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Reducing Vaccine Associated Pain in Pediatric Patients through a Quality Improvement Initiative

Partial requirements for the Doctor of Nursing Practice

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Reducing Vaccine Associated Pain in Pediatric Patients through a Quality Improvement Project

In the majority of the countries in the world, the administration of vaccines is recommended for all children beginning at birth. Although vaccines are of great importance to the overall wellbeing and health of every pediatric patient, it doesn't come without a certain amount of pain. Pain is a subjective experience perceived by many pediatric patients during vaccinations. It is believed that vaccines are the most common pain producing procedures in healthy pediatric patients. Increasing evidence suggests that painful experiences during early infancy has the potential to increase pain perception throughout childhood. Needle pain that is not treated early can lead to needle fear and needle avoidance in the future in adulthood (Halpert, Meier & Naus, 2015).

A quality improvement project will be implemented at a pediatric clinical site in the eastern gulf coast of South Texas. This host site highly advocates for vaccines but does not currently have an existing pain management protocol for vaccine administration. The focus of this DNP project consists of pediatric patient's ages newborn-21 years receiving vaccinations. This age group was chosen because it is the patient age group seen at the host site. The project will address the pain experienced by implementing evidence-based pain reducing procedures to decrease pain during vaccinations.

Background

In the hospital setting, needle procedures are possibly the main cause of pain in pediatric patients. (Ballard, et. al., 2018). Being that infants have an immature nervous system; it was once believed that infants did not perceive pain due to their underdeveloped nervous system. This misconception has now been debunked and pediatric pain management has changed (Anand, 2001). Increased literature review and studies are being developed on the need to manage pain early, help prevent pain sensitization and decrease needle fears in children (Kennedy, Luhmann & Zempsky, 2008). Pain that is not managed has a potential to cause short and long-term

consequences related to physiological, psychological, and emotional issues (Ballard, Khadra, Adler, Doyon-Trottier & Le May, 2018).

There are other methods of pain relief implemented by healthcare providers in efforts of decreasing the pain associated with vaccine administration. Methods used to decrease pain in neonates is breastfeeding, pacifier with sucrose, swaddling, distraction and EMLA cream during the painful experience. It appears that children with chronic medical conditions particularly benefit from distraction (DeMore & Cohen, 2005). School-aged children in the primary care settings had a decrease in self-reported pain, increased cooperation and increased needle stick procedure success when audiovisual distraction was provided as a routine psychological intervention (Wang, Sun & Chen, 2008).

For this project, pain relief be provided using the methods already mentioned as well as implementing the "Buzzy." The "Buzzy" is a device approved by the Federal and Drug Administration (FDA) and widely used in reducing pain in the pediatric patient population undergoing needle stick procedures (Canbulat, Ayhan, & Inal, 2015; "Frequently Asked Questions", n.d.). This device has its foundation in the gate control theory of pain which indicates that physical vibration effects at the injection site may be helpful in reducing pain (Cobb & Cohen, 2009).

Problem Statement

Many parents are concerned with the pain their child will experience through the administration of vaccines. In fact, findings of various epidemiological studies have indicated that almost one-third of the parents were worried about the vaccine-associated pain in their children, and in excess 85 percent of parents believed that the major responsibility lies on the health professionals to ensure that administration of vaccines are less painful (Shrivastava et al., 2016).

At this host site, no current protocol is implemented to decrease vaccine related pain in their pediatric patients. There is currently a gap between the clinic's current vaccine procedure

and the evidence-based procedures to decrease vaccine related pain. This quality improvement project will address this problem by educating the multidisciplinary team on the use of these pain reducing techniques by implementing a Vaccination Pain Reducing Protocol (VPRP) into their current practice as a standard care practice.

Purpose Statement

This project's purpose is to assist the host site in implementing a VPRP on newborns up to 21 years coming in for vaccines. Various pain reducing techniques will be implemented, of which all are based on evidence-based practice. The implementation of pain reducing techniques during vaccines helps decrease the negative connotation that is felt towards vaccines and also improves the parent's perception of the child's experience when receiving vaccines (Stockwell, et. al., 2011). The aim of this project is to standardize practice by implementing a VPRP when administering vaccines to pediatric patients' ages newborn to 21 years. The desired outcome would be the continued use of the VPRP by all multidisciplinary team members at the host site to decrease the vaccine associated pain experienced by their patients.

Project Question

Will implementing a Vaccination Pain Reducing Protocol (VPRP) aimed at pediatric patients, improve healthcare practices aimed at reducing pain during a 5-week period?

Population=Pediatric patients receiving vaccines ages newborn-21 years in an outpatient setting

Intervention=Utilizing evidence-based pain reducing procedures

Comparison=no pain reducing device

Outcome=Pediatric vaccine-associated pain will be reduced with the implementation of a VPRP.

Time=The data will be collected during a period of five weeks.

Objectives

By the completion of the DNP Project, the following objectives will be completed:

1. Create a Vaccination Pain Reducing Protocol (VPRP) for clinical use.

2. Educate the multidisciplinary team on the VPRP, including proper use of the "Buzzy" and implementation of other pain-reducing techniques.
3. The multidisciplinary team will assess pain scores on all patients before and after the vaccination process.
4. The VPRP will be utilized in at least 75% of patients receiving vaccinations between ages newborn and 21 years old that have verbal parental consent.
5. The VPRP will be implemented as a standard care protocol at the host site.

Significance

Procedural pain in children caused by vaccine injections is common. Vaccine associated pain is known to cause distress in pediatric patients as well as their parents (CDC, 2006). Although vaccines are highly advocated at the host site, they are lacking a protocol to decrease the pain associated with such vaccines. At the project site, the multidisciplinary team do not assess pain level before or after the administration of a vaccine and do not have a protocol in which to help decrease the pain. Nursing leaders are aware that pain is considered the fifth vital sign as assessing it is vital to determine if there a decrease with the pain reducing methods.

As one of our most vulnerable patients, we must advocate for the best care possible for all pediatric patients and provide special care. It is important for all healthcare provider to educate themselves on the topic of iatrogenesis. They should be able to recognize it, know how to avoid it if possible, and know what to do if it does occur (Michalska-Smith, 2017).

With the implementation of this VPRP, a universal approach will be used on all patients and will help increase patient satisfaction by decreasing vaccine related pain. The implementation will guide the multidisciplinary team to integrate pain-relieving methods appropriate by age and not have to guess which technique to implement. The implementation of this protocol can result in higher satisfaction during the vaccination process and can lead to possible referrals to the clinic site contributing to an increase in revenue.

Search Terms

A literature search was performed to determine the importance of implementing a VPRP in an outpatient pediatric setting. The search engines utilized for the project included PubMed, Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE and Google Scholar. More than 100 articles were found to be pertinent to this project after extensive research, review and analysis. The key search terms used were "Buzzy," "vibratory pain relief," "cold analgesia," "pediatric pain management/relief," "Buzzy clinical trial," "Buzzy pediatric," "vaccine pain management," "audiovisual distraction," "breastfeeding for pain management," & "swaddling for pain management, pain reducing distraction." During the search, search limitation utilized were full text, peer reviewed articles in the English language from 2015 to 2020. Studies older than 2015 were included only if historically relevant. These search terms were utilized in order to include most relevant and recent studies and clinical trials.

Policies and procedures from the project site were reviewed for administration of vaccines. Currently, there is no guidelines or protocol at the host site for reducing pain during vaccinations. With this lack of protocol, this project will implement a necessary VPRP that will be used by the multidisciplinary team as a standard of care during vaccine administration.

Inclusions and Exclusions

The articles were carefully reviewed for relevant inclusion and exclusion criteria. The inclusions for the articles used included clinical trials that implemented The Buzzy or vibratory and cold anesthesia, swaddling, breastfeeding, or distraction techniques on pediatric patients in outpatient and inpatient settings during a needlestick procedure. These clinical trials could take place in domestic and foreign countries as long as they were in the English language. Articles including "The Buzzy" clinical trials for pediatric patients ranging from ages 18 months through 21 years old undergoing procedures that involved needle sticks. For other pain relief methods all pediatric ages were included when available and appropriate.

Exclusion articles included trials on adult patients, children under 18 months using "The Buzzy", articles that only provided an abstract and those published more than 10 years ago. Clinical trials on children younger than 18 months were excluded because the device is not recommended for children under 18 months of age. For history purposes, the 10-year exclusion time frame was not adhered to. Other excluded articles were those not published in the English language.

Review of Literature

This review will examine the negative effects of pain on children, different pain assessment tools dependent on age, and methods that have been shown to decrease needle stick procedural pain in pediatric patients. Lastly, the Health Care Provider Intervention Documentation Tool (HCPIDT) will be explored as it will be the documentation tool implemented at the project site as a part of the VPRP. The HCPIDT is a documentation tool published in 2010 in the Canadian Medical Association Journal developed by Help Eliminate Pain in Kids and Adults (HELPinKids) team. The HELPinKids team is made up of 25 Canadian experts. These Canadian experts have expertise in pain, fear, pharmacology, vaccinology, epidemiology, guideline development, medicine and nursing. Other areas of expertise are knowledge translation, library sciences, health policy and library sciences (Taddio et. al., 2015).

Negative Effects of Pain

It is common for individuals to experience pain during vaccinations causing them to be hesitant about vaccines throughout their lives. (Taddio et. al., 2015). In addition to injections causing distress in the child and the caregiver, it can also cause distress on the healthcare provider administering the injection. If individuals have a negative experience during vaccine administration, they may develop noncompliant behaviors and acquire a fear of needles into adulthood (McMurtry, Pillai, Taddio, Racine, Asmundson, Noel, Chambers & Shah, 2015). In comparison to adults, children have a higher concern with needle pain and want to receive pain reducing interventions at a lower level of pain intensity (Dalley, McMurtry & Creary, 2014).

Even though the fear of needles is common, it is a health care issue that is unfortunately not prioritized. Both adults and children are commonly fearful of needles; which has contributed to negative experiences when undergoing needle procedures. This will also cause a negative connotation involving health care for care givers, patients and health care professionals (McMurtry et. al, 2016).

Although the topic of iatrogenesis has become more widely discussed in literature, less has been said about its presence within pediatrics. Vaccine associated iatrogenic pain has played a crucial negative role along with various other determinants in negatively influencing the attitude of people and thus a delay or avoidance in the future vaccinations (Shrivastava, Shrivastava & Ramasamy, 2016). When a child is so afraid of the pain they will experience during vaccinations, the added stress can be transferred to their caregivers. Minimizing the child's pain perception during the administration of vaccines can help with the adherence of the vaccination schedule, decrease or prevent distress, minimize fear to needles and healthcare providers. Minimizing fear towards healthcare providers, helps them maintain and promote trust (Taddio et. al., 2015).

Pain Assessment

In order to determine if a pain management intervention is warranted, assessing pain is necessary. When dealing with pediatric pain, it is important to assess pain as well as manage it as soon as possible. It can be especially difficult in younger pediatric patients to identify if they are experiencing pain and if so at what level the pain is at (Hauer & Jones, 2020). Pediatric patients undergoing vaccinations are at a high risk of experiencing a high level of pain; thus, an assessment should be done and effective pain reducing interventions should be implemented. Results from a randomized control trial conducted by Redfern et al. (2018) indicated that younger children reported higher pain scores and that age was the strongest factor associated with pediatric pain.

Pain Assessment Tools

Multiple pain assessment tools can be used to determine the pain level experienced by patients. The pain assessment tools used in this DNP project which are part of the HCPIDT can be found in Appendix A. These assessment tools in Appendix A consist of the Numeric Pain Scale, the Modified Behavioral Pain scale (MBPS), the Faces, Legs Activity, Cry & Consolability (FLACC), and the Faces Pain Scale-Revised (FPS-R). The different pain scales are dependent on the age of the patient as well as on the ability of the patient to interact with the healthcare team. Pain scales can be useful in allowing patients to communicate their pain and its' intensity. When communication is not possible as in young children, some pain scales allow the healthcare providers to rate pain level through observational assessment (Gregory, 2019).

Researchers and clinicians have utilized the MBPS as a valid way to assess immunization procedural pain in children (Crellin, Babl, Santamaria & Harrison, 2018). This tool is useful in young children since they are not verbal and unable to rate their own pain level. According to author's Crellin et al. (2018), a systemic review of the psychomotor properties of the MBPS was conducted on a sample of twenty-eight studies. The conclusion of this review determined that sufficient data to use the MBPS as a valid tool for assessing immunization pain in infants from 2 to 22 months but cannot be recommended for assessing other procedural pain.

Another common assessment tool used in children is the FLACC scale which is also a widely used observational behavior pain scales (Crellin, Harrison, Santamaria, Huque & Babl, 2018). The authors Crellin et. al., (2018), conducted a study to test properties of the FLACC scale such as psychometric and practical properties in order to determine a quantity of procedural pain in young children as well as in infants. The FLACC scale was applied to over 100 children ranging from 6 to 24 months while being videotaped from one of twenty-six clinicians. This study concluded that the FLACC scale is a reliable source to determine procedural pain in children.

For school aged children older than 4 years old, the FPS-R is a useful pain assessment tool. This tool is a revised version of the Faces Pain Scale and allows pain to be scored on a scale between 0-10. The FPS-R suggests a close linear relationship with visual pain scales in children ages 4-16 years (International Association for the Study of Pain, 2018). The authors in article, Cognitive Testing of an Electronic Version of the FACES Pain Scale-Revised with Pediatric and Adolescent Sickle Cell Patients published in 2016, conducted a cross-sectional, qualitative study that involved live interviews with children and adolescents in the United Stated and their parents or legal guardians. This article found that FPS-R measures pain reliably for children ages 7–17 with Sickle Cell Disease. The article also found FPS-R to be useful for future clinical studies (Gupta, Naegeli, Turner-Bowker, Flood, Heath, Mays & Dampier, 2016).

The numerical pain scale is useful in older children as well as in adolescents. This pain assessment tool rates pain level on a scale between 0-10. A score of 0 relates to not experiencing any pain and a score of 10 equates the wore pain they have ever experienced. This pain scale is appropriate for older pediatric patients who are verbal and can self-report their pain rate.

Pain Management

A "3-P" approach strategy is important when trying to manage pain. The three "3-P" involves using psychological strategies, physical strategies, as well as pharmacological strategies (Taddio et. al., 2010). While, pain assessment is important, this alone will not decrease a patient's pain level. Healthcare professionals must implement techniques that have shown to decrease the pain. Not a single technique works for everyone and not every technique is appropriate for all pediatric patients. Depending on the patient's age will determine which protocol procedure will be implemented. This protocol will be guided by the interventions from the HCPIDT.

Pediatric Pain-Reducing Guidelines

For this DNP project, the HCPIDT, (Appendix B) will be the guided protocol

implemented at the project site. The interdisciplinary guideline was developed in 2010 by panel experts whom are known as, the HELPinKIDS Team. These experts are from different disciplines and involved in pediatric medical organizations. These medical experts work in different University hospitals and both government and non-government organizations across Canada (Taddio et. al., 2015).

This tool includes evidence-based pain reducing technique and allows healthcare providers to document which techniques are used and which pain assessment tool was used on the patients. There were two objectives in the development of this clinical tool. One of the objectives was for it to serve as a clinical practice guideline to assist clinicians in managing procedure related pain and the other objective was to decrease the distress experienced by the children undergoing vaccine injections (Taddio et al., 2015). The tool consists of literature based on systemic review that are expertly interpreted by clinicians (Taddio et. al., 2015). When the guidelines were introduced in 2010 it concentrated only in children, but the team reconvened and implemented the guidelines to include adults also in 2013 (McMurtry et. al., 2016). The HELPinKIDS team used the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool as the methodology in developing a guideline (Taddio et. al., 2015). The Canadian Institutes of Health Research funded the guideline but had no input into the development of the guideline (Taddio et. al., 2015). This guideline is supported by both Canadian Center for Vaccinology and the BC Centre for Disease Control. It is also endorsed by numerous Canadian organizations (Taddio, et al., 2015).

Interventions for Infants

Breastfeeding is a process that is readily available in which infants can acquire nutrition but also provides maternal skin to skin contact. The positioning during breastfeeding proves effective in the infant feeling safe and can be very effective as well as very convenient. Breastfeeding is also safe and easy to implement at the host site where it can be easily supervised by the multidisciplinary team. This pain reduction technique can be easily implemented as part of

standard practice of care (Taddio et. al., 2015). To be effective, breastfeeding should be started with an adequate latch and continue for several minutes after the vaccine is delivered to decrease the painful stimuli (Taddio et. al, 2015). A randomized clinical trial by Modarres, Jazayeri, Rahnama & Montazari (2013), showed that the breastfeeding significantly reduced pain levels during minor invasive procedure in term babies and greatly decreased crying in infants who received immunizations. This study also concluded that breastfeeding decreased both physiological and psychological pain.

In another randomized controlled trial with a total of 1066 infants throughout 10 studies, the authors concluded that breastfeeding reduced crying in young babies undergoing vaccinations in comparison to other interventions. The other studied interventions where cuddling, vaso-coolant, oral glucose, no intervention, topical anaesthetic and massaging (Harrison, Reszel, Bueno, Sampson, Shah, Taddio, Larocque & Turner, 2016). On average, breastfed babies cried for 38 seconds less than babies who were not breastfed and significantly lowered their pain scores (Harrison, et. al., 2016).

Swaddling can also be implemented in infants during feeding**.** For infants who are not breastfed, they can be offered sugar water. Swaddling is a method that can mimic the closeness felt in the mother's womb during pregnancy and can also be implemented while an infant is breastfeeding. For those children who are not breastfed, they can use a non-nutritive sucking device such as a pacifier. To decrease a premature infants' pain score and heart rate during an invasive procedure, a pacifier can be given, or the infant can be swaddled. These two methods can be used as alternatives to pain management in infants (Efendi, Rustina & Gayatri, 2018). This analgesic mechanism is effective through distraction and release of endogenous opioids (Taddio et. al., 2015. In a randomized double-blind intervention study on 131 healthy term infants, authors Hashemia, Taheri, Ghodsbin, Pishva & Vossoughi (2016) studied what the effects of swaddling and breastfeeding would have on the infant's pain response. The authors

concluded that the pain reduction is lower on the control group that were swaddled and breast feeding during the time of vaccination.

Interventions for School Aged Children and Adolescents

Methods that have shown to be beneficial for school aged children and adolescents are topical anesthetics, tactile stimulation of the injection site and distraction methods such as deep breathing or bubble blowing.

Topical anesthetics work by blocking pain signal transmissions traveling through peripheral nociceptors and are effective on intramuscularly and subcutaneously administered vaccines (Taddio et. al., 2010). This method works by numbing the area that is to be injected and help reduce the pain level experienced by the patient. Another method found beneficial is the use of distraction in young children and adolescents. This method acts as a psychological intervention and it aids by allowing the child to concentrate on something that is not the injection. A method for children ages four years and older is to provide tactile stimulation such as massaging or stroking the area close to the injection site. This method works by blocking pain transmissions by competing with the sensations felt by the tactile stimulation (Taddio et. al., 2010). Another method that is effective for children three years and older is deep tummy breathing. It is an effective psychological intervention that can be implemented by asking the child to blow bubbles or even spinning a pinwheel. These strategies work by means of distraction (Taddio et. al., 2010).

Vibratory and Cold Analgesic Device

The vibratory and cold analgesia device that will be implemented will be on children 18 months and up which is the age recommendation of the device. The device which will be implemented is trademarked by the name of the “Buzzy” and is FDA approved. There are two models of the device, one version is for personal use and the other version is for healthcare use. For this project, the healthcare version will be used because it is reusable between patients. The device will remain at the facility and will be sanitized after each patient use. The device has

multiple indications with decrease of injection pain being one of the uses. The device is battery operated and reasonably priced at $99.95 and can be used hundreds of times between battery changes.

When searching for evidenced based procedures, there must be some sort of science behind to prove how and why this method is effective. The gate control theory is the basis for the design of Buzzy. The premise is that the brain stops pain signals from passing through when non-painful signals such as cold and vibratory impulses are applied (Pain Care Labs, 2020).

The article "The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children" (2015), discussed a prospective, randomized controlled trial. This trial was conducted on 104 7-year old children receiving the Tdap vaccine utilizing either the Buzzy or standard care during the vaccination. This study found that the group using the Buzzy for pain reduction indicated a pain decrease between 71%-75%. Coincidently, authors also concluded an average decrease in anxiety levels by 70% (Sahiner & Inal, 2015).

A prospective randomized controlled study conducted on 70 children in Italy with a median age of 9 concluded that children with cognitive impairment had reduced pain during vascular access with the use of vibratory and cold analgesia (Schreiber, Cozzi, Rutigliano, Assandro, Tubaro, Wiel, Ronfani & Barbi, 2015). The authors Redfern, Chen and Sibrel (2017), conducted a randomized controlled trial on fifty children between 3 and 18 years of age to examine the effectiveness of the Buzzy. The trial compared the device to using no intervention in reducing child reported pain during vaccinations. This study concluded that thermomechanical stimulation as produced by the Buzzy significantly reduced the pain experienced by the children during their vaccination procedure.

Conceptual Model

For this project, the Donabedian model (Appendix C) will be utilized to assist in identifying and categorizing the various components of the project (Moran, Burson, & Conrad,

2017). The Donabidian model is a conceptual framework that is used in quality improvement initiatives (Moran, Burson, & Conrad, 2017).

Historical Development of Theory

According to Moran et. al. (2017), the Donabedian model is a systems methodology conceptual framework that centers on structure, process, and outcome. The Donabedian model was developed by Avedis Donabedian (1919-2000), born on January 7, 1919 in Beirut, Lebanon (Best & Neuhauser, 2004). As a child, Donabedian fled with his Christian family to what is now Jerusalem to avoid the Armenian holocaust (Best & Neuhauser, 2004). His academic life consisted of receiving his BA degree in 1940, MD degree in 1944 from the American University of Beirut and an MPH degree from Harvard School of Public Health in 1955 (Best & Neuhauser, 2004). Donabedian is known for research in the area of quality assessment of public well-being and service (University of Michigan, n.d.). He was honored, in 1979, as the Nathan Sinai Distinguished Professor of Public Health at the University of Michigan for his contributions in public health where he served as professor (Best & Neuhauser, 2004). After graduating with his MPH, Donabedian began working on research in medical care evaluation which became his expertise (University of Michigan, n.d.).

One of his major contributions to healthcare was implementing ways to improve healthcare quality from what was once a guessing game. He implemented a quality improvement movement and collaborated with other leaders for adequate patient care. Back in 1965, when government Medicare and Medicaid were created, Donabedian was one of the leaders involved. Donabedian was given the task to review research on quality assessment in healthcare (Ayanian & Markel, 2016).

There was a time in history where best quality was not utilized in healthcare. The Donabedian model was developed in 1966 and aimed at achieving the best quality healthcare for all. The model was published in 1980 and provided the early framework for performance measurement and improvement in health care (Lighter, 2015). With this model, Donabedian

divided healthcare into three categories: structures, processes and outcomes (Lighter, 2015). Accordingly, every measured quality could be divided into at one of the three categories when conducting studies in healthcare quality improvements.

Major Tenets of Theory

The Donabedian model is one example of a conceptual framework that is centralized on three main categories: structure, process, and outcome (Donabedian, 1988).

Structure: Structure conveys the characteristics of the settings in which care occurs. This includes material resources, human resources as well as organizational structures. Material resources can be the facilities where the care will take place, the financial means for the care being provided and the equipment being utilized. Human resources can refer to the amount of personnel as well as their qualifications. Lastly, organizational structures can refer to methods of reimbursement and the organization of the medical staff (Donabedian, 1988).

Process: Process conveys what methods are being implemented when giving and receiving care. This takes into account which activities the patient is participating in when seeking care as well as the practitioner's activities when making a diagnosis and recommending or implementing treatment (Donabedian, 1988).

Outcome: Outcome determines what effects from the care provided had on the patients. The patient's health status is determined by increasing the patient's health knowledge from the care they will receive as well as increasing the patient's satisfaction with the care provided (Donabedian, 1988).

Application of Theory to Current Practice

The Donadebian model incorporates methods to investigate how medical care is delivered in organizations from small clinics to large health care systems (Ayanian & Markel, 2016). The Donabedian model is important to the nursing profession as a systems methodology for leaders in the healthcare industry to provide high quality best-practice care (Ayanian & Merkel, 2016).

The model is still useful now in providing best practices in the nursing field and can be implemented in different practices ranging from inpatient to outpatient settings. The model is still being used in studies of different healthcare setting in different countries in order to arrive at best practices that will be implemented on patients.

Study findings in Amir, Tan, Halfens, Lohrmann & Schols (2017), utilized the Donabedian model in a one-day, cross-sectional evaluation in multiple centers. The study of the quality of pressure ulcer care was conducted in a convenience sample of hospitals in Indonesia among patients 18 years of age and older admitted in either the medical, surgical, or intensive care units (ICU). Using the Donabedian model, the study findings concluded several quality indicator issues related to pressure ulcer care in these hospitals. There were several suboptimal preventive measures that needed to be updated as well as a need for a well-established pressure ulcer preventive program (Amir et al., 2017). A study by Munea, Degu & Tura (2020), used the Donabedian model in health facility-based cross-sectional study conducted in the West Gojjam zone. The study was assessing best practices to implement the best sexual and reproductive services in the underserved areas in this country. Donabedian's three-step approach allowed the development of much needed renovations of health facilities (structure), training on how to care for the clients(process) and modifying the current services they offered to their youth (outcome) (Munea et. al, 2020).

Application of Theory to DNP Project

Structure: The setting in which the care of this QI protocol will take place in an outpatient pediatric clinic in South Texas. The human resources will be made up by the multidisciplinary pediatric teams will consists of numerous nursing assistants, three Board Certified Family Nurse Practitioners, one Physician Assistant and a Board-Certified Pediatrician. They will work interchangeably with the clinic front desk staff and clinic manager to implement this QI pain reducing protocol.

Process: Several processes will take place during this QI protocol. This VPRP project will be implemented for five weeks for newborn and pediatric patients up to age 21 years old at the host site. This QI project will initiate an educational session for the multidisciplinary team on the pain assessment tools and which assessment tool to use on patients according to their age. The educational session will also include education on the pain reducing tool and which will be implemented according to the patient's age. The project will implement a pre-existing HCPIDT that will guide the multidisciplinary team on which pain reducing procedure is appropriate.

Outcome: The overall desired measurement of this QI protocol will be the reduction of pain during the vaccination process of the pediatric patients at the host site**.** The items that will be measured will include pediatric pain scores before and after vaccine administration, as well as utilizing the most appropriate pain reducing techniques dependent on the patient's age. The overall satisfaction of the patient and/or their caregiver will also be measured.

Setting

This QI project will take place in a private pediatric clinic in Brownsville, Texas in the county of Cameron. Brownsville is a city located in Texas. With a 2020 population of 183,748, it is the 18th largest city in Texas and the 142nd largest city in the United States (N.A, 2020). The location of the host site is located next to the only highway in the city which is a high traffic area. The host site sees newborn patients up to age 21. The clinic consists of seven patient rooms, one triage room, one exam room, an in-house laboratory, two doctor's office, a billing office and a front reception area. There is a large waiting area available for the patients with a large flat screen, seating area, television and a toy area. The office has approximately 8 staff members working everyday as well as 2 providers. Permission to conduct this project is granted by the office manager as a written statement (Appendix D). The electronic health record (EHR) that will be utilized will be eClinicals which all multidisciplinary team are fluent in using. By utilizing the EHR in this QI, it allows the multidisciplinary team to provide higher quality and safer care and allows for more accurate chart reviews through ICD codes (HealthIT.gov, 2019).

Population of Interest

The direct population of interest will consist of a multidisciplinary team who all work at the host site. The multidisciplinary team is made up of 6 medical assistants, 2 laboratory techs, 4 front office staff, 3 family nurse practitioners, 1 physician assistant, 2 office managers and one Board Certified Pediatrician. Both office managers will facilitate the educational sessions. The office managers as well as the Pediatrician will have a direct say as how this QI project will be implemented.

The indirect population will be all patients coming in for vaccinations as well as their parents or caregivers. Inclusion factors include all genders, sex and racial population will be included as the HCPIDT directs. Patients under the age of 18 require consent for vaccinations and pain management therapies. Those patients without parental consent will be excluded from this QI project. Patients 18 and over will be allowed to provide their own verbal consent for vaccination and pain control and will be excluded if they do not desire these measures. Patients under the age of 18 require consent for vaccinations and pain management therapies. Those patients without parental consent will be excluded from this QI project. Patients 18 and over will be allowed to provide their own verbal consent for vaccination and pain control and will be excluded if they do not desire these measures.

Stakeholders

Stakeholder can be made of different individuals or organizations but ultimately all their voices should be heard (Leviton & Melichar, 2020). Quality improvement efforts affect a broader range of people than we believe it does. These are the potential stakeholders for QI and its evaluation, and they have valuable perspectives to offer when they are consulted in planning, conducting and interpreting evaluations (Leviton & Melichar, 2020). All stakeholders have an important interest and all their opinions are important (Association for Community Health Improvement, 2020).

There are numerous stakeholders involved in this QI project. The stakeholders are made up of a multidisciplinary team of numerous medical assistants, building office personnel, two office managers, three Family Nurse Practitioners, one Physician Assistant and one Board Certified Pediatrician who is also the owner of the clinic. The pediatrician and Mid-Level providers will order the immunizations and the nursing staff will carry out the pain reducing protocol. Before the implementation of the QI project, all stakeholders will be gathered together for an explanation of how the QI project will be implemented and informed of the educational sessions that will be provided. All stakeholder's preference in training and schedule will be taken into account to accommodate their work schedule as much as possible. An affiliation agreement is not required by the University nor by the clinical administrative team.

Interventions

The preparation of this QI DNP project will take about eight months to complete all sections of the project proposal. After the preparation, it will be submitted to the DNP project committee for approval. The project approval date should take place by October23, 2020. The actual implementation of the VPRP will consist of five weeks. One week before implementing it, the multidisciplinary team will be educated on the pain assessments tools according by age (Appendix A) and the pain reducing techniques (Appendix B). The educational session will be scheduled for two hours on two different days so that the entire multidisciplinary team is able to attend. Charts will be audited during weeks two through five.

The sessions will be offered an hour before the clinic's opening time so that patient care is not affected. Project lead will be available an hour after each educational session to answer questions.

As previously mentioned, all patients coming in for vaccinations will be offered to take part in the VPRP. Verbal consent must be given by the parents or guardians and adult patients will provide their own consent. Patient's pain level will be assessed pre and post vaccination and the pain sore will be recorded in the EHR by the multidisciplinary team member that

administered the vaccine. Following the pain reducing techniques found in Appendix B that are categorized by age, an age appropriate pain reducing technique will be utilized

Charts will be audited twice a week during weeks two through five to evaluate the percentage the protocol is being implemented. If the percentage is lower than 75%, team lead will be available as needed for further education and further questions and/or concerns. It will be made clear to the multidisciplinary team that the goal of auditing the charts will be to verify the validity of the project and the VPRP.

Tools

VPRP Protocol

The HCPIDT (Appendix B), a pre-made and validated tool will be the documentation tool implemented at the project site that will serve as the VPRP. This tool is a documentation tool that was published in 2010 and developed by Help Eliminate Pain in Kids and Adults (HELPinKidsandadults) team. The HELPinKidsandadults team is made up of 25 Canadian experts from various specialties (Taddio et. al., 2015). This tool is a two-page tool used in assessing and addressing vaccine pain reduction. The protocol will be introduced to the multidisciplinary team as the same time as when the educational sessions are scheduled. The team will be educated on how this tool will be utilized and be effective in assessing and reducing vaccine associated pain in pediatric patients. This tool will guide the multidisciplinary team's care during the vaccination process and should be utilized on all patient coming in for vaccinations who have verbally consented use of the VPRP. Permission for use from the author has been included (Appendix E).

Educational Material

The multidisciplinary team will be educated by the project lead. The educational session will consist of a PowerPoint presentation (Appendix F) that will be developed by the project lead and validated through peer review of the project team and stakeholders at the project site. After the presentation, there will be a question and answer session for any concerns that might arise.

The presentation will be made available as a printed physical document for the team to review at a later date if they desire.

VPRP Codebook (Appendix G)

The codebook will be utilized for chart checks and the data collected will be used for VPRP data analysis and effectiveness. Codebook was a self-developed by project lead and will be utilized for data gathering once the VPRP implementation is completed.

Audit tool

An auditing tool (Appendix H) will be utilized to audit the multidisciplinary team's compliance in utilizing the VPRP during vaccinations. The required information will be gathered from the patient chart utilizing the ICD-10 codes for vaccinations. One objective of this VPRP is for the use the protocol on at least 75% of patients coming to the host site for vaccinations.

Date Collection Procedures/Intervention

Data Collection Procedures

The VPRP will be implemented at the host site on November 4, 2020. Participants will not be recruited from outside sources. Those coming into the host site for vaccinations will be invited to participate through verbal consent. Participants will have the option to opt out of participating in the VPRP with no consequences. The multidisciplinary team who normally take part in the vaccination process will be the individuals who directly apply the VPRP techniques and vaccinations.

Audits will also be conducted in order to monitor the adherence of the protocol and determine if the VPRP is being utilized in at least 75% of patients coming in for vaccinations. A total of 50 charts will be reviewed retrospectively before implementation and 50 charts will be reviewed post implementation. Charts with ICD code Z23, "Encounter for immunization," will be used during the auditing process. This ICD code indicated that an immunization was administered to the patient.

In order to determine compliance, the project lead will audit charts to determine if all patients receiving immunizations have a pain score documented before and after the vaccine as well as documentation of which pain assessment tool was used for the patient. During the audits, the project lead will also be auditing if the multidisciplinary team used an appropriate pain reducing technique as indicated by the VPRP and documented in the patient's chart.

Confidentiality will be maintained at all times by excluding any identifying information during the data collection process. The project lead will assign each patient record a random number which will be used for internal data collection purposes only. The laptop with the audit and the analytical information will be stored in a password protected file available only to the project lead.

Ethics and Human Subjects Protection

Institutional Review Board (IRB) determination forms will be submitted to the appropriate committee for DNP project determination as per Touro University project policy. This DNP project is a QI initiative project which would not require IRB review as the project lead will not have interaction with the human participants. The team lead has also participated and completed the Collaborative Institutional Training Initiative (CITI) program. The host site does not have an IRB team. All data collected from the patient's charts will be done so that no patient identifier is identifiable. A unique identifier will be created for every chart. All the data will be stored in a password protected laptop which will be in the project lead's possession at all times. No additional risk will be associated to the VPRP participants coming in for vaccinations. The only possible negative experience will be pain perceived due to the vaccination which is not directly linked to the VPRP. No perceived risk will be associated to the multidisciplinary team. There will be no monetary compensation to the patients nor to the multidisciplinary team. All participants will be aware they are voluntarily taking part in an evidence-based quality improvement project.

Measures/Plan for Analysis

For this DNP project, the project lead will utilize the Statistical Package from the Social Sciences (SPSS) software. The SPSS is a widely used program for statistical analysis in social sciences, particularly in education and research (Technopedia, 2017). The software will be utilized to analyze VPRP effective by comparing pain scores pre and post VPRP implementation as well as multidisciplinary compliance.

To analyze the effectiveness of the VPRP, pain scores will be assessed before and after vaccination administration. The statistical test that will be utilized for the pre and post vaccination pain score data will be the t-test. The t-test assesses whether the means of two groups are statistically different from each other. This analysis is appropriate whenever you want to compare the means of two groups (Trokim, 2020).

Statistical analysis test that will be used in order to measure the multidisciplinary team's adherence and compliance with the VPRP. The first measure that will be analyzed for compliance will be to audit if documentation of pain score were obtained pre and post pain reducing technique for all patients.

The second measure that will be analyzed will be whether the staff used an appropriate pain reducing technique as delineated by the VPRP. These would be analyzed using pre-implementation data compared to post implementation data. Results will be analyzed with chi square or Fischers exact if rare cells are present. This test will help determine the percentage of the team's adherence to the VPRP with a 75% confidence interval. For this QI project, the team lead will also be assessing compliance rates by using the Exact binomial test.

The host site doesn't count with a statistician, but the team lead did collaborate with Dr. Vanier, Touro University's statistician for appropriate statistical analysis input for the VPRP.

Analysis of Results

Statistical analysis was performed for this QI project to determine if the implementation of a VPRP is a reliable implementation in a pediatric clinical setting to decrease vaccine related pain. In order to obtain the necessary information, the team lead completed chart audits from week 2 through week 5 of the VPRP implementation. For analysis purposes, the SPSS software was utilized for this project. The information that was obtained during the auditing process was gathered from the clinic's electronic health record (EHR), eClinicals. The specific ICD-10 code, Z23 was utilized when searching for appropriate chart for this VPRP analysis. This ICD-10 code is used for all vaccines and by doing this, it allowed the team lead to eliminate charts that were not appropriate for this analysis. A total of 50 charts were used for analysis in this QI project. All charts used were audited for all required information and all charts used were those of patients coming in for administration of any vaccination.

Once the data collection was completed, the team lead gathered this data and input it into the SPSS software. To correctly analyze the data, the team lead verified to correctly input the variables necessary for this VPRP. The data analysis addressed the following statistical data.

Pre and Post Implementation Scores

In order to determine if there was a change in pain score before and after implementation, part of the VPRP was to acquire a pain level before and after vaccine administration from each patient. A paired sample t-test was the utilized for this analysis. A paired-samples t-test is used when you have only one group of people and you collect data from them on two different occasions or under two different conditions (Pallant, 2016)

Under Figure 1, looking at the mean values, it can be determined that the average pain scores were higher post implementation as opposed to pre-implementation. Before the implementation, the mean pain score was 2.82 as opposed to the mean score of 3.38 post implementation. From these mean scores, the goal of reducing pain was not met as the mean score was higher post implementation.

In table 2, The significance (2-tailed) value is less than .05, which means there is a significant difference in the mean scores (Pallant, 2016). For this VPRP, the significance value was 0.38, showing a significant change in pain scores pre- and post-pain reducing technique implementation. From figure 1, we are able to conclude that the mean post intervention pain score was 3.38 and the mean pre intervention score was 2.82. The mean post implementation score was higher than the pre intervention.

Figure 1

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	PPREI	2.82	50	4.689	.663
	PPOSTI	3.38	50	4.252	.601

Figure 2

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper			
Pair 1	PPREI - PPOSTI	-.560	1.853	.262	-1.087	-.033	-2.137	49	.038

Appropriate Pain Reducing Technique Used

When determining if an appropriate pain reducing technique was used for patients coming in for vaccinations, a Chi-square test was performed. This test is used when you wish to explore the relationship between two categorical variables (SPSS). As noted in figure 3, of the 50 charts audited, the appropriate pain reducing technique was performed on a total of 39 patients. Of those 39 patients, only 1 patient (2%) did not receive the appropriate pain reducing technique. Statistically, if only utilizing the charts that consented to take part in the VPRP, the correct pain reducing technique was used 98% of the time.

Figure 3

VPRPP * APPMETHOD Crosstabulation

			APPMETHOD			
			yes	no	not performed	Total
VPRPP	yes	Count	38	1	0	39
		% within VPRPP	97.4%	2.6%	0.0%	100.0%
		Adjusted Residual	6.7	.5	-7.1	
	no	Count	0	0	6	6
		% within VPRPP	0.0%	0.0%	100.0%	100.0%
		Adjusted Residual	-4.6	-.4	4.9	
	not performed	Count	0	0	5	5
		% within VPRPP	0.0%	0.0%	100.0%	100.0%
		Adjusted Residual	-4.2	-.3	4.4	
Total		Count	38	1	11	50
		% within VPRPP	76.0%	2.0%	22.0%	100.0%

Figure 4

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	50.000[a]	4	.000
Likelihood Ratio	52.691	4	.000
Linear-by-Linear Association	41.394	1	.000
McNemar-Bowker Test	7.000	2	.030
N of Valid Cases	50		

VPRP Compliance

When calculating for compliance a chi-square test was performed (Figure 5). Of the total 50 charts audited, 40 patients were asked to participate in the VPRP. Of those 40 patients, 39 patients had the appropriate pain reducing technique used on them. Only 1 patient did not have the appropriate pain reducing technique used.

Figure 5

CON * VPRPP Crosstabulation

			VPRPP			
			yes	no	not performed	Total
CON	yes	Count	39	1	0	40
		% within CON	97.5%	2.5%	0.0%	100.0%
		Adjusted Residual	6.7	-4.1	-4.7	
	no	Count	0	0	5	5
		% within CON	0.0%	0.0%	100.0%	100.0%
		Adjusted Residual	-4.4	-.9	7.1	
	not performed	Count	0	5	0	5
		% within CON	0.0%	100.0%	0.0%	100.0%
		Adjusted Residual	-4.4	6.4	-.8	
Total		Count	39	6	5	50

% within CON	78.0%	12.0%	10.0%	100.0%

Figure 6

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	90.625[a]	4	.000
Likelihood Ratio	58.496	4	.000
Linear-by-Linear Association	26.448	1	.000
McNemar-Bowker Test	1.000	2	.607
N of Valid Cases	50		

Discussion

The goal of the VPRP was to decrease pain experienced by pediatric patients coming to the host site for vaccines. As a result of the analysis, the project goal to decrease vaccine related pain was not met which could have been a result of several reasons. The measurements of pain were assessed dependent on a single episode by each patient and not with and without the VPRP. Also, the project was only implemented for a month and only 50 charts were assessed post implementation.

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Implementation of the VPRP did however improve appropriate pain assessment for all patients coming to the clinic for vaccinations. The VPRP built a better understanding on the importance of assessing pain using an age-appropriate pain assessment tool as well as using an appropriate pain reducing method. From the data analysis it was determined that the VPRP was in fact utilized in 97.5% of the patients that consented to take part in the VPRP. This percentage was greater than the objective goal of 75%. The correct pain reducing tool was utilized in 97.4% of the participants meeting the objective for compliance. The multidisciplinary team also assessed pain score pre- and post-implementation of vaccines. The leadership has not determined if the VPRP will be implemented as a standard of care or if changed are needed before complete implementation.

The major outcome of the project did not show a decrease in post implementation scores in relation to pre implementation scores. Before the implementation, the mean pain score was 2.82 and the mean score was 3.38. This score showed that the pain score was higher post implementation versus pre implementation. These findings were opposite of many articles demonstrating the pain reduction in vaccines scores with the implementation of these pain reducing techniques.

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Significance

The overall experience of this QI protocol and the receptiveness of the multidisciplinary team to implement it into practice was positive. Throughout the given educational sessions, the multidisciplinary team was receptive and open to the idea of implementing the VPRP protocol. All agreed that decreasing vaccine associated pain was important. Many were vocal in agreement and asked multiple questions to the team lead to learn the appropriate steps to put the VPRP into practice. There was a need to complete a follow up educational sessions for the new staff that were not present during the initial education sessions in order to address compliance issues. Pain during vaccination sessions is manageable and managing pain does not decrease the efficacy of the vaccine. There are general effective, feasible, non-costly, culturally acceptable, evidence-based strategies to mitigate pain at the time of vaccination (Would Health Organization, 2020).

The leadership team are huge advocates for vaccines and believe it is important to advocate for pain reducing techniques. They also appreciate the fact that the pain reducing techniques used in the VPRP were not expensive and within budget as well as already owned by the host site. With the COVID-19 pandemic, the host site lost revenue so they appreciate anything that can save them money. When implementing changes as DNP nurses, it is important to implement those that are evidence-based practices. When implementing changes, it is also important to work in collaboration as a team to implement best practices at a clinical site.

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Implications for Nursing

Studies from the USA and Canada indicate that 24%–40% of parents are concerned about vaccination-associated pain in children; 85% believe healthcare providers have a responsibility to make vaccinations less painful, and 95% wish to learn how to reduce pain during vaccination of their children (World Health Organization, 2015). As patient advocates, it is important to always look for improvements to decrease procedural pain. Pain is considered a vital sign and it is important to continuously assess for it. As in this VPRP, it was seen that there are numerous methods that can be used to decrease pain during vaccinations. This QI project is important because it advocates for reduction in pain and it includes evidence-based methods that were shown to decrease pain. It is vital for the multidisciplinary team to build a great rapport with the patient as well as with the parent in order to have a less stressful vaccination process.

There will be no financial implications to the clinical site from the results of this VPRP. The pain reducing techniques used in this VPRP either inquire no cost or were already owned by the host site. As a result of this VPRP analysis, the host site will continue implementation and the VPRP and compare post implementation pain scores on patients on multiple occasions. This will help them determine if the pain reducing techniques did decrease the pain levels. The multidisciplinary team is also fully aware of the need to always assess pain levels pre- and post-vaccinations.

Limitations

One of the limitations of the VPRP was the timeframe set by Touro University DNP program. The VPRP was only implemented for 5 weeks which was the time limit set by the University. This 5-week timeframe put a limit on the number of patients that could be included in the VPRP.

Another limitation that related to this project was that it was implemented during the COIVD-19 pandemic. The clinic had a decline in the number of patients coming in for

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vaccinations. Normally, the clinic has a minimum of 100 patients daily but during the 5-week VPRP implementation, half those numbers were showing up to the clinic.

The purpose of the VPRP was to decrease pain during the vaccine administration. The protocol did not take into consideration both the injection as well as the medication administration. The project only addressed the pain after the entire administration of the vaccine.

Dissemination

The results of the VPRP will be reported to all the stakeholders that were involved. Future and continued implementation of VPRP at clinical site will be discussed with administrative members. Dissemination will also be submitted to the Touro University instructors as well submission to the DNP project repository. The team lead will register this VPRP and submit to the Doctors of Nursing Practice 2022 National DNP Conference in Tampa, Florida. The project lead is considering publishing of the VPRP project in the future.

Project Sustainability

For project sustainability, the team lead would have to collaborate with administration leader as well as clinic owner to implement the VPRP. Although the results analysis did not show a decrease in pain levels overall, the administrative team appreciated the protocol in that it has the patient pain reducing alternatives that were not available at the clinic before the VPRP was implemented. The administrative team believe it is important to have a pain reducing protocol even if it helps decrease pain even in one patient.

There is no current policy the organization will adopt at this time, but the administrative team is willing to cooperate with the project lead to make some changes to this VPRP to possibly increase the pain reducing percentages.

In a financial aspect, the VPRP does not pose a financial hardship as all the pain reducing techniques are already owned by the host site or they do not inquire a cost.

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Appendix A Pain

Assessment Tools

Health Care Provider Pain, Distress and Fear Assessment Tools

HELP Children in Pain Kids Adults

HEALTH CARE PROVIDER-RATED DISTRESS

Modified Behavioural Pain Scale (MBPS) For Children ≤ 18 Months

FACIAL EXPRESSION
Definite positive expression: smiling ☐ 0
Neutral expression ☐ 1
Slightly negative expression: for example, grimace ☐ 2
Define negative expression: that is, furrowed brows, eyes closed tightly ☐ 3

CRY
Laughing or giggling ☐ 0
Not crying ☐ 1
Moaning, quietly vocalizing, gentle or whimpering cry ☐ 2
Full lunged cry or sobbing ☐ 3
Full lunged cry, more than baseline cry: to be scored only if infant crying at baseline ☐ 4

MOVEMENTS
Usual movements/activity, or resting/relaxed ☐ 0
Partial movement or attempt to avoid pain by withdrawing the limb where puncture is done ☐ 2
Agitation with complex movements involving the head, torso or the other limbs, or rigidity ☐ 3

TOTAL SCORE (0-10) _____

Reprinted from Journal of Pain and Symptom Management, 10, Taddio A, Nulman I, Koren BS, Stevens, B, Koren, G. A revised measure of acute pain in infants. 456-463. Copyright 1995, with permission from Elsevier.

Face Legs Activity Cry Consolability (FLACC) For Children >18 Months

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

TOTAL SCORE (0-10) _____

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Revised-FLACC For Children With Cognitive Impairment

Category	Scoring 0	1	2
Face Individualized behaviour: _____	- No particular expression or smile	- Occasional grimace/frown; withdrawn or disinterested; appears sad or worried	- Consistent grimace or frown; frequent/constant quivering chin, clenched jaw; distressed-looking face; expression of fright or panic
Legs Individualized behaviour: _____	- Normal position or relaxed; usual tone & motion to limbs	- Uneasy, restless, tense; occasional tremors	- Kicking, or legs drawn up; marked increase in spasticity, constant tremors or jerking
Activity Individualized behaviour: _____	- Lying quietly, normal position, moves easily; regular, rhythmic respirations	- Squirming, shifting back and forth, tense or guarded movements; mildly agitated (e.g., head back & forth, aggression); shallow, splinting respirations, intermittent sighs	- Arched, rigid or jerking; severe agitation; head banging; shivering (not rigors); breath holding, gasping or sharp intake of breaths, severe splinting
Cry Individualized behaviour: _____	- No cry/verbalization	- Moans or whimpers; occasional complaint; occasional verbal outburst or grunt	- Crying steadily, screams or sobs, frequent complaints; repeated outbursts, constant grunting
Consolability Individualized behaviour: _____	- Content & relaxed	- Reassured by occasional touching, hugging or being talked to. Distractible.	- Difficult to console or comfort; pushing away caregiver, resisting care or comfort measures

TOTAL SCORE (0-10) _____

Checklist of Nonverbal Pain Indicators for Adults with Cognitive Impairment

Behavior (all scored 0 = not present; 1 = observed)
1) Vocal complaints: nonverbal (sighs, gasps, moans, groans, cries)
2) Facial grimaces/winces (furrowed brow, narrowed eyes, clenched teeth, tightened lips, jaw drop, distorted expressions)
3) Bracing (clutching or holding onto furniture equipment, or affected area during movement)
4) Restlessness (constant or intermittent shifting of position, rocking, intermittent or constant hand motions, inability to keep still)
5) Rubbing (massaging affected area)
6) Vocal complaints: verbal (words expressing discomfort or pain [e.g., "ouch", "that hurts"]; cursing during movement; exclamation of protest [e.g., "stop," "that's enough"])

TOTAL SCORE (0-6) _____

CNPI figure has been reproduced from https://www.healthcare.uiowa.edu/igec/tools/pain/nonverbalPain.pdf
Feldt KS. The checklist of nonverbal pain indicators (CNPI). Pain Management Nursing 2000;1:13-21 .

r-FLACC figure has been reproduced from Pediatric Anesthesia, 16, Malviya S, Voepel-Lewis T, Burke C, Merkel S, Tait AR. The revised FLACC observational pain tool: improved reliability and validity for pain assessment in children with cognitive impairment, 258-265, Copyright 2006, with permission from Wiley.

PARENT-RATED DISTRESS (Children ≤ 3 Years; Should Be Used in Combination with Self-Report in Children 3-7 years)*

Numerical Rating Scale (NRS)

"Tell me how much distress you think your child had from the vaccine injection from 0 to 10, where 0 is no distress and 10 is the worst distress possible."

Visual Analog Scale (VAS)

No distress ——— Worst distress possible

INDIVIDUAL SELF-REPORTED PAIN AND FEAR

Pieces of Hurt Tool for Children 3-6 Years*

1. Say to the child: *"I want to talk to you about the hurt you may be having right now."*
2. Align the pieces of hurt (e.g., poker chips) horizontally in front of the child on the bedside table, a clipboard, or other firm surface.
3. Tell the child, *"These are pieces of hurt."* Beginning at the chip nearest the child's left side and ending at the one nearest the right side, point to the chips and say, *"This (first chip) is a little bit of hurt and this (fourth chip) is the most hurt you could ever have."* For a young child or for any child who may not fully comprehend the instructions, clarify by saying, *"That means this (one) is just a little hurt, this (two) is a little more hurt, this (three) is more yet, and this (four) is the most hurt you could ever have."*
   - Do not give children an option for zero hurt. Research with the Pieces of Hurt Tool has verified that children without pain will so indicate by responses such as, *"I don't have any."*
4. Ask the child, *"How many pieces of hurt do you have right now?"*
   - After initial use of the Pieces of Hurt Tool, some children internalize the concept "pieces of hurt". If a child gives a response such as "I have one right now", before you ask or before you lay out the chips, proceed with instruction #5.
5. Record the number of chips on the Pain Flow Sheet.
6. Clarify the child's answer by words such as, *"Oh, you have a little hurt? Tell me about the hurt."*

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Faces Pain Scale - Revised (FPS-R) for Children ≥ 5 Years*

In the following instructions, say "hurt" or "pain," whichever seems right for a particular child.
These faces show how much something can hurt. This face *[point to left-most face]* shows no pain. The faces show more and more pain *[pain to each from left to right]* up to this one *[point to right-most face]* – it shows very much pain. Point to the face that shows how much you hurt *[right now]*.
Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so '0' = 'no pain' and '10' = 'very much pain.' Do not use words like 'happy' and 'sad'. This scale is it intended to measure how children feel inside, not how their face looks. www.iappain.org/fpsr

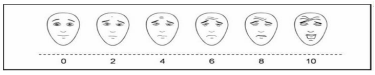


Figure reproduced with permission of the International Association for the Study of Pain® (IASP®). Hicks CL, et al. The Faces Pain Scale – Revised: toward a common metric in pediatric pain measurement. Pain. 2001;93:173-183.

Numerical Rating Scale (NRS) For Children ≥ 8 Years and Adults

Pain: "Tell me how much pain/hurt you had from the vaccine injection from 0 to 10, where 0 is no pain/hurt and 10 is worst pain/hurt possible."
Fear: "Tell me how scared you were during the vaccine injection from 0 to 10, where 0 is not scared at all and 10 is the most scared possible."

Fear Verbal Descriptor Scale for Children 5-12 Years*

Tell me how scared you were during the needle: not at all, a little bit, a medium amount, a lot, or very very much/most possible?

Children's Fear Scale (CFS) for Children 5-12 Years*

These faces are showing different amounts of being scared. This face *[point to the left-most face]* is not scared at all, this face is a little bit more scared *[point to second face from left]*, a bit more scared *[sweep finger along scale]*, right up to the most scared possible *[point to the last face on the right]*. Have a look at these faces and choose the one that shows how scared you were during the needle.
(Score the faces from 0 on the far left to 4 on the far right)

Figure reproduced with permission of the author. http://pphc.psy.uoguelph.ca/index.php/the-childrens-fear-scale/
McMurtry CM, et al. Children's fear during procedural pain: preliminary investigation of the Children's Fear Scale. Health Psychology. 2011;30:780-788.

Faces Anxiety Scale (FAS) for Critically ill Adults

These faces are showing different levels of anxiety. This face shows no anxiety at all, this face shows a little bit more, a bit more *[sweep finger along scale]*, right up to extreme anxiety. Have a look at these faces and choose the one that shows how much anxiety you felt during the needle.

(Score the faces from 1 on the far left to 5 on the far right)

Figure reproduced from Journal of Advanced Nursing 41, McKinley S, Coote K, Stein-Parbury J, Development and testing of a faces scale for the assessment of anxiety in critical ill patients, 73-79, Copyright 2003, with permission from Wiley.

*Children < 7 years may not be reliable in their self-report; ratings from multiple people are recommended (e.g., caregivers, healthcare providers, child)

VACCINATION PAIN REDUCING PROTOCOL

Appendix B

HCPIDT

Appendix 5 (as supplied by the authors): Sample tools for pain mitigation

Health Care Provider Intervention Documentation Tool

Use this document to track pain mitigation strategies used during vaccination and their effectiveness. Use this to prepare for the next vaccination.

Name of individual:	Infants					Toddlers		School Age	Adolescents > 12 - 17 years					Adults		Other Vaccinations (flu, travel...)		
	Birth	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	4-6 years	Age:	Age:	Age:	Age:	Age:	Age:	Age:	Age:	Age:	Age:
Vaccines Administered																		
Interventions:																		
Caregiver presence	☐	☐	☐	☐	☐	☐	☐	☐								☐	☐	☐
Breastfeeding OR	☐	☐	☐	☐	☐	☐	☐									☐	☐	☐
Sweet tasting solution	☐	☐	☐	☐	☐	☐	☐									☐	☐	☐
Positioning: skin to skin contact	☐															☐	☐	☐
holding	☐	☐	☐	☐	☐	☐	☐									☐	☐	☐
Non-nutritive sucking	☐	☐	☐	☐	☐	☐	☐									☐	☐	☐
Topical anesthetic	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Injection without aspiration	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Multiple injections: most painful vaccine last AND/OR	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Simultaneous injection	☐	☐	☐	☐	☐											☐	☐	☐
Inject in vastus laterals	☐	☐	☐	☐												☐	☐	☐
Positioning - upright/sitting								☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Distract – toy, video	☐	☐	☐	☐	☐	☐	☐									☐	☐	☐
Distract - music, video, breathe with toy, verbal distraction								☐								☐	☐	☐
Vibrating device with cold								☐	☐	☐	☐	☐	☐			☐	☐	☐
Breathing method - cough, breathhold														☐	☐	☐	☐	☐
Vapocoolant spray														☐	☐	☐	☐	☐
Neutral verbal signal of procedure	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Muscle Tension (if history of fainting)									☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Post-vaccination assessments (age-appropriate):																		
Provider-rated distress: MBPS (child ≤18 months); FLACC (child >18 months); r-FLACC (child with cognitive impairment/CI); CNPI (adults with CI)																		
Scale 0-10 (MBPS, FLACC/r-FLACC)																		
Scale 0-6 (CNPI)																		
Parent-rated distress: NRS or VAS (child ≤ 3 years or child with CI); (NCCPC-PV for parents of children with CI available at pediatric-pain.ca/our-measures)																		
Scale 0-10 (NRS, VAS)																		
Scale 0-81 (NCCPC-PV)																		
Child self-reported pain: Pieces of Hurt Tool (child 3-6 years); FPS-R (child ≥ 5 years); NRS (child ≥ 8 years)																		
Scale 0-4 (Pieces of Hurt)																		
Scale 0-10 (FPS-R, NRS)																		
Child self-reported fear: CFS or verbal descriptor scale (child 5-12 years); NRS (child ≥ 8 years)																		
Scale 0-4 (CFS, descriptor)																		
Scale 0-10 (NRS)																		
Adult self-reported pain: NRS																		
Scale 0-10																		
Adult self-reported fear: NRS; FAS (critically ill adults)																		
Scale 0-10 (NRS)																		
Scale 1-5 (FAS)																		
* MBPS = Modified Behavioural Pain Scale (0-10); FLACC = Face Legs Activity Cry Consolability and r-FLACC = revised version (0-10); NCCPC-PV: Noncommunicating Children's Pain Checklist-Postoperative version 0-81; CNPI = Checklist of Nonverbal Pain Indicators; CI = cognitive impairment; NRS = Numerical Rating Scale (0-10); VAS = Visual Analog Scale (0-10); Pieces of Hurt Tool (0-4); FPS-R = Faces Pain Scale - Revised (0-10); CFS = Children's Fear Scale (0-4); FAS = Faces Anxiety Scale (1-5). See reverse side for description of these scales and scores; NCCPC-PV available separately at pediatric-pain.ca/our-measures																	
Fainting response? Prodromal - dizzy, light headed, nauseated, sweaty. Actually fainted?																		
Prodromal? Fainted?																		

Appendix to: Taddio A, McMurtry CM, Shah V, et al. Reducing pain during vaccine injections: clinical practice guideline.
CMAJ 2015. DOI: 10.1503/cmaj.150391.

Appendix C

The Donabedian Model

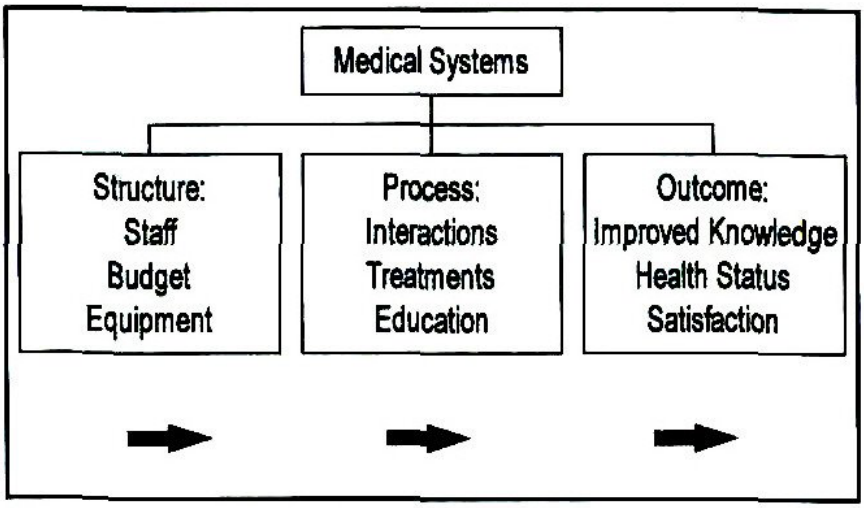
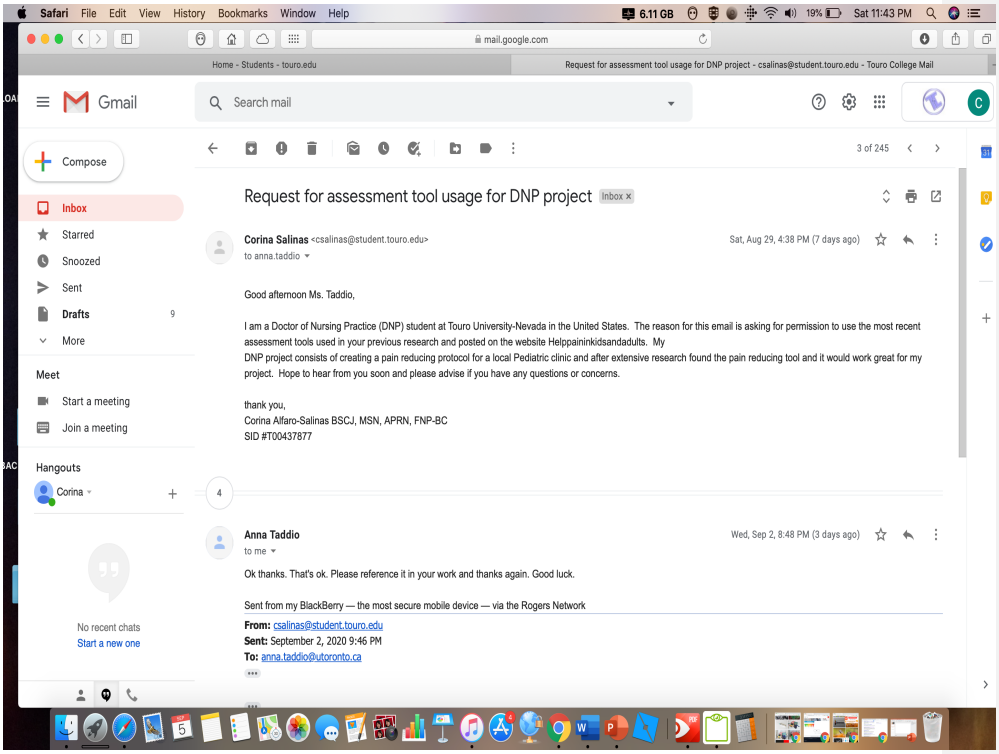


Figure 2. Donabedian Evaluation Model. Model developed by the authors based on concepts described in Donabedian, A. (1966). Evaluating the quality of medical care. *Millbank Memorial Fund Quarterly, 44*(Part 2), 166-206.

Appendix E

Permission to use HCIPT



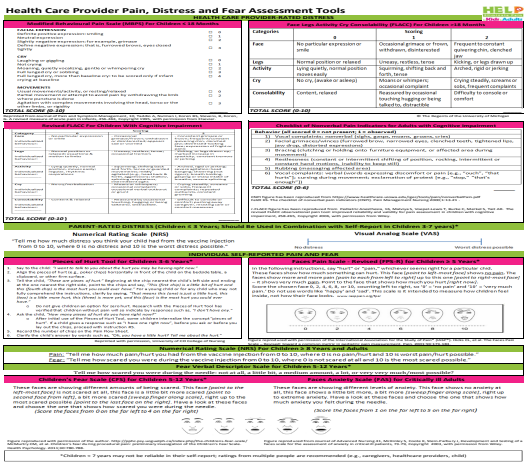
Appendix F

Educational Power Point Presentation

Pain Assessment

- It is important to assess pain as well as manage it as soon as possible.
- It can be especially difficult in younger pediatric patients to identify if they are experiencing pain and if so at what level the pain is at (Hauer & Jones, 2020).
- Pediatric patients undergoing vaccinations are at a high risk of experiencing a high level of pain
- An assessment should be done and effective pain reducing interventions should be implemented.
- Results from a randomized control trial conducted by Redfern et al. (2018) indicated that younger children reported higher pain scores and that age was the strongest factor associated with pediatric pain.

PAIN ASSESSMENT TOOL



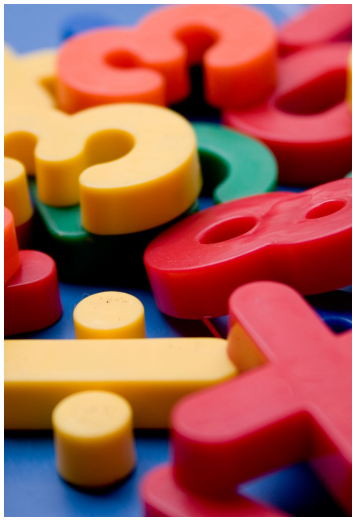
Pain Assessment Tools

Faces, Legs Activity, Cry & Consolability (FLACC)

- widely used observational behavior pain scales

Faces Pain Scale-Revised (FPS-R)

- For school aged children older than 4 years old
- is a revised version of the Faces Pain Scale and allows pain to be scored on a scale between 0-10
- suggests a close linear relationship with visual pain scales in children ages 4-16 years



Pain Assessment Tools

Numeric Pain Scale

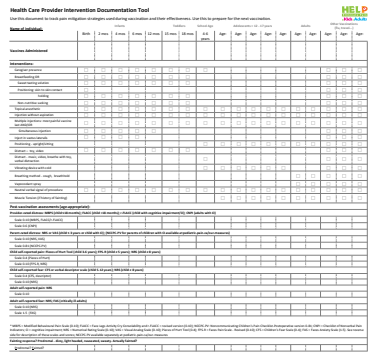
- appropriate for older pediatric patients who are verbal and can self-report their pain rate
- This pain assessment tool rates pain level on a scale between 0-10
- A score of 0 relates to not experiencing any pain and a score of 10 equates the wore pain they have ever experienced

Modified Behavioral Pain scale (MBPS)

- This tool is useful in young children since they are not verbal and unable to rate their own pain level.

Health Care Provider Intervention Documentation Tool (HCPIDT)

Appendix 5 (as supplied by the authors): Sample tools for pain mitigation



Health Care Provider Intervention Documentation Tool

Appendix to: Taddio A, McMurtry CM, Shah V, et al. Reducing pain during vaccine injections: clinical practice guideline. CMAJ 2015. DOI: 10.1503/cmaj.150391

Health Care Provider Intervention Documentation Tool

- The interdisciplinary guideline was developed in 2010 by panel experts who are known as, the HELPinKIDS Team.
- Includes evidence-based pain reducing technique and allows healthcare providers to document which techniques are used and which pain assessment tool was used on the patients.
- There were two objectives in the development of this clinical tool.
  - serve as a clinical practice guideline to assist clinicians in managing procedure related pain
  - decrease the distress experienced by the children undergoing vaccine injections (Taddio et al., 2015)

Pain Reducing Techniques for Infants

- Breastfeeding
  - readily available in which infants can acquire nutrition but also provides maternal skin to skin contact
  - positioning during breastfeeding proves effective in the infant feeling safe and can be very effective as well as very convenient
  - To be effective, breastfeeding should be started with an adequate latch and continue for several minutes after the vaccine is delivered to decrease the painful stimuli (Taddio et. al, 2015)

Appendix G
Project Codebook

ITEM	VARIABLE COD	RESPONSE CODE	COMPLIANCE
Participant's Age	AGE	1=newborn 2=3-6 3=7-11 4=12-17 5=18-21	
Birth Gender	GEN	1=male 2=female	
Verbal Consent	CON	1=yes 2=no	1=yes 2=no
VPRP Participant	VPRPP	1=yes 2=no	
Pain level pre immunization	PPREI	0=0 1=1 2=2 3=3 4=4 5=5 6=6 7=7 8=8 9=9 10=10	
Pain level post immunization	PPOSTI	0=0 1=1 2=2 3=3 4=4 5=5 6=6 7=7 8=8 9=9 10=10	
Pain Assessment tool	PAT	1=Modified Behavioral Pain Scale 2=Face Leg Activity Cry Consolability (FLACC) 3=Revised-FLACC 4=Nonverbal pain indicator f adults 5=Faces Pain Scale 6=Numerical Rating Scale 7=Children's Fear Scale	
Pain relieving method	PRM	1=Caregiver Presence 2=Breastfeeding 3=Sweet tasting solution 4=Skin to Skin 5=pacifier 6=Topical Anesthetic 7=Simultaneous injection 8=Distraction with toy/music/verbal 9=vibrating device with col 10=breathing method/cough/h breath	

Appendix H
Audit Tool

Evaluation Date	Pain Assessment Yes/No	VPRP Utilized Yes/No	Appropriate Pain technique utilized