Reducing Pediatric Pain During Immunizations

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Abstract

Background: Immunizations are often associated with pain and fear in the pediatric population. These negative emotions can have lasting effects on a patient's willingness to receive future medical care, including immunizations. Therefore, it is important to attempt to minimize the amount of pain and fear during all vaccination encounters.

Purpose: A small West Michigan rural clinic had no formal process or tools for reducing pediatric pain during vaccinations. After an extensive literature review, it was decided to implement Buzzy®, a thermomechanical device, into the clinic's standardized practice for all pediatric immunizations. The goal was to improve the pediatric vaccination experience within the clinic.

Methods: Using the PDSA model, two DNP students provided an in-service to the medical assistants on the use of the device. Education was also provided on the data collection tool that included an unvalidated survey assessing the parent/guardian's perception of their child's past and current vaccination experience, as well as the patient's pain level using one of three validated pain scales. Participants between the ages of 0-18 years and their parents/guardians had to be willing to use the Buzzy® device in order to enroll. Data was collected from October 2021 to January 2022.

Results: Forty-five participants agreed to participate in this evidence-based practice (EBP) project. Participants' average pain score was mild with the use of Buzzy® at 2.9 out of 10. The average experience with Buzzy® was found to be significantly higher than the previous average vaccination encounter ($p=.04$). Finally, 95% of participants recommended continued use of Buzzy®.

Conclusion: The implementation of Buzzy® during pediatric immunizations improved the immunization experience in a rural West Michigan clinic. These significant results support the continued use of Buzzy® at the clinic.

Keywords: pediatric, immunization, pain reduction, buzzy, thermomechanical

Reducing Pediatric Pain During Immunizations

Throughout childhood and adolescence there are many vaccinations that are required or suggested for pediatric patients to receive (Centers for Disease Control and Prevention [CDC], 2021). These childhood immunizations have been shown to prevent multiple serious diseases that otherwise could cause health complications or even death (Mical, Martin-Velez, Blackstone, & Derouin, 2021). Immunizations are an important part of routine wellness visits for pediatric patients, but can cause significant pain and anxiety (Redfern, Chen, & Sibrel, 2018).

There are products and procedures that can decrease the pain of childhood immunizations (Canbulat Sahiner et al., 2015; Friedrichsdorf & Goubert, 2019; MacDougall, Cunningham, Whitney, & Sawhney, 2019; & Redfern et al., 2018). Despite this, not all clinics utilize pain reduction strategies during these immunizations. This paper describes an evidence-based project that sought to implement a procedure to reduce pain and improve the patient experience of childhood immunizations in a rural primary health care clinic servicing pediatric patients in West Michigan.

Background and Significance

Immunizations are thought to be one of the most common painful experiences for children and adolescents (Redfern et al., 2018). The pain and distress caused by needle procedures decreases with age, making it a crucial topic to address with pediatric patients (McMurty et al., 2015). It is estimated that immunizations cause severe distress for 50% of school-aged children and 90% of toddlers (Taddio et al., 2009). The fear and anxiety that these vaccinations create can directly affect how the patient receives future immunizations and medical care into adulthood (Canbulat Sahiner, Inal, & Sevim Akbay, 2015). Fear of needles in adults is a public health issue. An example of this is adults who choose not to get the yearly influenza

vaccine because they are scared, which causes an increased risk to people in vulnerable populations, like the elderly (McMurty et al., 2015). Patients who correlate going to primary care offices with painful experiences may delay or avoid coming in for routine visits, causing critical care to be missed (Redfern et al., 2018). Vaccination programs have been negatively affected by fear and anxiety related to prior painful experiences in healthcare settings (Redfern et al., 2018). Therefore, it is imperative that simple interventions to reduce pain and fear should be used whenever possible during immunizations.

Evidence shows that there are several nonpharmacological interventions that can help to reduce the pain associated with childhood immunizations (Taddio et al., 2009). In breastfed infants from birth to two years of age, immediately breastfeeding prior, during, and post vaccination has been found to decrease the acute distress experienced (Shah et al., 2015). In the same age group, administering an oral sucrose solution two minutes prior to vaccinations decreased acute pain and shortened the recovery time (Shah et al., 2015). In older children, there are options for pain and anxiety reduction by using topical lidocaine 30 minutes before vaccination, comfort positioning with parents, and vibrating devices (Friedrichsdorf & Goubert, 2019; Redfern et al., 2018). Despite the efficacy of these interventions, not every clinic utilizes them, making vaccination experiences difficult for pediatric patients.

In addition to the fear and anxiety associated with vaccinations for pediatric patients, there is further concern regarding the geographical area that a patient resides. From a geographical perspective, rural areas historically have had less access to healthcare, lower vaccination rates, and worse health outcomes than their suburban or urban peers (Zhai et al., 2020). For example, in rural communities the human papillomavirus vaccination rates are 12% lower than in urban communities (Gunn et al., 2020). With annual influenza vaccination, the

same difference is noted; rates of pediatric vaccinations in urban settings are 12.6% higher than suburban settings (Zhai et al., 2020). Suburban settings vaccination rates are 7.4% higher than their rural counterparts (Zhai et al., 2020). Multiple factors have been identified that have contributed to these lower vaccination rates in rural areas including access to transportation, misinformation, affordability, and parental attitude to vaccination (Gunn et al., 2020). For healthcare providers, some barriers to vaccination at rural clinics include inadequate education about communicating with parents about vaccines, administration time constraints, and infrequent adolescent visits (Gunn et al., 2020). Clinics with more successful vaccination programs in rural counties had vaccine protocols, a vaccine champion, used every patient visit as an opportunity to vaccinate, and education for staff on how to talk to patients about vaccination (Gunn et al., 2020).

Problem Statement

There are many researched and validated tools to minimize pediatric pain when giving immunizations (Canbulat Sahiner et al., 2015; Friedrichsdorf & Goubert, 2019; MacDougall, Cunningham, Whitney, & Sawhney, 2019; & Redfern et al., 2018). However, the use of these products are not implemented in every clinic. In rural West Michigan, there was a healthcare clinic where there were no evidence-based practice guidelines for pain diversion during pediatric immunizations. This information led to development of a PICO (population, intervention, comparison, outcome) question. In pediatric patients receiving immunizations in a rural West Michigan healthcare clinic, does the use of a pain reduction tool like Buzzy® improve the vaccine experience from the patients', parents' and staffs' perspectives?

Organizational Assessment

Strengths, Weaknesses, Opportunities, and Threats

A strengths, weaknesses, opportunities, and threats (SWOT) analysis was performed to better understand the necessary steps needed to implement this project. The SWOT framework was first developed by Albert Humphrey at Stanford University in the 1960s to understand strengths, weaknesses, opportunities, and threats to implementing change (British Library, n.d.). Some strengths identified in the clinic were a facility team member's enthusiasm about the process change and employee use of patient-focused teamwork. Weaknesses included a gap in knowledge about pain management, as well as staff being short on time. Opportunities existed to improve the overall patient experience during childhood immunizations. The potential resistance to change by staff members presented as a key threat. More detailed information of the SWOT Analysis can be found in Table 1 of Appendix A.

Fishbone Diagram

In addition to the SWOT analysis, a fishbone diagram was created to better understand the clinic's organizational need for this project. The fishbone diagram was developed by Kaoru Ishikawa in the 1960s as a way to discover the root cause for a problem (Mindtools, n.d.). Four main themes were present when assessing the lack of pain and anxiety management during pediatric immunizations in the rural healthcare clinic. These themes include the people, materials, methods, and measurements. The 'people' theme had multiple problems that appeared: fear and anxiety from pediatric patients during immunizations, increased pain response by children, hesitancy from parents to be active participants, lack of staff experience with pediatric patients, and hesitancy from staff to change current practice. The clinic also lacked materials including thermomechanical devices for pain distraction, training on such devices, and the

financial resources to purchase the device. Concerns regarding the methods of vaccination administration were no standardized process for pain and anxiety reduction, clinic wariness of comfort positioning by parents, staff injuries (i.e. accidental needle sticks to staff when a patient moves), partial administration of vaccines to patients or scratches to the patient if they move, and time constraints. Finally, there was no standardized tool utilized to measure the pediatric patient's experience during immunizations. Further details can be found on the fishbone diagram in Figure 1 of Appendix B.

Evidence Based Improvement Model

PDSA Model

In order to complete this clinical practice change, the Plan, Do, Study, Act (PDSA) model was used. This model was designed to help implement change into various healthcare settings through continuous improvement and monitoring of the implementation process (Institute for Healthcare Improvement [IHI], 2021; Taylor et al., 2013). The PDSA model allowed flexibility to carry out change as it was learned what did and did not work within a particular clinical setting (Taylor et al., 2013). This process can help save time and resources during a practice change while minimizing risk to the patients (Taylor et al., 2013).

The '**P**lan' step of the model included identifying the practice problem and brainstorming how to address this problem (IHI, 2021). Creating a plan takes time to develop and requires meeting with stakeholders to decide on what data will be collected as well as how the data will be acquired (IHI, 2021). After a plan is established, the process is tested in the '**D**o' phase. Initial results are recorded as well as any problems or issues with implementation (IHI, 2021). The '**S**tudy' phase is where results are analyzed and the process is reflected on to assess what worked and to identify barriers or obstacles to implementation (IHI, 2021). These results were then taken

into consideration as the final step of the model, '**A**ct', is implemented and modifications are made to the plan for further change implementation (IHI, 2021). For further information on the PDSA model please refer to Appendix C Figure 2.

The specific steps of how the PDSA model will be used in this project are outlined in the methodology section of this paper.

Review of the Literature

Search Strategies

Two databases, PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL), were searched to identify up-to-date and relevant literature regarding thermomechanical interventions to reduce pain, anxiety, and fear of childhood immunizations. An identical search was conducted in both databases. The keywords used were "Buzzy® OR vibrat* OR thermomechanic*" and "pediatric* OR child OR adolescen*" and "immuniz* OR vaccine* OR procedure". The initial search yielded 85 articles from PubMed and 37 articles from CINAHL. Articles published before the year 2011 were excluded, leaving 69 articles from PubMed and 31 articles from CINAHL. One additional article was excluded from PubMed that was not in the English language. After an abstract review to evaluate the applicability of the articles to this project, 10 articles remained from PubMed, and 9 from CINAHL. There were 8 duplicates between the two databases, leaving 11 articles total. These 11 articles were reviewed in more detail and 3 were excluded because they were found to have multiple other variables and therefore were not completely applicable, leaving the final 8 articles.

Of the eight articles, three were systematic reviews and five were randomized control trials. They looked at children of various age groups from 0-18 years of age. All studies reviewed the effectiveness of immunizations using a pain reduction tool compared to traditional

immunizations in an outpatient setting. More information on these articles can be found in Table 2 of Appendix D, including the level of evidence, purpose of the research, framework, results, and implications for practice.

Pain in Childhood and Adolescence

It is well known that vaccines are one of the most common painful experiences that children and adolescents experience (Benjamin et al., 2016; Canbulat Sahiner et al., 2015; Redfern et al., 2017; Taddio et al., 2015). It is also recognized that children experience pain differently than adults and may have a lower pain threshold (Ueki et al., 2021; Ueki et al., 2019). Negative experiences with childhood immunizations can have a lasting impact and lead to needle phobias in adulthood (Ballard et al., 2019; Canbulat Sahiner et al., 2015; Sapci et al., 2021). Non-compliance with immunization programs and low immunization rates are thought to be related to painful needle experiences early in life (Benjamin, Hendrix, & Woody, 2016; Redfern, Chen, & Sibrel, 2017). For these aforementioned reasons, addressing the pain, fear, and anxiety associated with childhood vaccinations needs to be addressed.

Gate Control Theory

Four of the studies referenced the Gate Control Theory as a potential solution to the pain caused by needle related procedures (Benjamin et al., 2016; Canbulat Sahiner et al, 2015; Redfern et al., 2017; Ueki et al., 2021). This theory hypothesizes that non-painful stimulation including vibration and cold at the injection site interferes with the transmission of pain from the injection site towards the brain , therefore reducing the amount of pain experienced from the injection of a needle (Ballard et al., 2019; Benjamin et al., 2016; Canbulat Sahiner et al, 2015; Redfern et al., 2017; Ueki et al., 2021). The addition of a cold sensation to the site may further alter the perception of pain (Benjamin et al., 2016; Canbulat Sahiner et al., 2015). The “Buzzy®”

device is an option for this type of vibration and cooling at the injection site (Benjamin et al., 2016; Ueki et al., 2021).

Buzzy® Device

Buzzy® is a reusable plastic device shaped like a bee that vibrates and has an attached ice pack (Benjamin et al., 2016; Ueki et al., 2021). Many of the studies identified that when Buzzy® was used with both the vibration and cooling feature during immunizations, it was effective in reducing pain in children (Ballard et al., 2019; Canbulat Sahiner et al., 2015; Redfern et al., 2017; Sapci et al., 2021; Taddio et al, 2015). A systematic review of nine studies, found that the use of Buzzy® significantly reduced self-reported pain ($p<0.0001$) and also reduced the pain observed by parents ($p=0.006$; Ballard et al., 2019). A randomized control trial of 104 7-year-olds found that Buzzy® significantly reduced self-reported pain between the experiment and control groups ($p=0.001$; Canbulat Sahiner et al., 2015). Another randomized control trial of 50 children ages 3-18 found that Buzzy® significantly reduced pain in the experimental group ($p=0.015$; Redfern et al., 2017). A third randomized control trial of 95 first grade students found that the use of Buzzy® reduced self-reported pain significantly ($p= 0.000$; Sapci et al., 2021).

Using Buzzy® without the cooling feature was not effective in reducing pain (Benjamin et al., 2016; Ueki et al., 2021). A randomized control trial of 100 children aged 2-7 found that Buzzy® used without the cooling analgesia was not effective in lowering pain ($p= 0.737$; Benjamin et al., 2016). There was no significant difference in pain between the experimental and control group when Buzzy® was used without the cooling in a randomized control trial of 118 children aged 0-6 years old ($p=0.25$; Ueki et al., 2021).

Using Buzzy® with vibration and cooling was successful in reducing anxiety in children (Ballard et al., 2019; Sapci et al., 2021; Ueki et al., 2019). Parents reported a significant decrease

in their children's anxiety ($p=0.0004$), in a systematic review that included 1138 participants (Ballard et al., 2019). Self-reported anxiety was significantly reduced ($p=0.004$) in a randomized control trial of 95 first grade students (Sapci et al., 2021). Buzzy® additionally lowered self-reported anxiety in pediatric patients ($p<0.01$; Ueki et al., 2019). Since Buzzy® is a device that can be used for multiple patients, it is a cost-effective option for pain intervention during immunizations.

Cost-Effectiveness

Buzzy® is a fairly quick, easy, and cost effective intervention to implement (Benjamin et al., 2017;Redfern et al., 2017 Sapci et al., 2021). This product is multi-use and can be easily disinfected between patients (Canbulat Sahiner et al., 2015). The implementation of Buzzy® only added about 30-50 seconds to each patient's visit (Redfern et al., 2017). The estimated cost of the reusable Buzzy® is only $0.09 for each use (Redfern et al., 2017).

Goals and Expected Outcomes

The intent for this evidence-based project is to improve the pediatric patients' experience during routine immunizations. This goal was measured through a questionnaire and a validated pain scale applicable to the patient's age. The expected outcome was that patients would report a low pain score and there would be a significant improvement in parents' perception of the vaccination process with the use of Buzzy®.

Methods

Clinic Description

This project was implemented in a small rural primary care clinic that is associated with a large healthcare organization in Western Michigan. This organization's mission statement is to "improve health, inspire hope, and save lives" (Spectrum Health, 2019). The clinic strives to

fulfill that mission in the rural community in which it serves. One of the ways it achieves this goal is through its routine child immunizations.

The clinic provides primary healthcare for patients across their lifespan. The population in focus for this project include pediatric patients from newborn to eighteen years old. According to statistics provided by the clinic, they have 2037 children that they are actively providing care to (J. Synder, personal communication, June 29, 2021). The breakdown of patients that they see are as follows: 562 patients - zero to two years old; 684 patients - three to six years old; 348 patients - seven to ten years old; 129 patients - eleven to twelve years old; and 314 patients - thirteen to eighteen years old (J. Synder, personal communication, June 29, 2021). The clinic accepts all insurance types including Medicaid, private, and self-pay (J. Synder, personal communication, June 29, 2021). In 2019, the clinic administered 4577 vaccinations to pediatric patients, whereas 4097 vaccinations were given in 2020 (J. Synder, personal communication, May 25, 2021). Younger patients received the majority of these injections with 76% of them given to those between zero and two years old, followed by 11% of the vaccinations given to three and six years old (J. Synder, personal communication, May 25, 2021).

There are many staff members that work in the clinic to provide care to these children and their families. The team consists of ten medical assistants (MAs), two registered nurses (RNs), one licensed practical nurse (LPN), two physicians, two physician assistants (PAs), nine resident physicians, a social worker, and a care manager (J. Synder, personal communication, May 25, 2021). Each one of these team members have a unique role to provide care to the patients within the clinic.

For a typical immunization encounter, the process normally starts the day prior to the visit (J. Synder, personal communication, June 25, 2021). The MAs pre-chart within the

electronic health record (EHR) on each patient for the following day and note if a patient is due for an immunization by checking the state immunization record, Michigan Care Improvement Record. They add preliminary orders for the vaccinations due to the EHR flagging the provider that the patient is due for these vaccinations. When the patient arrives, the MA brings them to their exam room where they complete vitals and get a medical history including reason for the visit. They also provide a vaccine information sheet to the patient or parent/guardian for any immunizations the patient is due for, so they can read through it prior to the provider entering the room. The provider then comes into the room to continue with the physical exam and plan of care, including a conversation about if the patient or parent/guardian(s) want to proceed with outstanding immunizations. If the patient or parent/guardian(s) refuse vaccinations, the MA will bring in a refusal form for them to sign. If they agree to updating immunizations, two MAs will return to the room with the vaccinations. One MA will then position the patient in an appropriate comfort hold for their age while the second provides the intramuscular injection(s). After the immunization is complete, the visit is over and the patients leave. The MA then strips and cleans the room, preparing it for the next patient (J. Synder, personal communication, June 25, 2021).

Although this process had been used by the clinic for years, they wanted to improve it by including techniques for pain reduction while administering immunizations (J. Synder, personal communication, May 25, 2021).

Ethical Considerations/Protection of Human Subjects

Prior to the implementation of this evidence-based project, approval was obtained from both the Michigan State University Internal Review Board (IRB) and Spectrum Health's IRB. The Buzzy® device was to be used for all immunizations at the clinic on patients 0-18 years unless the patient or their parent/guardian refused. The Buzzy® device is approved by the Food

and Drug Administration for pain reduction during immunizations (Pain Care Labs, 2021). As part of this evidence-based project, the patient's pain level was assessed or self-described and the vaccination experience was rated. No personal identifiable patient information was collected during this project.

Setting Facilitators and Barriers

As described in detail above, this evidence-based project took place in a rural primary care clinic that services patients of all ages, however, the focus of this project was only on pediatric patients 0-18 years. Full support for this project was given by the clinic's operations manager, and a letter of support can be found in Figure 3 Appendix E. The organizational onboarding practices for DNP students was completed.

In order to better understand the needs of this clinic, facilitators that could have eased the implementation of this project, and barriers that could have impeded this project's success, a SWOT analysis and fishbone diagram were created (Appendix A and B), and were previously described.

The Intervention and Data Collection Procedure

The purpose of this project was initially quite broad. The original goal was to improve patient experience with painful procedures in this rural primary care clinic. After much discussion, research, and planning, the goal of this project was narrowed to improving the immunization experience by reducing pain in patients aged 0-18 years. The PDSA Model was utilized to guide the implementation of this project (Appendix C).

Plan

In the summer of 2021, two family nurse practitioner students met via Zoom with the operations manager of several rural primary care clinics in West Michigan. The purpose of this

meeting was for the DNP students to learn about the needs of these clinics, and to discuss and identify the goals of the operations manager. It was identified that there was a need to improve painful experiences for children in general, but particularly during immunizations, as they were noted to be the most common painful experience that children encountered in these clinics. The decision was made to focus on one clinic to start. The operations manager chose to start with the largest clinic with the hope of implementing this evidence-based project at the remaining clinics if successful.

Following the meeting with the operations manager, the DNP students spent several weeks researching interventions to improve the immunization experience in children and adolescents 0-18 years. There was significant research supporting the use of Buzzy® during immunizations to reduce pain (Ballard et al., 2019; Canbulat Sahiner et al., 2015; Redfern et al., 2017; Sapci et al., 2021; Taddio et al, 2015). It was decided between the DNP students and the operations manager that several Buzzy® devices would be purchased for the clinic, with the cost being covered by the clinic.

The DNP students decided that they would not have any patient contact during the implementation of this project. The DNP students planned to train the MAs on several different validated pain scales, so a pain score could be collected on every child 0-18 years old receiving an immunization. In order to evaluate the effectiveness of Buzzy® during immunizations, the DNP students also developed an unvalidated Likert scale that assessed parent/guardian perception of their child's previous immunization experience and the current response using Buzzy®. The pain and Likert scales used can be found in Appendix F, Figures 4, 5, 6, and 8.

Do

In mid-October of 2021, the DNP students held an in-person education session with MAs at the clinic who administer vaccines to patients 0-18 years old. This education session included information on how to use Buzzy®, how to clean Buzzy®, how to administer pain scales to patients who are old enough to rate pain themselves, and how to assess pain in children with an age-appropriate pain scale who are too young to rate their own pain. The DNP students familiarized the MAs with the survey (Appendix F, Figure 8) and instructed them on how to give the survey to the parent/guardian accompanying their child to their immunization. Some MAs were not present for the training, so the DNP students composed a detailed email explaining the goal of the project and the MAs role in it. The email was also sent to the MAs who were in attendance so they could use it as a point of reference.

The MAs administered a survey to all parents that included the Likert scales discussed above. On this survey, the MAs documented a pain score for every patient. The completed surveys, which had no personal identifiable information, were kept secure in the office managers office. Participation in this project was on a voluntary basis, so the parent/guardian could choose not to use Buzzy® or not to fill out the survey.

During this phase, the clinic manager had the DNP students' schedule available and could email or call them with any questions or concerns that the MAs may have had as they implemented this project. The DNP students reached out to the clinic manager after one week to evaluate the implementation of the project. The clinic manager noted that things were off to a slow start, however, she did have some surveys completed. Further communication with the clinic manager determined that the low participation seemed to be a workflow problem. The DNP students offered to hold another education session, but it was deemed unnecessary as there

did not seem to be any confusion on the implementation process, more so just an adjustment period as the MAs got used to the Buzzy® device. At this time, the clinic manager included her clinic supervisor into the discussion to see if she could offer any other insight.

Approximately one month after the implementation began, the DNP students collected the completed surveys from the clinic. It was found that eight surveys had been collected and out of those, three were completed fully. The DNP students reached out to the clinic manager and the clinic supervisor to identify barriers to increased participation. It was decided that the clinic manager would "re-rollout" the implementation and encourage the MAs to use Buzzy®. The clinic manager also sent out information about the project in the clinic's weekly newsletter, in hopes of increasing participation.

Study

The DNP students collected and reviewed the surveys in late January of 2022. When reviewing the surveys, the DNP students hoped to see an improvement in the parent/guardian's perception of their child's immunization experience when Buzzy® was used. The DNP students also hoped to see a low pain score in the majority of patients with the implementation of Buzzy®. During this phase, the DNP students were available to talk with the MAs to learn about any barriers that they encountered during the implementation of this project.

Act

The first PDSA cycle was completed at the end of March 2022. At this time, the DNP students discussed the results of the surveys with the operations manager of the clinic via email. Topics discussed included the results of the project, what went well, what did not work, and improvement opportunities in the process. One of the main proposals for improvement the DNP students suggested was to provide education in a more formal environment instead of during a

brief huddle in between patients. The practice manager was satisfied with the results of the project and had already started rolling out the use of the Buzzy® device to the other clinics she manages.

Measurement Instruments/Tools

In order to measure the outcomes of this evidence-based DNP project, a combination of validated pain scales were chosen to develop a questionnaire (Appendix F). The pain scales used in this study include: the FLACC pain scale, the Wong-Baker Faces® pain scale, and the numeric pain scale. Depending on the patient's age, the MAs determined which scale to use to measure the patient's pain following immunization using Buzzy®. The FLACC pain scale is an observed pain score that has been validated for patients two months to seven years of age (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997). The Wong-Baker Faces® pain scale is a self-reported pain scale that has historically been used with school aged children but has been validated for patients three to 18 years of age (Wong-Baker Faces® Foundation, 2020). Permission was granted to use the Wong-Baker Faces® pain scale for this project, and can be found in Appendix F. The numeric pain scale is another self-reported pain scale that has been validated for patients ages eight and older (Kemp, 2018). A questionnaire was developed to assess the parent or guardian's perspective on their child's previous immunization experience versus the vaccination experience with the Buzzy® device. This unvalidated questionnaire was created because a validated tool to evaluate the parent or guardian's perspective did not already exist.

Timeline

This evidence-based practice improvement project occurred over the course of three semesters. The planning phase occurred during the summer of 2021, the implementation phase

occurred in Fall 2021, and data analysis and completion of the project occurred in Spring 2022. The timeline of this project is demonstrated in Table 3 of Appendix G.

Analysis

The goal of this project was to improve the pediatric vaccination experience in a rural health clinic in Western Michigan. The implementation of the Buzzy® device occurred in mid-October and data collection was completed in January. Initially, there was resistance from the medical staff to use the device so primary data collection was slower than expected.

There were a total of 45 pediatric patients and their parents who agreed to use the Buzzy® device and complete the associated survey. At least eight patients and/or parents were documented as refusing to participate. Of these 45 surveys, 29 were completed with both the parent's perception of their child's vaccination experience and the child's pain score fully filled out. The majority of the incomplete surveys (13) did not include the post-vaccination pain score with Buzzy®. The authors decided, with the help of the university statistician, to still use the data collected from the incomplete surveys to measure the parent's perception of the vaccination experience.

To analyze the data, the first four questions on the data collection tool (seen in Appendix F) were converted into numerical figures in order to be entered into an excel spreadsheet. Questions 1 & 4 on the survey had "yes" or "no" responses and these were converted into a score of "1" or "2". Questions 3 & 4 were qualitative Likert scale questions and had five responses that parents could choose from including "good", "somewhat good", "neutral", "somewhat bad", or "bad". These qualitative responses were changed to 5 through 1 respectively and entered into the spreadsheet. All entries were double checked by both DNP students.

The average age of the pediatric participant in this project was 3.9 years, with 25 males and 20 females. The average number of injections each patient received at the visit was 2. The average pain score that was recorded by MAs (n=31) was 2.9. This score is consistent with low/mild pain of less than 3 on a 10-point scale (Boonstra et al., 2016).

To compare the vaccination experience with the Buzzy® device to a previous vaccination experience, the DNP students used the responses from questions 2 & 3 and completed a paired t-test. The average previous vaccination experience was rated as 3.88 or neutral. The students had to input one average response to question 3 for a missing response in one survey. With that average response inputed for one survey, the average vaccination experience with Buzzy® was rated as a "4.16" or "somewhat good". This improvement in scores was enough to show a significant difference between the previous vaccination experience and the one with Buzzy® ($p=.04$). It was also found that 95% of participants that fully completed the survey would recommend the use of the Buzzy® device in future immunizations. See Appendix I for further information.

These results were consistent with the goal of the DNP project at improving the vaccination experience for pediatric patients by using the Buzzy® device. When speaking with the MAs at the clinic, they also supported the success of the project. They stated that it was easy to use and they were going to continue to use it with every willing participant. This feedback further supported the success of this EBP project.

Budget

The costs associated with this evidence-based project were thoroughly examined as part of the planning process. The largest initial cost associated with this project was the cost for buying the Buzzy® device. Each Buzzy® device costs approximately $100 (Pain Care Labs,

2021). With the size of the clinic, a minimum of six Buzzy® devices was suggested to start the project. Additional costs that were needed included office supplies, such as paper, printer ink, and clipboards for the production and distribution of the surveys. There was also a need to include the cost for cleaning supplies to disinfect the Buzzy® between uses. The total cost for this project was estimated to be $730. Cost of the Buzzy® device and office supplies were covered by the clinic. If this project were to be reproduced, there would be the additional cost of one to two RNs to lead the evidence-based project. See Table 4 in Appendix H for more information.

Sustainability Plan

Sustainability of this project is feasible. Since the Buzzy® devices have already been purchased by the clinic, the only additional cost associated with their continued use is to replace the batteries as needed. Per the manufacturer, two AAA batteries will supply each Buzzy® with 20 hours of use, meaning that each device can be used for hundreds of immunizations before batteries need to be replaced (Buzzy4Shots, 2022).

The current MAs at the clinic have voiced their support of Buzzy® and their plan to continue its use. The office manager also stated that the use of Buzzy® for pediatric immunizations is an expectation for the MAs to use with parental and patient permissions. Support of the device by current staff is crucial to sustainability, as it will be up to them to train future MAs on the use of Buzzy®. Training materials on the device were left at the clinic for future reference.

Discussion/Implications for Nursing

Pain management in patients is a responsibility of nurses at every level, from undergraduate nursing students to advanced practice nurse practitioners. Adverse and painful

experiences with immunizations as children can cause a fear of healthcare that follows patients into adulthood (Canbulat Sahiner, Inal, & Sevim Akbay, 2015). The fear and anxiety related to prior painful experiences in healthcare settings has negatively affected vaccination programs (Redfern et al., 2018). The Covid-19 pandemic has shown how crucial vaccine participation is for public health. This project has demonstrated that the implementation of a simple device, like Buzzy®, has the potential to improve the immunization experience in children. Hopefully, these positive experiences will stay with these patients as they become adults and encourage them to continue receiving routine health care from primary care.

Conclusion

For children and adolescents, immunizations are thought to be one of the most common painful experiences (Redfern et al., 2018). It is estimated that 90% of toddlers and 50% of school-aged children experience severe distress from immunizations (Taddio et al., 2009). The negative experiences that these immunizations create can have lasting consequences into adulthood (Canbulat Sahiner, Inal, & Sevim Akbay, 2015). There is significant evidence to support the use of nonpharmacological interventions to help reduce the pain associated with childhood immunizations (Taddio et al., 2009).

This evidence-based DNP project sought to improve the vaccine experience of pediatric patients at a rural health clinic where no pain reduction strategies were utilized to decrease the pain experienced during pediatric immunizations. The use of Buzzy®, a thermomechanical device, was implemented at the clinic for all pediatric immunizations, unless the patient or guardian refused. The MAs administered an unvalidated survey to willing participants evaluating the parent/guardian's perception of their child's previous vaccine experience without Buzzy® and the current vaccine experience with Buzzy®. Each survey also rated each patient's pain

using one of three age-appropriate validated pain scales. Of the 45 participants, the average pain score with the use of Buzzy® was 2.9 out of 10. Buzzy® was shown to improve the immunization experience, with a statistically significant increase in the parent/guardian rating of the immunization experience ($p=.04$). Lastly, 95% of participants recommended the continued use of Buzzy® for future immunizations. These results were consistent with the goal of this project.

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Appendix A

Table 1

SWOT Analysis of the Healthcare Clinic's Current Vaccination Process

Strengths	**Weaknesses**
• Patient focused teamwork • Facility team member enthusiastic about the process change • Willingness to try new things • Access to obtain/purchase supplies • Established communication and education opportunities	• Lack of understanding of pain management techniques • Staff inexperience working with the pediatric patient population • Short on time during patient encounters
Opportunities	**Threats**
• To improve patient experience during childhood immunizations • Development of a standard work process • Staff education on pain management techniques during immunizations	• Resistance to change by staff members • Non-adherence to the new standard of work • Patient/parent hesitancy to new immunization technique

Appendix B

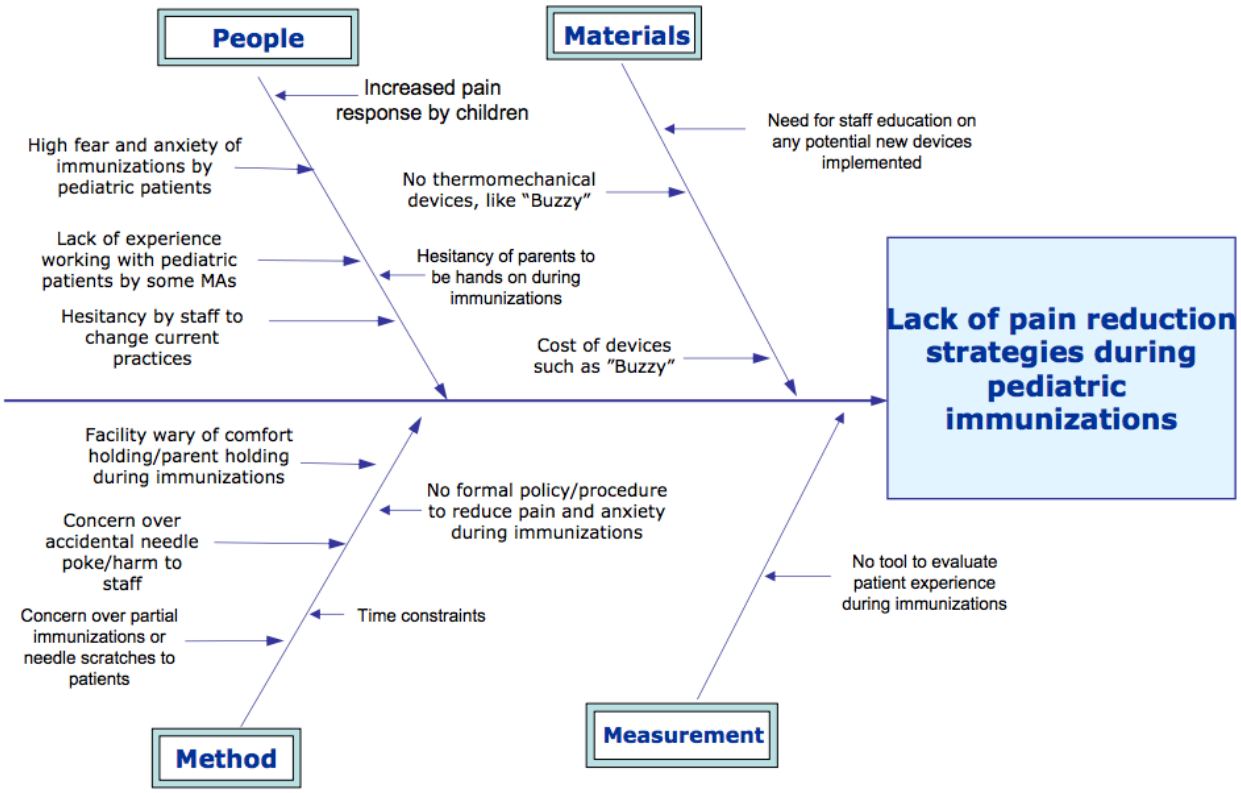


Figure 1. Fishbone diagram

Appendix C

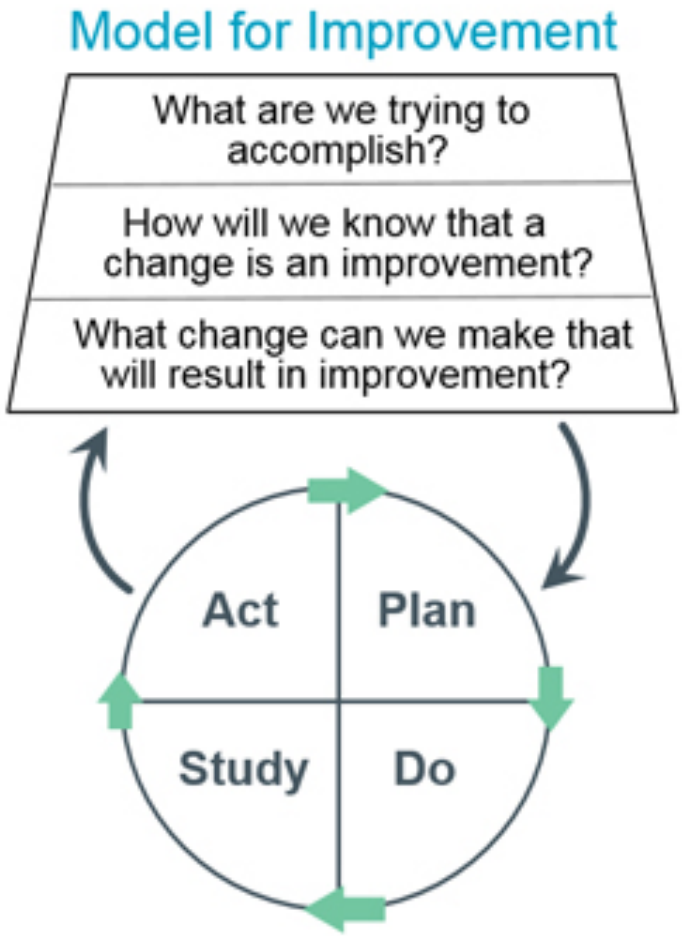


Figure 2. PDSA Model. Adapted from "Science of Improvement: Testing Changes" by the Institute for Healthcare Improvement, 2021. Retrieved from http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

Appendix D

Table 2

Literature Synthesis

Author/Title	Level of Evidence	Purpose of the project/research	Framework	Results	Relation to this project	Implications for Practice
Ballard et al. (2019) Efficacy of the Buzzy® device for pain management during needle procedures	Systematic Review Included 9 studies with 1138 participants between 3-18 years	To review the efficacy of the Buzzy® device for procedural pain in children	Review followed PRISMA guidelines No specific framework Multiple pain scales used	Buzzy® significantly reduced: -self reported pain ($p<0.0001$) -parent reported pain ($p=0.006$) -observer reported pain ($p=0.001$) -observer reported anxiety ($p< 0.00001$) -parent reported anxiety ($p=0.0004$)	The significant reduction in pain and anxiety noted by the Buzzy® device in this systematic review would be a helpful tool to use during immunizations	Buzzy® is an easy to use, inexpensive, reusable device that can quickly work to diminish pain in pediatric patients during needle procedures through vibration and cooling sensations

Benjamin, Hendrix & Woody (2016) Effects of vibration therapy in pediatric immunizations	Randomized Control Trial Not able to blind 100 children 2 months to 7 years	To determine if vibration therapy (via Buzzy®) without cold therapy reduces pain in children during vaccinations	No framework Pain Scale: FLACC	Buzzy® without the cooling analgesia was not effective on lowing pain (p=0.737)	The use of Buzzy® for vibration as a distraction without ice pack is not effective for pain relief	Vibration alone is not effective in reducing pain in pediatric patients
Canbulat Sahiner, Inal, & Akbay (2015) The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children	Randomized Control Trial Not able to blind 104 school children age 7 years	Investigate the outcome of external cold and vibration via Buzzy® on a child's pain and anxiety during intramuscular immunizations	No framework Pain Scale: Wong-Baker Faces® Anxiety Scale: Children Fear scale	Buzzy® significantly reduced: -self reported pain between experiment and control groups (p=0.001) - observed pain between experiment and control groups (p=0.001) -observed anxiety between experiment and control groups (p=0.001)	Buzzy® was effective on school age children for fear and pain reduction	The use of external cold and vibration can be used to reduce pain and anxiety in pediatric patients during immunizations

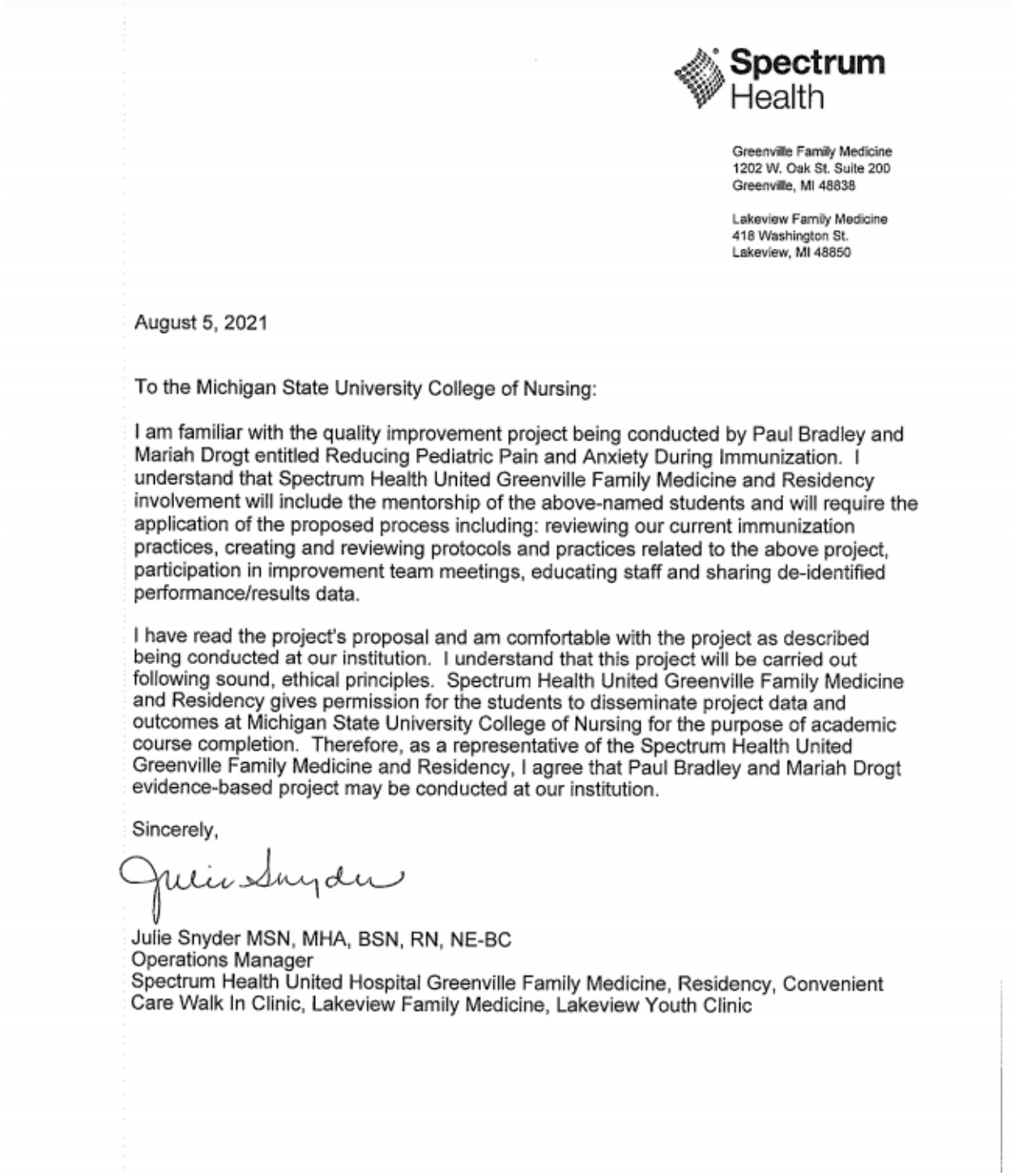
Redfern, Chen, & Sibrel (2017) Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients	Randomized Control Trial Not able to blind 50 kids aged 3-18	Investigate the impact of a nonpharmacological vibration and cooling intervention (Buzzy®) to reduce pediatric pain	No framework Pain Scale: Wong-Baker Faces® Anxiety scale: Modified Wong-Baker Faces®	Buzzy® significantly reduced pain in the experimental group (p=0.015) Buzzy® did not reduce anxiety (p=0.43)	Buzzy® significantly reduced pain in pediatric patients, but not anxiety. No validated anxiety tool was used.	The Buzzy® is an easy intervention to use to reduce pain during pediatric vaccination.

Sapci, Bilsin Kocamaz, & Gungormus (2021) Effects of applying external cold and vibration to children during vaccination on pain, fear, and anxiety	Randomized Control Trial Not able to blind 95 first grade students	Evaluate effectiveness of external cold and vibration (Buzzy®) on children's pain, fear, and anxiety during immunization	No Framework Pain Scale: Wong-Baker Faces® Anxiety: State anxiety inventory for children Fear scale: Children's fear scale	Buzzy® significantly reduced: -self reported pain (p=0.000) -Nurses observed pain (p=0.000) -Self reported anxiety (p=0.004) Buzzy® did not lower a child's reported fear (p=0.081)	Buzzy® is effective in reducing pain and anxiety but not fear in pediatric patients receiving vaccines	External cold and vibration during immunizations helps lower a child's pain and anxiety

Taddio et al. (2015) Procedural and physical interventions for vaccine injections	Systematic Review 31 studies included	Evaluating the effectiveness of various physical and procedural interventions for reducing pain during immunizations	GRADE and Cochrane methodologies guided review process No framework	2 studies focused on the use of Buzzy® in children 4-7 years old. Pain was significantly reduced in those who used Buzzy®. There was not a correlation between the Buzzy® and fear reduction	Buzzy® helps with pain reduction but not fear in pediatric patients receiving vaccinations	There are benefits of using Buzzy® for pain reduction in children receiving vaccinations.
Ueki et al. (2021) The effectiveness of vibratory stimulation in reducing pain in children receiving vaccine injection	Randomized Control Trial 118 children ages 0-6 years old Single blinded	Previous research has shown that Buzzy® works well to reduce pediatric pain during immunizations. This study wanted to explore if using just vibration and no cold would still reduce pain during vaccinations.	No Framework Pain Scale: FLACC	There was not a significant difference in observed pain between the experimental group and the control group with using the Buzzy® with no ice. (p=0.25)	Do not use Buzzy® without the cooling feature because it is not effective.	Using the Buzzy® without the cooling feature is not beneficial in lowering pediatric pain

Ueki, Yamagami, Makimoto (2019) Effectiveness of vibratory stimulation on needle-related procedural pain in children	Systematic Review 21 RCT were reviewed. Vibrating devices with and without thermal components were included.	Gather evidence of the effectiveness of vibratory stimulation for pain reduction in children during routine vaccinations	Joanna Briggs Institute methodology for systematic reviews	Vibratory stimulation was significant in reducing self reported and observed pain during needle procedures ($p<0.01$) It was also helpful in lowering self-reported anxiety in pediatric patients. ($p<0.01$)	Buzzy® was effective in lowering the pain and anxiety in pediatric patients during immunizations	Vibratory stimulation is effective in lowering pain in pediatric patients. Low level of evidence since blinding could not be completed, individual preference should be used when thinking of using in practice

Appendix E



Spectrum Health

Greenville Family Medicine
1202 W. Oak St. Suite 200
Greenville, MI 48838

Lakeview Family Medicine
418 Washington St.
Lakeview, MI 48850

August 5, 2021

To the Michigan State University College of Nursing:

I am familiar with the quality improvement project being conducted by Paul Bradley and Mariah Drogt entitled Reducing Pediatric Pain and Anxiety During Immunization. I understand that Spectrum Health United Greenville Family Medicine and Residency involvement will include the mentorship of the above-named students and will require the application of the proposed process including: reviewing our current immunization practices, creating and reviewing protocols and practices related to the above project, participation in improvement team meetings, educating staff and sharing de-identified performance/results data.

I have read the project's proposal and am comfortable with the project as described being conducted at our institution. I understand that this project will be carried out following sound, ethical principles. Spectrum Health United Greenville Family Medicine and Residency gives permission for the students to disseminate project data and outcomes at Michigan State University College of Nursing for the purpose of academic course completion. Therefore, as a representative of the Spectrum Health United Greenville Family Medicine and Residency, I agree that Paul Bradley and Mariah Drogt evidence-based project may be conducted at our institution.

Sincerely,

Julie Snyder

Julie Snyder MSN, MHA, BSN, RN, NE-BC
Operations Manager
Spectrum Health United Hospital Greenville Family Medicine, Residency, Convenient Care Walk In Clinic, Lakeview Family Medicine, Lakeview Youth Clinic

Figure 3. Agency Support Letter.

Appendix F

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- Arched, rigid, or 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; distractile 2- Difficult to console or comfort	
Total score (0-10)	

Figure 4. FLACC Pain Scale. Adapted from "The FLACC: a behavioral scale for scoring postoperative pain in young children." by Merkel, S. I., Voepel-Lewis, T., Shayevitz, J. R., & Malviya, S. , 1997, *Pediatric Nursing*, *23*(3), 293–297.

Appendix F

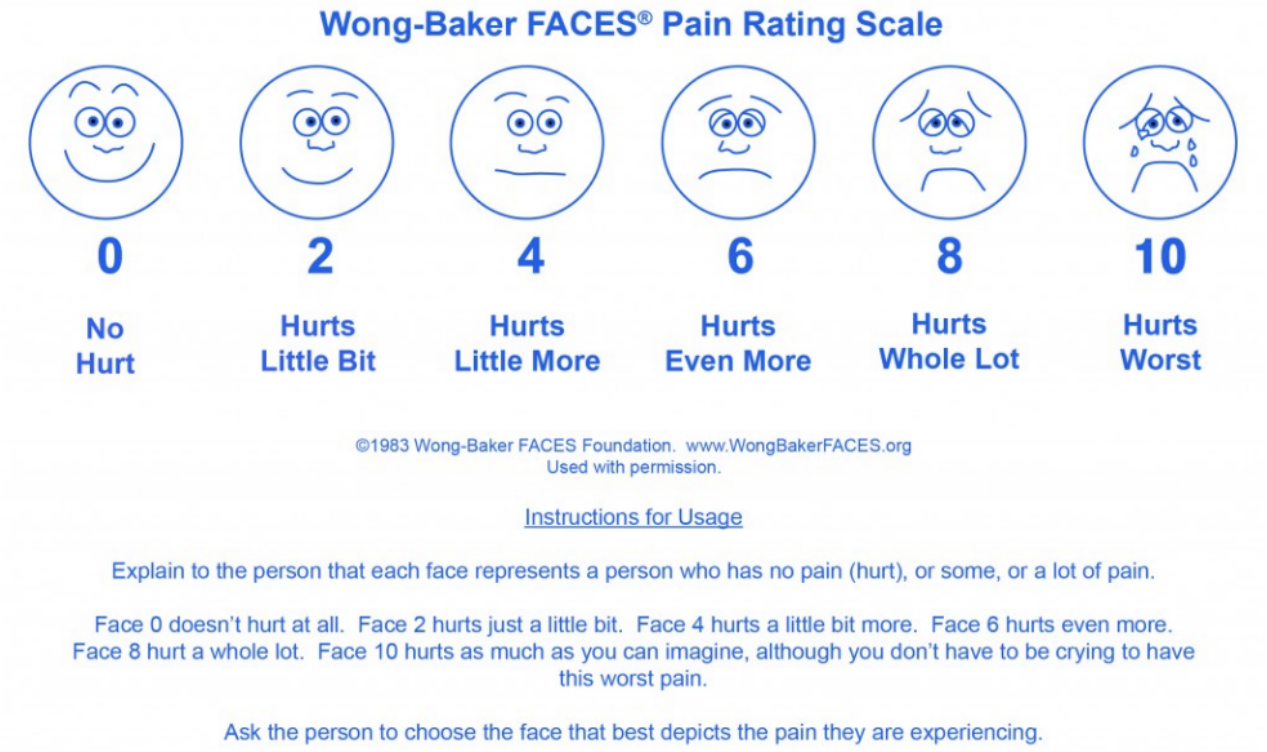


Figure 5. The Wong-Baker Faces® Pain Scale. Adapted by the Wong-Baker Faces® Foundation, 2020. Used with permission. Retrieved from https://wongbakerfaces.org/ Copyright 2020 by the Wong-Baker Faces® Foundation.

Appendix F

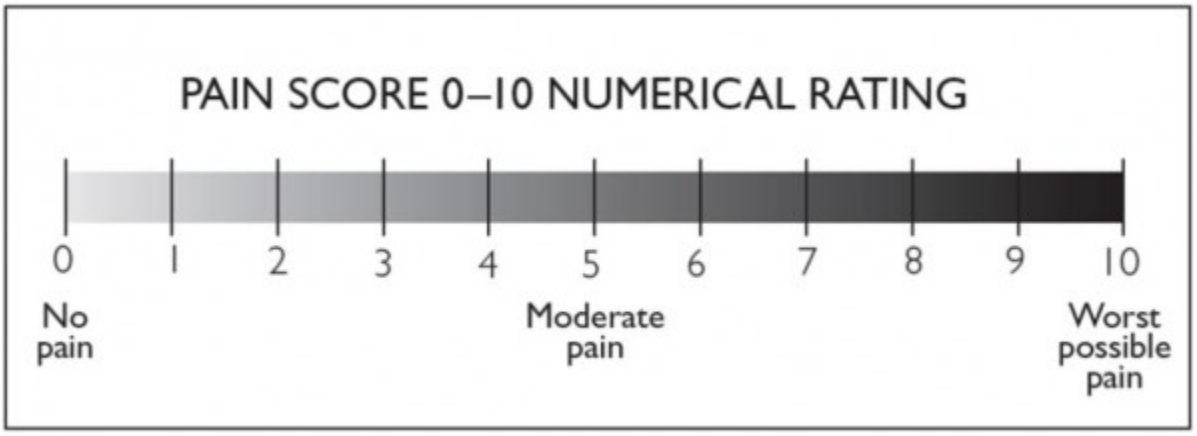
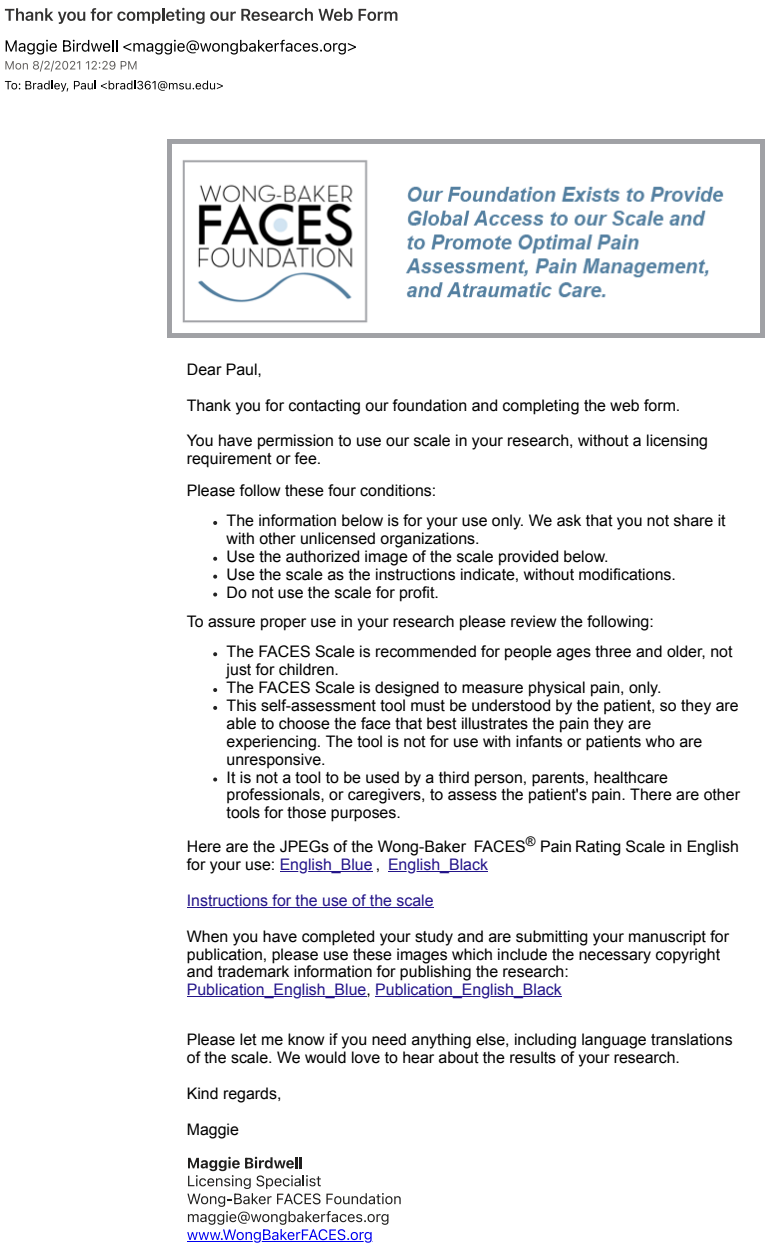


Figure 6. Numeric Pain Scale. Adapted from "Numeric Pain Rating Scale" by Physiopedia, 2021. Retrieved July 28, 2021, from https://www.physio-pedia.com/Numeric_Pain_Rating_Scale#cite_note-6

Appendix F



Thank you for completing our Research Web Form

Maggie Birdwell <maggie@wongbakerfaces.org>
Mon 8/2/2021 12:29 PM
To: Bradley, Paul <bradl361@msu.edu>

WONG-BAKER FACES FOUNDATION

Our Foundation Exists to Provide Global Access to our Scale and to Promote Optimal Pain Assessment, Pain Management, and Atraumatic Care.

Dear Paul,

Thank you for contacting our foundation and completing the web form.

You have permission to use our scale in your research, without a licensing requirement or fee.

Please follow these four conditions:

- The information below is for your use only. We ask that you not share it with other unlicensed organizations.
- Use the authorized image of the scale provided below.
- Use the scale as the instructions indicate, without modifications.
- Do not use the scale for profit.

To assure proper use in your research please review the following:

- The FACES Scale is recommended for people ages three and older, not just for children.
- The FACES Scale is designed to measure physical pain, only.
- This self-assessment tool must be understood by the patient, so they are able to choose the face that best illustrates the pain they are experiencing. The tool is not for use with infants or patients who are unresponsive.
- It is not a tool to be used by a third person, parents, healthcare professionals, or caregivers, to assess the patient's pain. There are other tools for those purposes.

Here are the JPEGs of the Wong-Baker FACES® Pain Rating Scale in English for your use: English_Blue , English_Black

Instructions for the use of the scale

When you have completed your study and are submitting your manuscript for publication, please use these images which include the necessary copyright and trademark information for publishing the research:
Publication_English_Blue, Publication_English_Black

Please let me know if you need anything else, including language translations of the scale. We would love to hear about the results of your research.

Kind regards,

Maggie

Maggie Birdwell
Licensing Specialist
Wong-Baker FACES Foundation
maggie@wongbakerfaces.org
www.WongBakerFACES.org

Figure 7. Authorization to use the Wong-Baker FACES pain scale in this DNP project.

Appendix F

Pediatric Immunization Pain Reduction Survey

Disclaimer: This survey is a tool being used to assess the vaccination experience. This survey is optional, however results will be used to assess the change in the vaccination process.

To be filled out by the Parent/Guardian:

1. Have you been present with your child during previous vaccinations?

   Yes or No

2. If yes, please rate your child's previous vaccination experience.

   Good Somewhat Good Neutral Somewhat Bad Bad

3. Please rate the current vaccination experience with the use of the Buzzy.

   Good Somewhat Good Neutral Somewhat Bad Bad

4. Would you recommend continued use of the Buzzy device during future immunizations?

   Yes or No

To be filled out by the Medical Assistant:

Patient's age _____ Patient's Gender_____ Number of injections _____

Patient's rating of pain (please only use one of the following pain scales)

FLACC pain rating (2 months-7 years old) _____

Wong Baker Faces pain rating (3-18 years old) _____

Numeric pain scale rating (8-18 years old) _____

Figure 8. Parent survey and MA data collection tool. Created by DNP students Paul Bradley and Mariah Drogt for this project.

Appendix G

Table 3

Project Timeline

Task	**Summer Semester 2021 Planning**				**Fall Semester 2021 Implementation**				**Spring Semester 2022 Evaluation**			
	May	June	July	August	September	October	November	December	January	February	March	April
Meet with Agency	X											
Clinical Question	X											
Literature Review		X										
Project model, SWOT, and Fishbone		X	X									
Develop Methodology			X									
IRB preparation and submission			X	X								
Meet with Clinic Staff					X	X						
Implement project and Data Collection						X	X	X	X			
Analyze data									X	X		
Interpret results										X		
Finalize Project											X	X

Note: X= Complete, I = Incomplete

Appendix H

Table 4

Project Budget

Item	Cost
Paul Bradley DNP student	$30/hr x 180 hrs = $5,400*
Mariah Drogt DNP student	$30/hr x180 hrs =$5,400*
Buzzy® devices	$99.95 x 6 = $599.70
Office supplies	$100
Cleaning supplies	$30
Snacks for staff during training	$50*
Total Cost	**$729.70**

Note: * indicates a donation by the authors.

Appendix I

Table 5

Participant Demographics

Demographics Table		
Age Range	2 Months	13 Years
Average Age	3.9 Years	
Gender	25 Males	20 Females
Average number of Injections	2	

Appendix I

Table 6

Project Results

Results Table	
Average Pain Score	2.9
Previous Vaccination Experience	3.88
Vaccination with Buzzy	4.16
Significant change between vaccination experiences	p=.04*

Note: * indicates statistical significance.

Appendix I

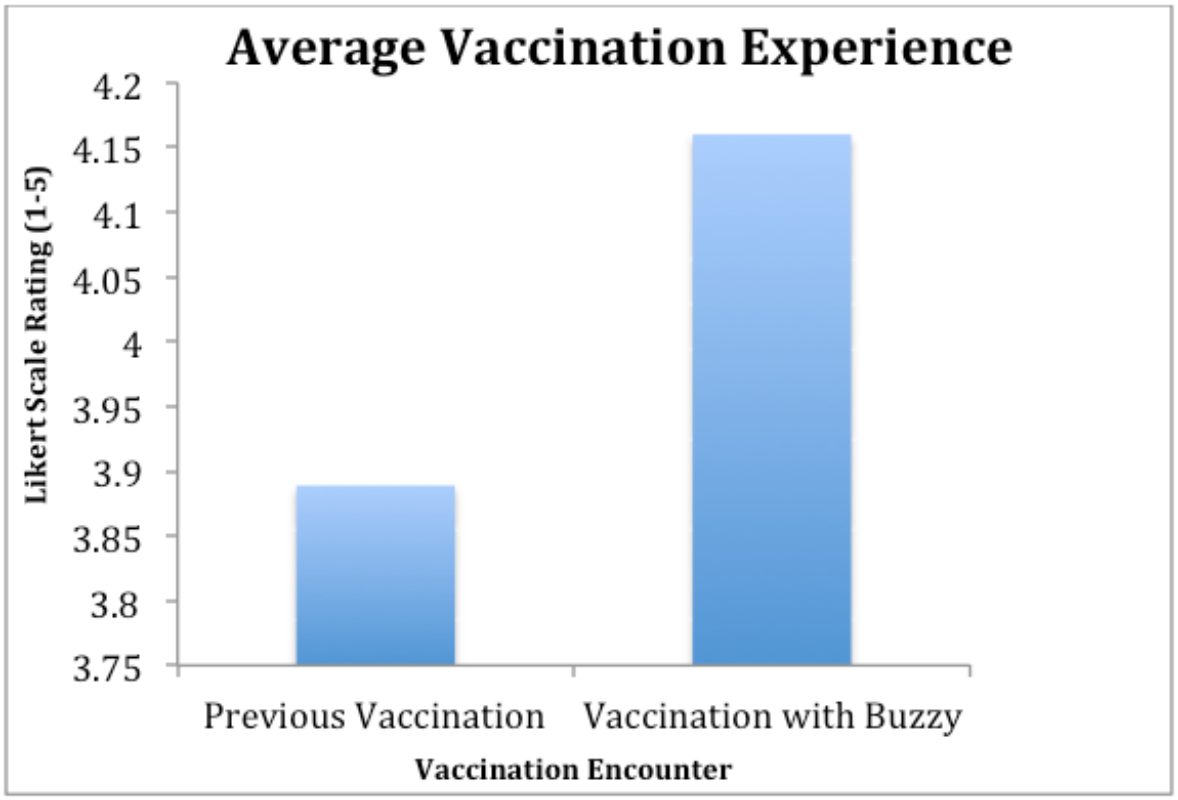


Figure 9. The average vaccination experience at previous vaccinations vs those with the use of the Buzzy® . The vaccination experience with the use of Buzzy® was rated significantly higher than previous vaccinations (p=.04).