

# Implementing a clinical protocol using breastfeeding to mitigate vaccination pain in infants

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## ARTICLE INFO

### Article history:

Received 2 May 2020

Revised 23 May 2020

Accepted 24 May 2020

Available online xxxx

### Keywords:

Breastfeeding

Vaccination

Pain-relieving

Protocol

## ABSTRACT

**Background:** Although an effective public health intervention and a routine pediatric practice, vaccines are a common source of iatrogenic pain in childhood. Techniques, such as exam table restraint may cause infants to struggle and heighten distress, but studies demonstrate that breastfeeding and lap holding are effective strategies to reduce injection pain during vaccination.

**Local problem:** Adoption of pain-relieving techniques into clinical practice is often underutilized. In a pediatric clinical practice in southern Connecticut, there were no guidelines for providing pain mitigation strategies, including breastfeeding, during infant vaccination.

**Methods and interventions:** The Plan-Do-Study-Act (PDSA) cycle was used for the improvement process. A clinical protocol introduced breastfeeding as a pain-relieving strategy during vaccination; lap holding was a second option. All clinical staff were educated on the infant pain experience, and nurses were further trained on vaccine administration techniques during breastfeeding.

**Results:** A total number of 354 infants were seen for vaccination during the 12-week project: 168 were breastfed infants, of which 53% were breastfed during vaccination; 234 were placed on the parent/caregiver's lap during vaccination; and only 13 infants were restrained on the exam table. There was no documentation of position for 18 infants.

**Conclusions:** A clinical protocol was an effective tool to guide nurses on pain-relieving options, such as breastfeeding and lap holding, during vaccine administration. Positive experiences during vaccination administration have the potential for short-term and long-term benefits including, compliance with routine care and adherence to vaccination schedules.

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## Introduction

### Problem description

Routine vaccinations are a common source of pain in infancy and childhood, and the pain associated with injections is a source of distress for children, parents, and healthcare providers (Ouach et al., 2019). An estimated 30% of adults have a fear of needles. In most cases, needle fear develops in childhood and may result in avoidance of vaccinations (McLenon & Rogers, 2019). Minimizing pain during vaccination may decrease distress, fear of needles, and subsequent healthcare avoidance behaviors, such as non-adherence with vaccination schedules (Taddio et al., 2010). In early infancy, there are six different recommended vaccine series by the Centers for Disease Control and Prevention (CDC),

including the Vitamin K injection administered at birth, totaling 16 injections for infants of ages 0–6 months (CDC, 2016).

A growing body of evidence supports the efficacy of non-pharmacologic interventions to reduce newborn and infant pain related to minor procedures (Aydin & Inal, 2019; Reece-Stremtan & Gray, 2016). Endogenous opiates in human milk, suckling, skin-to-skin contact, and holding while breastfeeding decrease signs of pain during newborn immunizations (Bembich et al., 2018; Benoît, Martin-Misener, Latimer, & Campbell-Yeo, 2017; Fallah, Naseezadeh, Ferdosian, & Binesh, 2017; Harrison et al., 2018; Obeidat & Shurique, 2015; Reece-Stremtan & Gray, 2016). Avoiding pain while delivering health care is recognized in the medical ethics principle of non-maleficence. Given the potential for short- and long-term consequences of vaccine related pain and the responsibility to apply the “First, do no harm” dictum, clinical practice protocols are needed to incorporate strategies for pain reduction during vaccination injections.

As is the case for many pediatric clinics, there was no protocol for mitigating pain during vaccine administration at the practice site prior

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to the quality improvement (QI) project. Techniques for vaccine administration varied from nurse to nurse and were primarily determined by nurses' training and prior experience. The WHO along with the CDC recommends holding children during vaccination (CDC, 2019; WHO, 2016); however, infants were routinely placed supine on the examination table. Despite evidence-based practice supporting non-pharmacologic interventions to reduce pain, providers and nurses were not advocating using breastfeeding as a pain management strategy, and the lack of a vaccination administration protocol allowed for individual techniques.

The QI project was performed in an outpatient pediatric setting for the purpose of increasing the use of breastfeeding as a pain management strategy during routine infant vaccine administration at the clinic. A clinical protocol was developed and implemented, which served to ensure consistency in nursing and provider practice. The specific aim of the project was to have 25% of breastfeeding mothers breastfeed their infant, age six months or younger, during routine vaccination at the clinic by the end of the 12-week project.

#### *Available knowledge*

Taddio, Ilersich, Ipp, Kikuta, and Shah (2009) supported the role of breastfeeding during vaccination utilizing a systemic review of randomized controlled trials summarizing physical, non-pharmacologic interventions to reduce pain during immunization. The articles authored by Taddio over the course of nearly a decade, provide the clinical foundation and background for practice change by incorporating pain relieving strategies into practice (Taddio et al., 2002, 2007, 2009, 2010). Taddio et al. (2010) provided clinical guidance to better manage pain during vaccination. The guideline recommends 17 pain relieving strategies for healthcare providers to offer parents and children (as appropriate) when counselling on immunization administration. This research continues to be a reference and resource for pain relieving strategies of the infant and child in the pediatric outpatient setting. Additional authors have continued to study the analgesic effects of breastfeeding for painful procedures.

Obeidat and Shurique (2015) compared the efficacy of breastfeeding with maternal holding to maternal holding without breastfeeding during minor painful procedures in term neonates. The findings indicated that breastfed infants who were also held by their mothers experienced less pain than those who were only held by their mothers. Aydin and Inal (2019) also conducted a randomized controlled trial demonstrating that breastfeeding and heel warming are effective in reducing heel stick-related pain in newborns; however, breastfeeding contributed to a greater calming effect.

Russell and Harrison (2015) provide practice recommendations promoting breastfeeding, not only during, but also after immunization administration. The World Health Organization published its first policy paper in 2015 on pain mitigation during vaccination. The recommendations include breastfeeding of infants, during or shortly before the vaccination session, or having the caregiver hold the infant during vaccination. Additional clinical guidelines were established in 2016, when Reece-Stremtan, Gray and the Academy of Breastfeeding Medicine (ABM) published Clinical Protocol #23 outlining non-pharmacological management of procedure-related pain in the breastfeeding infant. The protocol endorsed breastfeeding as the optimal choice to mitigate pain in infants undergoing a painful procedure.

A systematic review by Benoit et al. (2017) provides an update on the evidence regarding the effectiveness of direct breastfeeding versus offering expressed breast milk to reduce procedure associated pain. Expressed breast milk was not shown to be an effective analgesic, rather direct breastfeeding was endorsed as a primary intervention in reducing pain for infants undergoing minor procedures, such as heel stick, venipuncture, and intramuscular injections. This conclusion is further supported by Harrison et al., (2018) in a Cochrane Review of studies examining the effect of breastfeeding on procedural pain in infants.

The review's conclusion was that breastfeeding consistently reduced behavioral responses to pain such as cry duration; however, there was no supporting evidence to show that breastfeeding impacted the physiologic response to pain.

Bembich et al. (2018) examined neonatal cortical brain response to non-pharmacological analgesia while undergoing heel stick. The study looked to differentiate the effect of either oral glucose or breastmilk given alone or combined with maternal holding or maternal holding and breastfeeding. As demonstrated in other studies, direct breastfeeding while being held as well as oral glucose administration while being held were more effective than either offering the infant oral glucose or expressed breastmilk alone.

Ouach et al. (2019) conducted a survey to assess parents' perception of children's pain and distress during vaccination. The observational study reinforces the importance of implementing age-appropriate evidence-based support for children and families during vaccination administration. One practice guideline discussed in the paper suggest several pain mitigation strategies including direct breastfeeding, lap holding, kangaroo care, oral sucrose, topical anesthesia, and distraction.

#### *Rationale*

Cognitive theories guide the application of principles in a variety of situations. Albert Bandura, a renowned psychologist in the field of education, proposed a social learning theory in the late 1970's and further refined the theory throughout his career. The Social Cognitive Theory suggests a continuous interaction between the person, environment, and behavior. Behavior is directed by expectations and reinforcement or rewards, and Bandura concluded reinforcement as an influencer increases the likelihood of adoptive behavior. A collaborative approach to observational learning requires the use of peers and expert role models, and a person's self-efficacy, or self-confidence, for performing a behavior is influenced by his/her capabilities as well as environmental facilitators and barriers (LaMorte, 2016).

Bandura's theory was relevant to the introduction of a new clinical protocol that required a change in behavior, change in the environment, and change in practice. Nurses were asked to change their current practice of vaccination administration to incorporate a new technique, necessitating greater interaction with parents. Environmental changes included changes the documentation process, room setup, and workflow. Learning and performing a new skill to influence and guide mothers to put an infant on the breast during vaccination administration required observation, self-efficacy, and reinforcement through feedback and praise. Reinforcement of nurses' behavior was directed by the project coordinator and project champions primarily through staff meeting discussions and weekly reminders upon review of nurses' documentation of interventions. Nurses' own observation of benefits associated with project interventions served to reinforce behavior. Self-efficacy was promoted by providing the opportunity for nurses to practice techniques during a role modeling in-service and self-confidence was strengthened over time through deliberate practice, resulting proficiency of the new skill.

#### **Methods**

##### *Context*

The pediatric practice for the QI project is a private office setting in southern Connecticut. The clinic provides routine primary care to infants, children, adolescents and young adults and sees approximately 500 primary care patients a week, ranging in age from newborn to 26 years. The practice follows the vaccination recommendations outlined by the CDC (CDC, 2019). Nurses are paired with a provider who usually sees the patient before ordering appropriate vaccinations. With parental consent, vaccines are administered by a nurse (licensed practical nurse or registered nurse). Prior to QI project, the manner or style of vaccine

administration was determined by the individual nurse, and since there was no standardized way to administer vaccines for the practice, technique was determined by the individual nurse's clinical experience. Additionally, there were no set guidelines for providing non-pharmacologic pain strategies, including offering mothers the option to breastfeed, during infant vaccination. Nurses documented vaccine administration and site in the EHR, but there was no documentation of infant positioning during vaccination.

## Interventions

### Planning

IRB review concluded that the project did not meet the definition of human subject research and approved it as a quality improvement project. Stakeholder engagement was essential in the initial stages of planning. From the onset, the managing partners were excited about the project and required little convincing, as the practice is viewed as a breastfeeding friendly. However, the various members of the interdisciplinary team of practitioners, physician assistants, nurses, and medical assistants had different perspectives on the project. Discussions during the planning stage served to communicate the project mission and solicit input prior to project implementation. Nurses were concerned about providing consistent messaging to patients, so laminated cards with a four-paragraph script were placed in the nurses' workstations. The cards fit nicely within the vaccination tray so nurses could read the script to parents when reviewing infant positioning prior to vaccination.

The Plan-Do-Study-Act (PDSA) cycle was utilized in the clinical improvement process, which allowed for real time adjustments, such as discussion of the QI initiative at the weekly nursing meetings. To better understand nursing issues and concerns, the project coordinator attended weekly nursing meetings to answer questions, review problems encountered by nurses, and share ideas nurses could use when talking about the intervention with mothers. Meeting also ensured adoption and sustainability of the project by supporting the nurses who were essential in the change process.

Room Preparation was also part of the planning stage. The practice had two designated baby rooms for well visits, which were equipped with a rocking chair, ottoman, and designated breastfeeding pillows for mothers to use if needed. Since these rooms were not always available, the routine clinic rooms were also set up to facilitate breastfeeding during vaccine administration. No additional costs were incurred, rather existing furniture and supplies were simply re-allocated. Working with the head nurse and practice management, a few modifications to the rooms were made, including adding armless chairs to clinic rooms, which facilitated breastfeeding during vaccination while allowing full access to the infant's leg. Receiving blankets were moved from the baby rooms to the scale cart, ensuring that each room had access for additional privacy during a breastfeeding session. An adjustable roller chair seat was added to each room, giving nurses mobility and flexibility in her own positioning as to administer vaccines at the same level as a seated breastfeeding mother. Each nurse had a vaccine tray which held the injections, alcohol, Band-Aids, allowing her to enter the room with all necessary supplies.

### Clinical practice protocol development

The primary ethical consideration for the project concerned non-breastfeeding mothers and infants. It was imperative that the clinical protocol contained a provision for pain management if breastfeeding was not an option. Lap holding has been shown to be an effective physical intervention to reduce vaccine injection pain (Taddio et al., 2009); therefore, the option of lap holding was included in the CPG and offered to all parents, while breastfeeding during vaccination was encouraged for breastfeeding mothers. The protocol outlined the procedure to standardize vaccination administration for infants 0–6 months. Components of the procedure included having nurses determine breastfeeding

status, encourage and provide breastfeeding mothers with the rationale for to nurse the infant during vaccination, assist with proper positioning (including when infant pulls off the breast during the injection), recommend lap holding for non-breastfed infants, discourage placement on exam table, administer most painful vaccines last, and document infant position in the EHR.

### Electronic health record modification

The electronic health record required revisions to include a new section within the immunization tab with check boxes to indicate infant position during vaccination administration. The check boxes included breastfeeding, parent lap position, positioning on the examination table, as well as an "other" section for additional positions or a combination of positions to be captured. After vaccination, nurses documented infant positioning in the well visit template within the EHR. A free text option was available under each check box for nurses to provide additional documentation, such as "infant started on the mother's breast for two vaccines but sat on father's lap for the third vaccine" or "mother is pumping only and not putting the infant directly to the breast." Free text documentation was instrumental for understanding parental/caregiver choices, but succinct documentation was encouraged in an effort to not impact nurses' workflow or productivity.

### Clinical staff education

The project coordinator provided education and training to the entire clinical staff using a power point presentation about the infant pain experience and evidence-based research supporting breastfeeding as a pain relieving intervention during a painful procedure, specifically, vaccination administration. The new clinical practice protocol was introduced as part of the presentation. To assess baseline knowledge and nurses' self-confidence, a pretest was given immediately before the presentation; the same test was administered as a posttest at the conclusion of the educational session. A 5-question knowledge section focused on general questions about the infant pain experience, while 5 self-efficacy questions explored clinician confidence in the vaccination process, including administering vaccines in different positions and directing the parent/caregiver on how to position the infant. Approximately 85% of the clinical staff attended the presentation, and those unable to attend received one-on-one education about the QI project and new clinical protocol. A separate nursing in-service was conducted to demonstrate vaccine administration during breastfeeding, which allowed nurses to practice positioning with infant dolls. Approximately 80% of nurses attended. The in-service employed role playing, clinical scenarios, and script review to help nurses become more confident with to new protocol.

### Measures

As a process measure, pre and posttest scores were compared to determine if the clinical staff's basic knowledge about managing procedural pain and their self-confidence in offering and assisting mothers to breastfeed during vaccine administration improved following the educational intervention. The proportion of total correct responses for the knowledge questions was calculated and mean scores pre and post-educational intervention were compared. Responses to Likert-scale items that measured self-efficacy were converted to a numerical value and the mean scores before and after the educational intervention were compared.

The project's primary outcome measure was the percentage of breastfeeding mothers who breastfed their infant during routine vaccination. Only infants who directly breastfed at home (exclusively or in part) were included in the breastfeeding during vaccination rate calculation. Nurses documented infant feeding status at home (breast, bottle) and whether breastfed infants nursed during vaccine administration. Data were obtained from the EHR. The secondary outcome measure was infant position (held in parent/caregiver lap, breastfed, placed on

exam table) during vaccine administration, which nurses documented in the EHR.

### Analysis

There were no baseline data related to infant position or the frequency mothers chose to breastfeed during routine infant vaccination, as clinic staff had not considered breastfeeding a pain management strategy or realized the relevance of documenting position prior to the QI project. The percentage of breastfeeding mothers who breastfed their infant during vaccine administration was plotted on a run chart to visually illustrate improvement in rates following project implementation. Analysis of the run chart data in real time guided rapid cycle PDSA methodology, explained variations in rates of breastfeeding during vaccination, and helped validate achievement of the project goals. Other project outcomes, such as infant position and reasons for lap placement, are graphically described. All data were collected, reviewed, and analyzed on a weekly basis.

### Results

#### Staff knowledge and self-efficacy

Eighty-five percent of the clinical staff (MD, NP, PA, RN, MA) attended the educational session. One nurse practitioner and one physician received one-on-one education because neither was able to attend the scheduled group session. One RN did not participate in the training, but she only worked in primary care when the clinic was short-staffed (i.e., twice during the project period). Following the educational session designed to increase nurses' and providers' general knowledge of the infant pain experience and self-efficacy for using strategies to decrease procedural pain (i.e., breastfeeding and lap placement), scores improved by 10.2% and 4.3%, respectively.

#### Breastfeeding during vaccination

Breastfeeding during vaccination was the primary outcome measure for the QI project. Studies have shown most women return to work between 8 and 12 weeks postpartum (Ogbuanu, Glover, Probst, Liu, & Hussey, 2011); therefore, the age range of 0–6 months was chosen to

capture the greatest number of breastfeeding infants for the QI project. Most infants who breastfed at the time of vaccination were one, two, or three months in age, resulting in 20.2%, 23.6%, and 21.3% of the total infants, respectively. The percentage of breastfed infants decreased for infants over three months of age (Fig. 1).

During the 12-week intervention period, a total of 354 infants were seen in the office for well care and routine vaccination. Of the total number of infants, 168 (47.5%) were breastfed infants, and the number of breastfed infants who nursed during vaccination totaled 89 (53.0%) (Fig. 2).

Fig. 3 illustrates the percentage of breastfed infants who were breastfed during vaccine administration over the length of the project. Following implementation of project interventions, the run chart illustrates an initial increase in rate between weeks 1–4, as nurses became engaged in the project, and weekly nurse champions were assigned at the staff meetings to support the new protocol and answer staff questions. There was a subsequent decline in infants breastfeeding between weeks 5–6, during which the majority of vaccinations were administered by a nurse who had a particularly heavy caseload and poor buy-in with the QI project; she thought it was more convenient and saved time to place the infant on a parent's lap. Through weeks 7–12, there was an overall increasing trend, save for a dip at week 10 when the majority of infants (67.7%) seen in the clinic were not breastfed infants. Of the 10 infants who were breastfeeding at home, 4 (40%) breastfed during vaccination. Even with the periods of declining rates, a mean of 53.4% of infants breastfed during vaccination.

#### Infant positioning during vaccination

A secondary goal was to reduce the incidence where infants were placed on the examination table, rather than being held, during vaccination. Positioning and restraining infants on the exam table heightens distress during immobilization, causing the infant to struggle (Russell & Harrison, 2015). For the total infant population, without differentiating breastfeeding status (i.e., regardless of bottle or breast at home), 66.1% were placed on the lap during vaccination, 25.1% were placed on the breast, and only 3.7% were placed on the exam table. Approximately 5% of infants had no documentation of position in the EHR (Fig. 4).

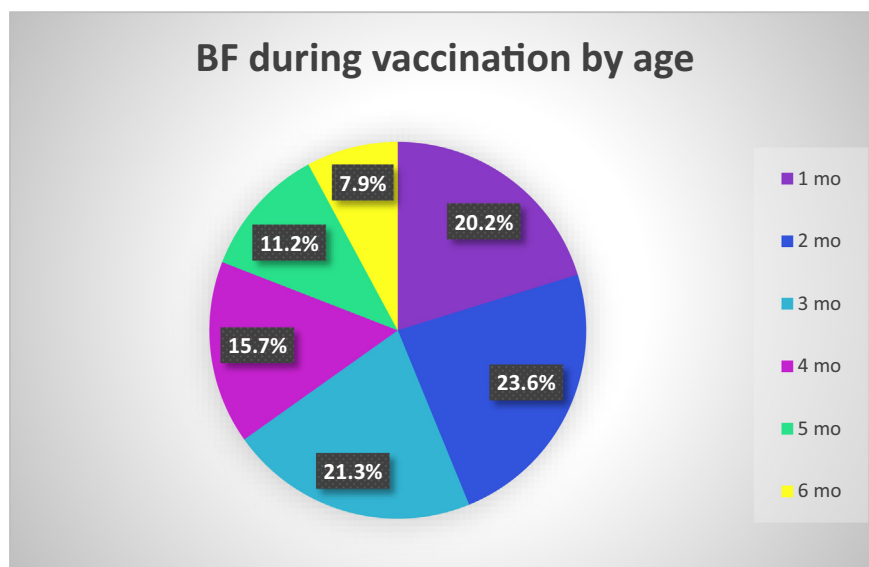


Fig. 1. Breastfeeding during vaccination by age (months).



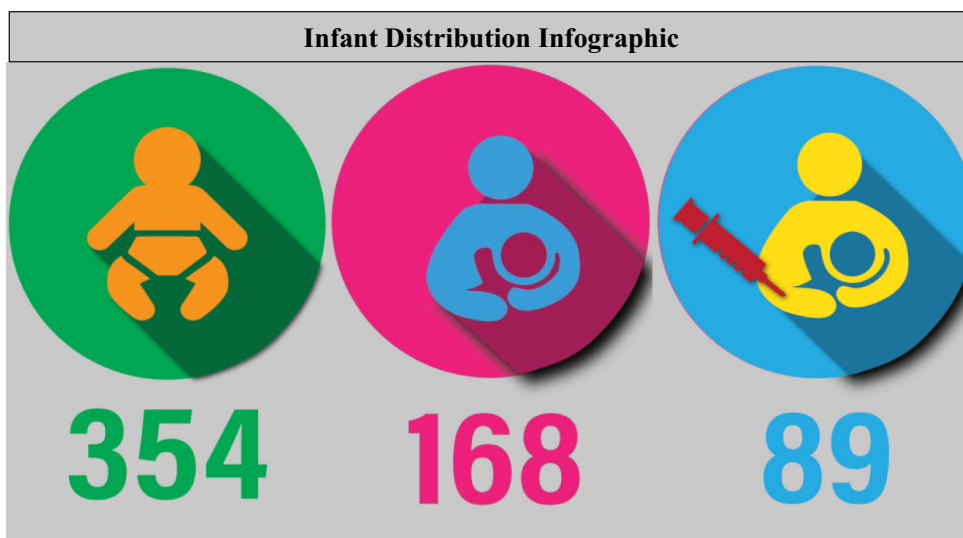


Fig. 2. Distribution of infants seen in clinic for vaccination, breastfed at home, breastfed during vaccination.

It was important to understand reasons for lap placement of breastfeeding infants so that interventions might be modified, consistent with PDSA QI methodology. By allowing nurses a free text option in the EHR, additional information about the reason for lap placement was collected. Fifty percent of infants placed on the lap were bottle fed at home. Of the 168 breastfed infants who were held in the lap rather than breastfed during vaccination, nurses documented the following reasons (Fig. 5): 27% of mothers preferred to place the infant on the lap rather than the breast during vaccination; 13% of women only gave pumped milk rather than direct breastfeeding at home; 7% of breastfeeding mothers did not accompany the infant at the office visit; and 3% of mothers had other reasons (e.g., breastfed before or after, but not during vaccination, infant would not latch). Documentation of reason why some mothers chose to hold the infant rather than breastfeed was not always specific, representing an opportunity for improvement, but reasons included modesty and fear of infant jerking during the injection.

## Discussion

### Summary

A new clinical protocol using breastfeeding to mitigate pain during routine vaccination of infants 0 to 6 months of age was introduced in a pediatric practice with interprofessional collaboration between the providers and nurses. The project's primary and secondary goals were achieved. On average, 53% of breastfeeding mothers chose to nurse their infant during vaccine administration, exceeding the project aim of 25%; and only 3.7% of infants were vaccinated while positioned on the exam table. Several nurses added comments in the EHR when charting to describe the infant's response, noting decreased crying when breastfed during the vaccine administration. Witnessing the success of the intervention was instrumental in nurses' adherence to the

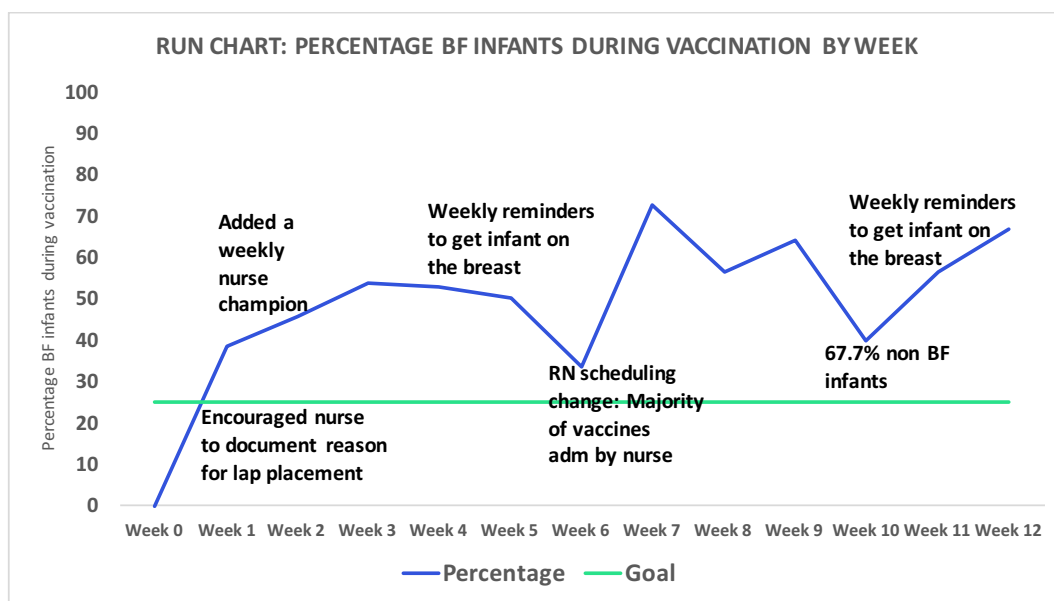


Fig. 3. Percentage of infants who breastfeed during vaccination per week.

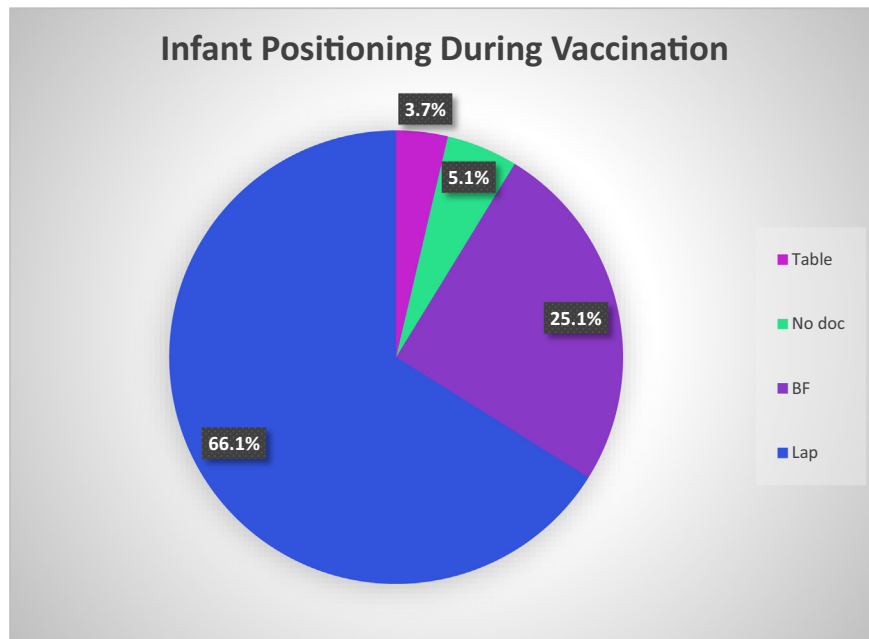


Fig. 4. Infant positioning during vaccination.

protocol and mothers' plans to breastfeed during subsequent visits to the clinic for routine vaccination.

With the new protocol, nurses were tasked with teaching mothers about breastfeeding during vaccine administration to decrease injection pain, demonstrating and explaining preferred positioning techniques, and sometimes assisting mothers with getting the infant on the breast. While the actual extra time incurred with these tasks was not captured, informal interviews with clinical staff and discussions during staff meetings revealed that as nurses became more comfortable and proficient over the 12-week project period, the new process added no more than one to three minutes to their routine. Most nurses easily integrated the intervention into their vaccine administration practice without negatively impacting workflow. With subsequent clinic visits, mothers

were already aware of the benefits and opportunity to breastfeed during vaccination, adding no additional time to the nurses' workflow. Weekly nursing meetings facilitated communication related to the project interventions and goals and allowed nurses to share success stories, ask questions, and express any concerns.

#### Interpretation

There was only a modest improvement in clinician knowledge following the educational session provided at the start of the project. Staff nurses, nurse practitioners, and physicians all participated in order to inform the entire practice of the project mission and goals. However, due to the small number of clinicians in the practice, provider

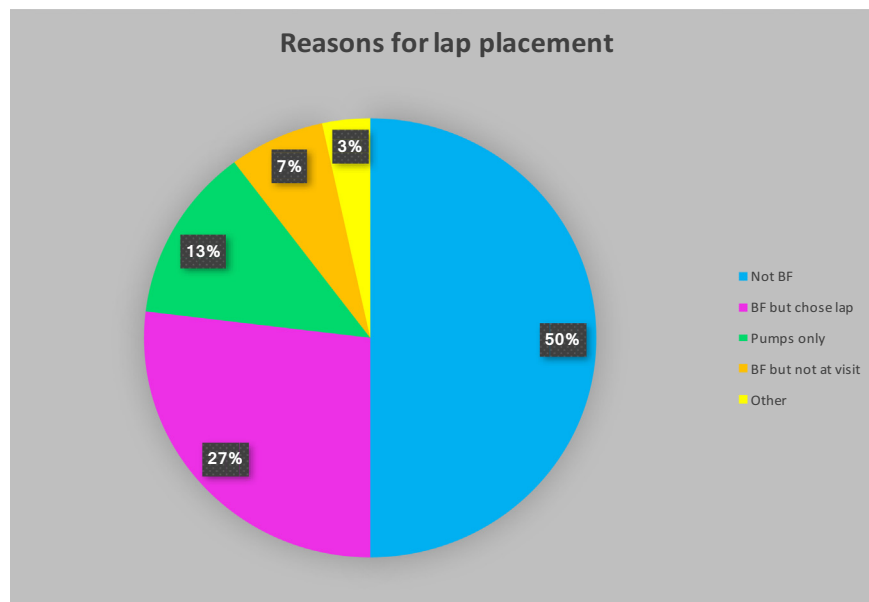


Fig. 5. Reasons for lap placement.

and nurse test scores were not analyzed separately. Analyzing scores separately may have better represented a change in nurses' knowledge and served to identify content areas in which to focus ongoing educational efforts, which is important considering that project outcomes hinge on a change in nurses' behavior. Given the use of experiential learning through role-play, larger improvements in nurses' self-efficacy scores may have been appreciated had nurses been evaluated before and after the hands-on in-service rather than with the general educational session. While nurses' behavior, and therefore, project outcomes, were influenced by educational endeavors and changes in the EHR to prompt nurses to document infant position during vaccination, the weekly staff meetings and reminders may have had the largest impact on nurses' adherence to the clinical protocol. Nurses documented only after administering vaccines, and the option to document the exam table for position remained. However, regular scheduled meetings and reminders allowed project leaders to present the project's progress and continuously reinforce project interventions. Once new expected behaviors are hardwired into the practice, fidelity to the new protocol is more likely.

Project interventions required nurses to adjust clinical flow, which may have impacted the overall success or buy-in from some of the staff. Infants ages 2, 4, and 6 months received oral Rotavirus, DTaP, and Prevnar injections at the same clinic visit. Prior to the quality improvement intervention, nurses administered oral Rotavirus and fluoride (if indicated) before the injections; however, the project protocol specified that injections be administered first, requiring the nurse to wait for the infant to finish breastfeeding, which could take be several minutes. The sequence of fluoride application and oral vaccine administration influenced some of the nursing staff who opted to place infants on the lap rather than have the infant breastfeed in order to save time. In addition, if the infant required 3 injection vaccines (i.e. addition of the flu vaccine given at age 6 months), the infant needed to be re-positioned on the breast in order to have the opposite thigh accessible for the third injection. Few nurses re-positioned the infant and simply placed the infant on the lap for the 3rd vaccine.

All examination rooms needed adequate space for mothers to breastfeed while accommodating the nurse who needed to position themselves next to the mother. Body habitus was an influencing factor, as some nurses had difficulty in some of the smaller exam rooms. The room layout may have influenced vaccine practices, resulting in lap positioning rather than breastfeeding.

Finally, the provider-nurse pairing may have been another influencing factor. Most providers saw patients prior to vaccine administration, allowing the provider to introduce breastfeeding as a pain relieving intervention and offer support of the intervention. However, one provider saw patients after the nurse had administered vaccines. Most infants were placed on the parent's lap for vaccine administration for this particular provider-nurse pair, likely to avoid having to invest the extra time explaining the benefit of breastfeeding during vaccination.

#### Limitations and recommendations

Variation between provider workflow (e.g., MD seeing the infant after rather than before the nurse administered the vaccine) may have affected the nurses' ability to have mothers breastfeed during vaccination. Mothers may have felt rushed knowing the provider was waiting. There was greater success noted when the nurse administered the vaccines after the provider completed their portion of the visit.

The 12-week data collection period allowed for some changes in the initial implementation plan, but certain patterns of compliance and success were not captured until the project was completed. A longer study would have allowed subsequent iterations of the PDSA cycle and possibly improve outcomes. For example, some mothers were resistant to putting their infants on the breast out of concern that the infant might pull or kick during vaccination, resulting in a vaccine administration error. Nurses were limited in their responses and did not spend the

extra time to provide parental support or request a provider to offer additional explanation, presenting an opportunity to expand role-modeling techniques and edit the nursing script.

This particular pediatric practice is committed to breastfeeding and offers lactation services to mothers and their infants; therefore, incorporating breastfeeding into routine care was generally accepted by the clinical staff. Other organizations may find the initiative more challenging to implement without comparable support, nursing resources, and commitment to promote breastfeeding. Based on lessons learned throughout project implementation, the following recommendations may assist practices to adopt a similar clinical protocol for using breastfeeding to mitigate pain during routine infant vaccination: create an office setting that promotes and supports breastfeeding; employ an interdisciplinary team, including champions and resistors, to help plan and guide efforts; endeavor to have consistency in vaccination workflow between clinicians; expand nurses' script and experiential learning opportunities to include handling difficult situations; provide promotional materials in the form of clinic room posters and fact sheets for parents describing the benefits of breastfeeding or lap-holding during vaccination; allow for a longer implementation period to hardwire changes into routine practice.

#### Conclusions

Project outcomes add to the body of literature supporting non-pharmacologic pain interventions, including breastfeeding, during routine procedures such as vaccination injection.

The project has implications for patients, parents, and clinicians. When breastfed, infants experience less pain and distress during vaccination, which likely decreases parental concern and anxiety and may ensure adherence to the CDC vaccine schedule. Nurses and other clinicians acquired additional pain management techniques effective for decreasing pain during vaccine administration, and the positive experience with the interprofessional improvement project may facilitate its sustainability and even garner support for future quality improvement initiatives. To further ensure sustainability of the project interventions, the protocol was adopted as an office policy; however, continued training during the on-boarding process for new hires in the clinic will be required. Consistent with PDSA methodology, the project started with testing small changes in a limited setting or population—in this case, only infants aged 0–6 months were considered. However, the clinical protocol could easily be expanded to include older children without making any changes to the intervention plan. The next steps include expanding the project to target infants over 6 months of age and educating clinicians on combined strategies for pain management, thereby improving the healthcare experience for all infants and parents.

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