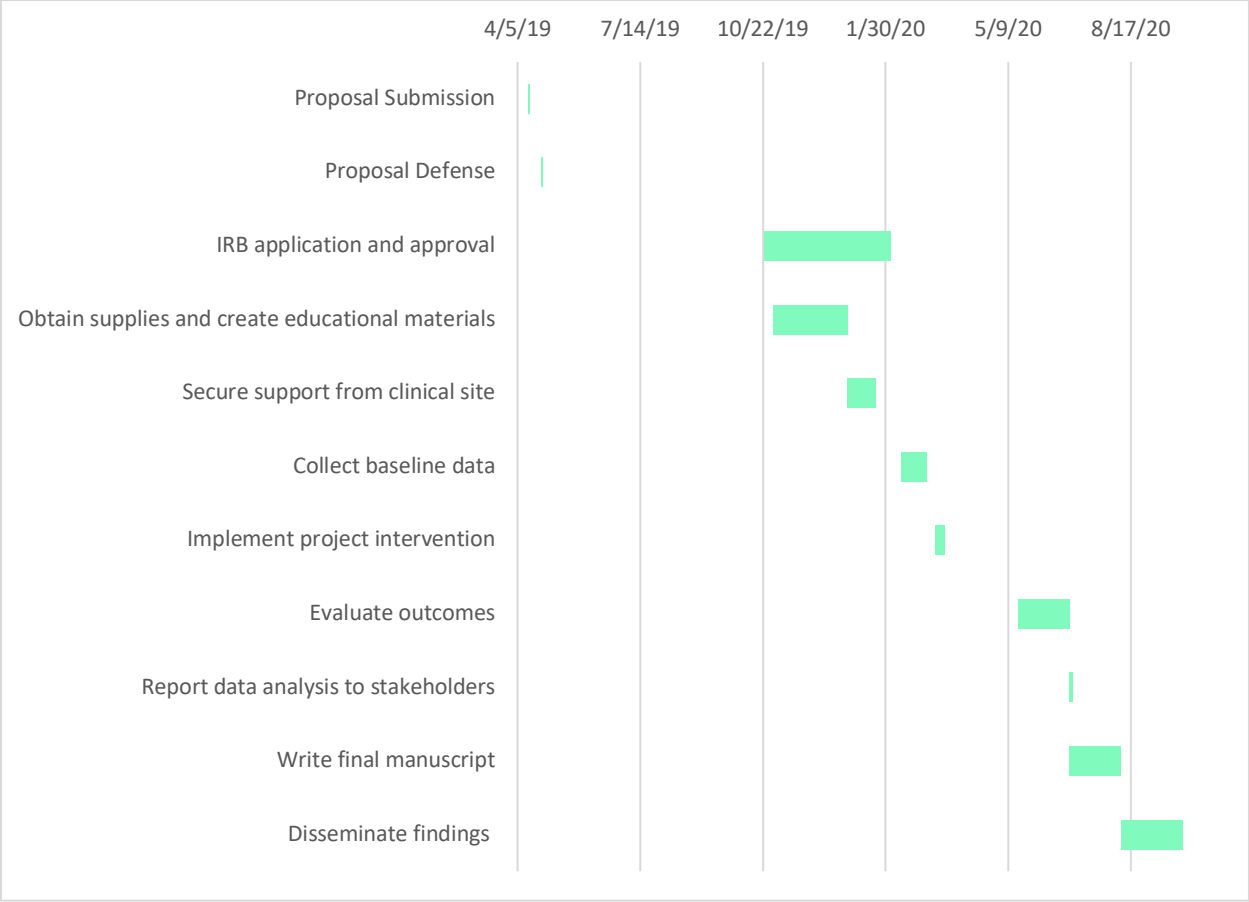
Budget

This budget intends to outline the direct costs of project implementation. If all offices that cared for pediatric patients implemented methods to reduce pediatric procedural pain, the positive outcomes could be quite large. Therefore, it was difficult to estimate the exact revenue that the practice site will see as a result of this project. Instead, the focus was placed upon improving the overall quality of care provided, with the hope that this impacted the healthcare atmosphere as a whole in the future.

Project Expenses		
	Monthly	Total
8x10 paper for printing of: -Summary Explanation of Research -FLACC observation pages -Demographic Data Collection forms	$5	$15
Educational Handouts (8x10 cardstock)	$10	$30
Ink	One time purchase	$100
Distractions Kits		
Bubbles	40 pack- $13.50	$40.50
I Spy wand	One time purchase	$20
Light globe	One time purchase	$5.00
Glitter wand	One time purchase	$5.00
Relaxation Stories (2)	One time purchase	$20
Mindful Kids card deck	One time purchase	$14.99
Rainmaker	One time purchase	$12.99
Operational Costs		
Electricity (Heating/Cooling included)	$750.00 (actual cost $0.00)	$2,250 (actual cost $0.00)
Internet	$150.00 (actual cost $0.00)	$450.00 (actual cost $0.00)
Vaccines and Immunization Supplies	$5,000 (actual cost $0.00)	$15,000 (actual cost $0.00)
Total Project Expenses	$6,132.98 (actual cost 28.50)	$17,963.48 (actual cost $263.48)

Appendix L

GANTT Chart



	Proposal Submission	Proposal Defense	IRB Application and Approval	Obtain supplies, create educational materials	Secure support from clinical site	Collect baseline data	Implement project intervention	Evaluate Outcomes	Report data analysis to stakeholders	Write final manuscript	Disseminate findings
Start Date	4/14/19	4/24/19	10/23/19	10/30/19	12/30/19	2/12/20	3/10/20	5/17/20	6/28/20	6/28/20	8/920
Days to Complete	1	1	103	61	23	21	8	42	3	42	145

Appendix M

IRB Approval Letters

Institutional Review Board
Human Subjects Protection Office
Mail Code A115, Room 1140
90 Hope Drive
P.O. Box 855, Hershey PA 17033-0855

Tel: 717-531-5687
hspo@pennstatehealth.psu.edu

APPROVAL OF SUBMISSION

Date: February 3, 2020

From: Daniel McBride,

To: Kelly Thomas

Type of Submission:	Initial Study
Short Title:	DNP Project
Full Title of Study:	Implementation of Interventions to Reduce Pediatric Pain Associated with Vaccination: A Quality Improvement Initiative
Principal Investigator:	Kelly Thomas
Study ID:	STUDY00013704
Submission ID:	STUDY00013704
Funding:	Not Applicable
IND,IDE, or HDE:	Not Applicable
Documents Approved:	• Educational Handout-v2.docx (2), Category: Recruitment Materials • FLACC scale (1), Category: Other • HRP-591 Protocol (2), Category: IRB Protocol • HRP-598 - Research Data Plan Review Form-v.2.pdf (2), Category: IRB Protocol • Summary Explanation (2), Category: Consent Form
Review Level:	Expedited

On 1/20/2020, the IRB approved the above-referenced Initial Study. This approval is effective for one year from date of approval. You will be required to submit an annual administrative review form through CATS IRB. You will receive reminders prior to the administrative review form due date.

If an administrative review form is not submitted within one year of approval, the study will be closed administratively. Attached are stamped approved consent documents. Use copies of these documents to document consent.

Messiah College IRB *Approval Notification*

To: Kelly Snyder
From: Michael Shin, IRB Chair
Subject: Protocol #2019-047
Date: 02/06/2020

As chair of the IRB, I approve the delegation of IRB responsibility for the protocol titled:

Implementation of Interventions to Reduce Pediatric Pain Associated with Vaccination: A Quality Improvement Initiative

If you have any questions, feel free to contact me.

Michael Shin,
IRB Chair
mshin@messiah.edu

Appendix N

Demographic Description of Participants

	Total Sample N=16	Control Group N=11	Intervention Group N=5
Gender			
Male	10 (62.5%)	6 (54.5%)	4 (80%)
Female	6 (37.5%)	5 (45.5%)	1 (20%)
Ethnicity			
Caucasian	15 (93.8%)	10 (90.9%)	5 (100%)
Hispanic	1 (6.3%)	1 (9.1%)	0 (0%)
Religion			
Unknown/ Unspecified	13 (81.3%)	10 (90.9%)	3 (60%)
Christian/ Evangelical/ Mennonite	3 (18.7%)	1 (9.1%)	2 (40%)
Age	*M* = 2.51 *SD* = 2.14	*M*= 2.77 *SD* = 2.09	*M* = 1.95 *SD* = 2.37
Number of Shots Received	*M = 2.13* *SD = .72*	*M = 2.27* *SD = .65*	*M= 1.80* *SD = .84*