



Children's Pain and Distress at a Public Influenza Vaccination Clinic: A Parent Survey and Public Observation Study

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Abstract

Immunizations are a necessary but distressing and painful procedure that most infants and children regularly undergo. Each year, a tertiary pediatric hospital in Canada holds an influenza vaccination clinic for all staff and their families. Evidence-based interventions to reduce pain and distress in babies and children are used. Despite this, infants and children continue to be distressed throughout the vaccination procedure. The objectives of this study were to: (1) measure the prevalence of distress among infants and children before, during, and after vaccine administration at the clinic, and (2) evaluate parents' perception of their child(ren)'s distress before, during, and after vaccine administration and the effectiveness of pain management interventions used during the clinic. A cross-sectional design of naturalistic observation and parent surveys was used and data was analyzed using descriptive statistics. A total of 283 children between 6 months and 18 years were vaccinated at the clinic, with 52% observed to be distressed before, during, or after the procedure. There were 115 parents of 206 children that completed the survey; 47% of these parents perceived that their children were distressed before, during, or after vaccination, and 42% perceived that the pain treatments used for their child(ren) were very effective. The results of this study will continue to inform interventions for needle-related pain and distress management, as well as improvements for future public vaccination clinics.

Keywords Fear · Pain management · Pediatrics · Immunization · Influenza

Background

Immunizations throughout infancy and childhood are necessary to provide protection against harmful infectious diseases. Current vaccination schedules in Canada and the United States recommend children are vaccinated against seventeen infectious diseases, which require approximately 20 injections and can include up to 5 being administered in one visit [1]. One of these recommended vaccines is the annual influenza vaccination [2]. The World Health Organization (WHO) recommends annual influenza vaccination beginning at age 6 months, and identifies children under the

age of 5 years as a priority population for influenza vaccination due to their risk of serious complications from contracting influenza [3].

While immunizations are necessary, they are also painful and may be distressing for infants and children. The pain associated with injections is brief, but can result in anxiety and fear for subsequent needle-related procedures, and lead to non-adherence to the recommended vaccination schedule [4–6]. In one study, pediatric care providers believed that the average 4–6 year old patient is very anxious about injections and find them moderately painful [5]. A focus group of nurses performing immunization injections found that reduced control over the environment in which the vaccination is held led to heightened anxiety in children, particularly when waiting in lines where there are other frightened children [7]. Multiple non-pharmacological and pharmacological procedural pain management strategies have been shown to reduce pain in infants and aid children in managing their pain and distress during vaccinations [8–11]. A Canadian clinical best practice guideline for reducing pain during vaccine injections recommends the use of breastfeeding, skin-to-skin contact, and

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sucrose solutions in infants, and upright holding, topical anesthetics and distraction in children [12]. In addition, recommendations from the WHO suggest breastfeeding infants during vaccination and giving sweet tasting oral medications prior to injections [13]. Despite these recommendations, and primary care providers' perception of a moderate degree of anxiety and fear experienced by pediatric patients during vaccination, many studies report infrequent utilization of evidence-based pain or anxiety-reducing interventions for infants and children during injections [1, 5, 14–16]. These findings demonstrate a knowledge to practice gap surrounding pain management during pediatric vaccine administration.

In Canada, children may receive their annual influenza vaccination at family physician, pediatrician or nurse practitioner offices, public health units, and in some provinces, if over the age of 5 years, at pharmacies. In addition, staff at a Canadian tertiary level pediatric hospital have the option of bringing their children to their workplace one evening for a 4-hour annual influenza vaccination clinic hosted by the hospital's occupational health team, known as the Family Flu Clinic (FFC). Since 2011, a formal collaboration between hospital teams such as occupational health, child life, and pain research have resulted in a concerted effort to prioritize implementation of evidence-based pain management strategies and monitoring of pain and distress management for all children attending the annual FFC. While previous quality assurance (QA) projects conducted at the FFC have identified areas for improvement and informed planning for future clinics, infants' and children's pain and distress remain an important priority. For example, our team's previous QA work included a brief online survey of 222 hospital staff which reported that 104 (47%) had at least one member of their family that is fearful of needles [17].

Purpose

This study aimed to assess: (1) the prevalence of distress in children ages 6 months to 18 years before, during, and after influenza vaccination; (2) how often pain and fear-reducing interventions were being implemented; and, whether these interventions were perceived by parents to be effective in reducing children's distress. The findings of this study will be used to assist healthcare providers and parents in planning appropriate pain and distress management strategies during future vaccinations and/or future vaccination clinics.

Methods

Study Design

This study used a cross-sectional design with two sources of data: (i) naturalistic observation and (ii) parent survey.

Naturalistic observation was used to identify signs of distress in children ages 6 months to 18 years before, during and after vaccination. A parent survey was also distributed after vaccination to learn about parents' perceptions of their child(ren)'s distress and the effectiveness of the pain reducing interventions used at the FFC.

Setting

An annual influenza vaccination clinic for all staff and families at a level III pediatric hospital in Canada. Typically, this clinic sees between 400 and 700 individuals in a 4-hour period. Vaccinators are experienced registered nurses, registered practical nurses and pharmacists employed with the hospital. Standard injection technique at this hospital for intramuscular injections includes rapid injection with no aspiration. Vaccinators have sucrose and vapocoolant spray available to them, and Child Life Specialists (CLS) are onsite to support children, providing distraction with electronic tablets, appropriate toys and activities, therapy dogs and cognitive support. A few days prior to the FFC, brochures detailing evidence-based developmentally-appropriate pain management interventions are posted to the hospital's intranet site and sent to staff through the hospital's email distribution lists. Most immunizations are conducted in the cafeteria, a large open room with vaccinators stationed at multiple tables. In addition, two private quiet rooms with 1:1 support from a CLS are offered to parents for children who are either perceived, or known to be anxious or distressed about the vaccination. After the vaccine is administered, all families are asked to wait in a designated area of the cafeteria for at least 15 min in case of adverse reactions. During this waiting period, families are offered ice cream and activities for children, such as drawing or colouring.

Study Sample

Naturalistic Observation

All children between the ages of 6 months to 18 years receiving their influenza vaccination at the FFC were observed for signs of 'maximum' distress before, during, and after vaccination. Only children who displayed at least one sign of distress before, during, or after the vaccination procedure were included in the final study sample for data analysis. Descriptors of distress used for the purpose of this study as well as previous QA activities at the same setting are presented below (Fig. 1). These signs are considered quick and easy to identify consistently by multiple observers in such a large clinic, whereas the use of validated composite pain assessment tools would not be feasible in this setting. Since the purpose of this component of the study was to observe children in their natural setting during vaccination, individual

consent was not obtained as an awareness of being observed might influence behaviour. A waiver of consent was obtained from the hospital’s research ethics board and all participants were made aware of the naturalistic observation component of the study when they were subsequently approached to participate in the parent survey, as well as offered debriefing by the study research assistants.

Parent Survey

All parents of children vaccinated at the FFC were approached by trained research assistants during the 15 min onsite waiting time after the vaccination to invite them to participate in the survey. If parents expressed interest, they were given a consent form to review that was attached to the survey. Research assistants stayed with the parents to answer any further questions related to the study or consent form. The bottom of the consent form page stated that by commencing the survey, parents will have implied consent. All surveys were included in the final parent survey study sample.

Data Collection Tools and Procedures

Naturalistic Observation

Trained volunteer data collectors recorded their observations using a checklist (Fig. 1). Data collected included age and sex of child, signs of distress before, during and after vaccination, the length of the vaccination procedure, the number of other children present and whether the child had to be restrained. Age groups on the observations checklist were categorized as follows:

Infant = < 12 months

- Toddler = 13 months to 2 years
- Preschool = 4–6 years
- Grade school = 7–12 years
- Teenager = 13–18 years

No other identifying characteristics were observed or collected to ensure anonymity. In this study, distress is defined as the combination of anxiety or fear and pain experienced by a child during a painful procedure such as vaccination [18]. Signs of distress can be, but are not limited to crying, screaming, struggling, hiding, and/or resisting.

To ensure consistency between observers, precise definitions were given for the three time points of the vaccination procedure. “Before” was defined as from the time the child leaves the front of the line to when the vaccinators begins swabbing the child’s arm; “during” was defined as from swabbing the child’s arm to the application of a bandage; and, “after” was defined as from the placement of a bandage until the child leaves the chair.

Parent Survey

A paper-based survey was distributed to parents during their post-vaccination waiting period. The survey was developed by the study team and piloted at the previous FFC for a quality improvement project (Harrison unpublished report) [19]. The final survey contained nine questions, including:

- a. Attendance in the past years at the FFC
- b. Location of child(s) immunization (main cafeteria room or private rooms)
- c. Number of children, and their age and sex
- d. Perceived distress level of the children before, during, and after vaccination
- e. Pain treatment used and its perceived effectiveness

Signs of maximum distress - BEFORE	Signs of maximum distress - DURING	Signs of maximum distress - AFTER	Still distressed after leaving chair?	Approx age (years)	Sex	Child needed restraining?	# of children present	Length of procedure
<input type="radio"/> None <input type="radio"/> Crying <input type="radio"/> Screaming <input type="radio"/> Struggling <input type="radio"/> Hiding <input type="radio"/> Resisting <input type="radio"/> Other:	<input type="radio"/> None <input type="radio"/> Crying <input type="radio"/> Screaming <input type="radio"/> Struggling <input type="radio"/> Hiding <input type="radio"/> Resisting <input type="radio"/> Other:	<input type="radio"/> None <input type="radio"/> Crying <input type="radio"/> Screaming <input type="radio"/> Struggling <input type="radio"/> Hiding <input type="radio"/> Resisting <input type="radio"/> Other:	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Infant (<1 years) <input type="radio"/> Toddler (1-3 years) <input type="radio"/> Preschooler (4-6 years) <input type="radio"/> Gradeschooler (6-12 years) <input type="radio"/> Teen (≥13 years)	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknwn	<input type="radio"/> Single child <input type="radio"/> >1	Start: _____ (hh:mm) End: _____ (hh:mm)

Fig. 1 Observation checklist

- f. Comments about the distress and pain treatment
g. Planned attendance at next year's FFC

Age groups in the parent survey were categorized slightly different than the observation survey, as they matched the hospitals' parent consent forms for the vaccination, as follows:

Infant = 6–12 months
Toddler = 13 months to 2 years
Child = 3–12 years
Teenager = 13–18 years

Data Analysis

All data collected from both the naturalistic observations and surveys were entered by trained research assistants into Research Electronic Data Capture (REDCap) [20]. Descriptive statistics were used to analyze and summarize the data. No records were excluded and any missing data is specified in the results.

Results

A total of 283 children between 6 months and 18 years of age attended the FFC.

Naturalistic Observations

In total, 146 children (52%) were observed to show at least one sign of distress throughout the vaccination procedure with 75/283 (27%) showing distress before, 123/283 (42%) showing distress during, and 59/283 (21%) showing distress after. Data on the 146 children showing signs of distress, as determined by the data collectors, is presented in Table 1.

Observed Prevalence of Distress

Figure 2 shows the distress levels of each age group observed before, during, and after vaccination, as well as after leaving the vaccination area. After leaving the vaccination chair, 31/141 (22%) children continued to show signs of distress, despite the procedure being completed. Additionally, 92/133 (69%) children who were observed to be distressed needed to be restrained by an adult other than the vaccinator administering the vaccine. As shown in Table 2, hiding was the most commonly observed sign of distress before vaccination, while crying was the most common during and after the vaccination.

Table 1 Characteristics of children showing at least one sign of maximal distress included in naturalistic observation forms (n = 146)

Characteristic	n (%)
Sex	
Male	76 (52)
Female	69 (47)
Unknown	1 (1)
Age	
Infant (6 months–12 months)	6 (4)
Toddler (13 months to 3 years)	41 (28)
Preschool (4–6 years)	50 (34)
Grade school (7–12 years)	39 (27)
Teenager (13–18 years)	10 (7)
Location of vaccination	
Main cafeteria	134 (92)
Private room	12 (8)
Number of children present in family during vaccination	
Single child	41 (28)
> 1	101 (69)
Missing data	4 (3)
Length of vaccination procedure (min) ^a (n = 141) ^b	
Mean	2.6
SD	2.1
Minimum	1
Maximum	13

^aFrom the time the child first sits in the vaccination chair to the time the bandage is applied on the injection site

^bDenominator change is due to missing data

Parent Surveys

Perceived Prevalence of Distress

A total of 115 parents attending the FFC completed the parent survey, providing data on 206 (73%) children vaccinated at the FFC (Table 3). From this surveyed population, 66 (32%) children were perceived by parents to be distressed before the vaccination procedure, 69 (33%) during, and 26 (13%) afterwards. Surveys indicated that parents most frequently perceived their child(ren) to be distressed before the vaccination procedure began, with the exception of toddlers, whose parents most frequently perceived to be distressed during the vaccination procedure (Fig. 3). Of the 206 children, 110 (53%) children were perceived by their parents as not distressed at any point throughout the vaccination procedure.

Perceived Effectiveness of Treatments

Most of the 206 children (n = 140, 68%) received at least one pain management strategy during vaccination, as reported

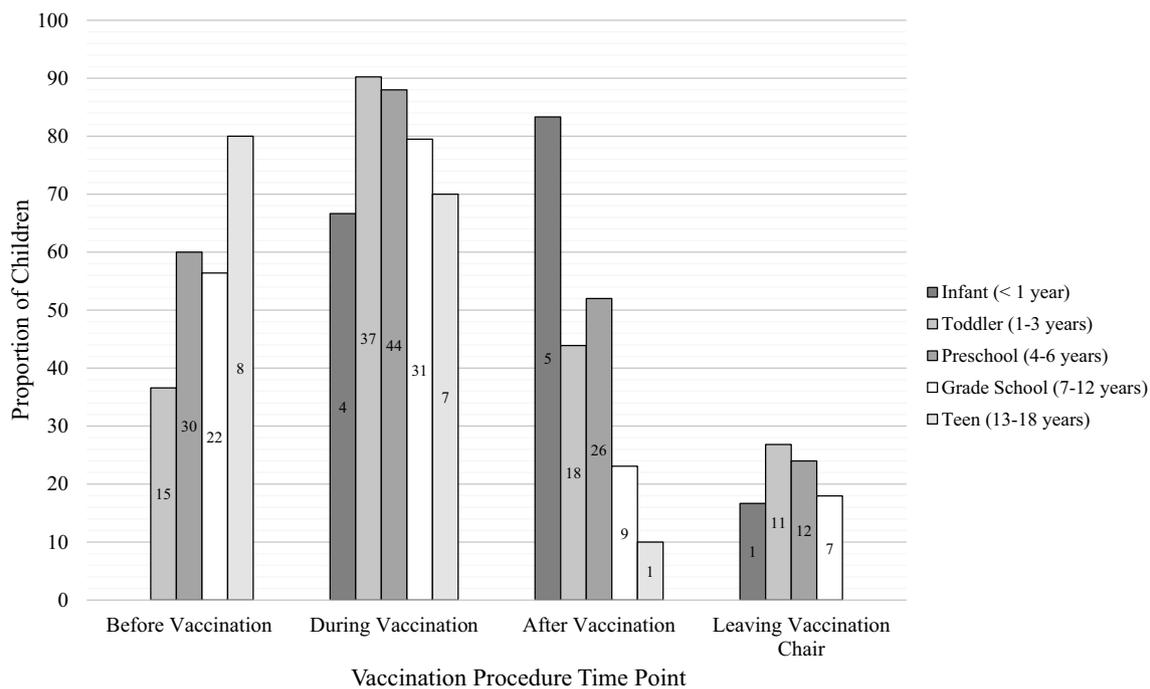


Fig. 2 Proportion of total children observed showing at least one sign of distress throughout the vaccination procedure (n = 146)

Table 2 Frequency of signs of distress displayed by children throughout the vaccination procedure (n = 146)

Sign of distress	Before vaccination n (%)	During vaccination n (%)	After vaccination n (%)
Any sign of distress	75 (51)	123 (84)	59 (40)
Crying	28 (19)	100 (68)	52 (37)
Screaming	10 (7)	45 (31)	11 (8)
Struggling	23 (16)	46 (32)	5 (3)
Hiding	46 (32)	23 (16)	5 (3)
Resisting	39 (27)	50 (34)	1 (1)

by parents. Specifically, parents reported that 79 (38%) children received distraction, 84 (41%) received vapocoolant spray, 14 (7%) received support from a CLS, 13 (6%) had the presence of a therapy dog, 3 (1%) were given oral sucrose solution, 2 (1%) were breastfed, and 1 (0.5%) was held skin-to-skin. Some children received more than one pain management strategy (n = 46, 22%).

Overall, of the 140 that received a minimum of one pain management strategy, 59 (42%) perceived the pain treatment their child(ren) received as very effective, 56 (40%) as somewhat effective, and 25 (18%) as not effective at all. Figure 4 displays the perceived effectiveness of treatments used for children by parents. For infants, the 3 that received sucrose and 2 that were breastfed all reported the interventions to be very effective (100%). The one that was held skin-to-skin reported the intervention to be somewhat effective (100%). The parent surveys also reveal the number of children who

were perceived as distressed by their parents at some point throughout the vaccination procedure, but did not receive any pain management strategies. Of the 66 children whose parents reported no use of pain management interventions, 7 (11%) were perceived as distressed before vaccination, 6 (9%) during vaccination, and 3 (5%) after vaccination.

Discussion

The overall findings from the naturalistic observations of children receiving vaccination and from parental surveys at a large influenza vaccination clinic show that despite many children receiving evidence-based pain management strategies, over half of the attending children were observed to be distressed by the study observers, and almost half of children were perceived by parents as being distressed. It was noted

Table 3 Characteristics of children (n=206) and families (n=115) reported on by parents in survey

Characteristic	n (%)
Characteristics of children	
Sex	
Male	97 (47)
Female	105 (51)
Missing data	4 (2)
Age	
Infant (6 months–12 months)	5 (2)
Toddler (13 months to 2 years)	31 (15)
Child (3–12 years)	139 (67)
Teenager (13–18 years)	27 (13)
Missing data	4 (2)
Characteristics of families	
Location of vaccination	
Main cafeteria	104 (90)
Private room	10 (9)
Missing data	1 (1)
Number of children present in family receiving vaccination at FFC	
Mean	1.8
SD	0.77
Minimum	1
Maximum	4
Families that attended FFC last year	
Yes	79 (69)
No	35 (30)
Missing data	1 (1)
Plan to attend the FFC the following year	
Yes	114 (99)
No	0 (0)
Unsure	1 (1)

in both datasets that children continue to display signs of distress throughout the vaccination procedure, as well as after the injection has been given.

Distress Levels of Children Before, During and After Vaccination

Needle fears and distress during pediatric vaccination are common. For instance, a survey on needle fears found that 63% of children and 24% of parents reported a fear of needles [4]. Another study also found that 90% of 15–18 month old children and 45% of 4–6 year old children showed serious distress during a vaccination procedure [21]. While in our study the proportion of children showing distress before and during the vaccination procedure were lower than what was reported in these studies, our findings still showed a substantial proportion of children distressed before and during the vaccination procedure. This highlights the need to

ensure consistent use of effective pain treatment strategies from an early age. The fact that just under half of the distressed children were distressed before the procedure, demonstrates a high prevalence of fear of needles. This is of concern and emphasizes the need to work at reducing the negative perception of needles, with the aim to minimize the risk of developing needle fears. Fear levels have been shown to be higher than pain levels during needle insertion with subcutaneous ports in children with cancer [22]. This study also reported that children experienced higher fear levels than pain when a topical anesthetic was used, indicating a need to also apply fear-reducing interventions during needle procedures [22]. Support for children who are anxious or fearful about the vaccination and their parents/caregivers needs to be given prior to receiving the vaccine, as well as in the days leading up to the procedure to reduce their fears.

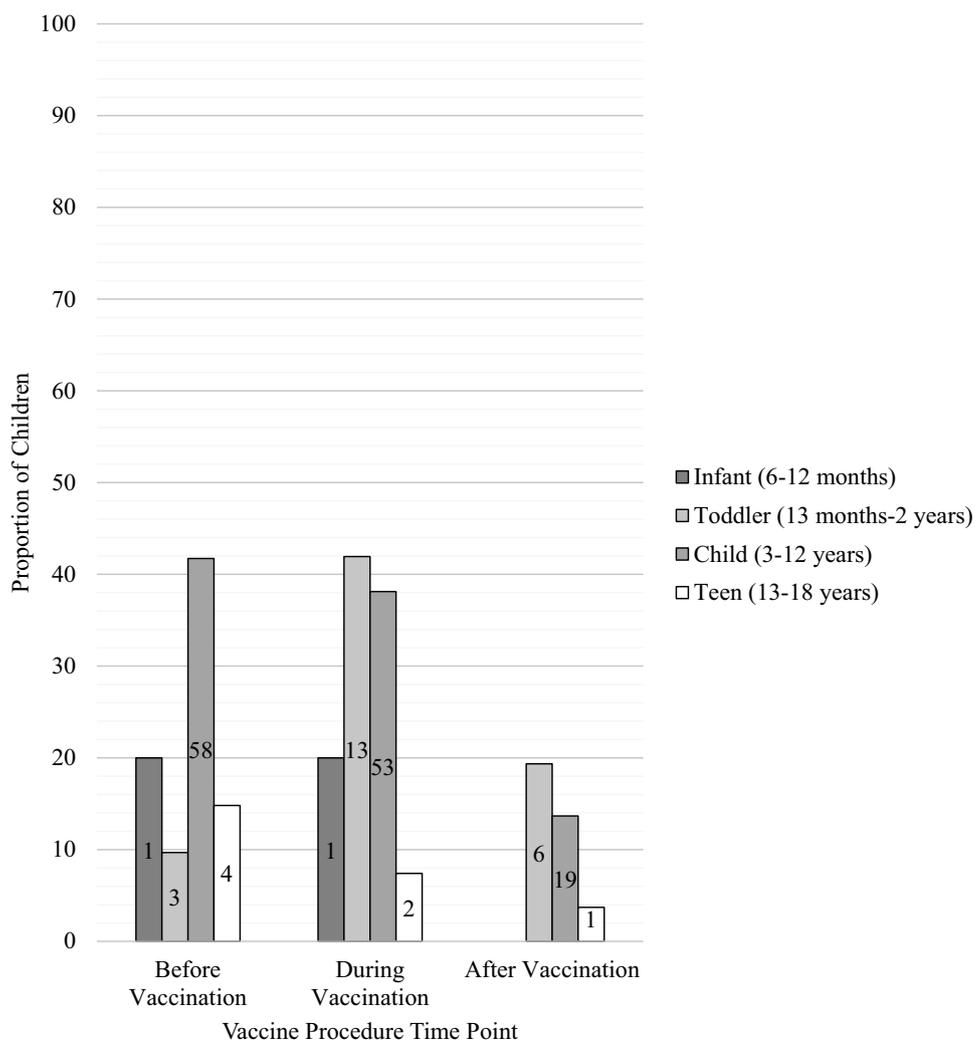
The parent surveys demonstrated that children were perceived to experience distress throughout the needle procedure and were similar to the findings from naturalistic observation. These results also highlighted that parents perceived more children experiencing distress before and during vaccination, with less children experiencing distress after the injection was given. The surveys provided to parents did not have the prescribed procedure time period definitions stated, and thus parents may have also considered “before” to include the time spent in transport to the FFC or before leaving their home.

Despite the availability and administration of pain reducing interventions, many children were still distressed, with some requiring restraint by their parent/caregiver to receive their vaccine safely. This may impact levels of fear and distress when receiving future vaccinations [7] and indicates a need for the vaccinators to utilize all pain-reducing interventions available before resorting to restraining the child. A study on needle fears in Australia found a strong association between fear of needles and past traumatic experiences, further emphasizing that it is necessary to provide atraumatic care during regular immunizations [23].

Use of Pain Management During Vaccination and Parental Satisfaction

Previous studies have shown that pain management interventions are not always implemented during vaccination [24, 25]. In our study, about two-thirds of children attending the FFC were reported to have received at least one type of pain management strategy during vaccination. Many parents reported that the interventions used for their child(ren) were very effective, which is in agreement with the literature supporting some of the pain management strategies that were used at the FFC [8–11]. Breastfeeding, skin-to-skin and sucrose have been shown to be the most effective for infants [8, 11]. In our study, these 3 interventions were rated as very

Fig. 3 Proportion of children perceived as distressed by parent(s) throughout the vaccination procedure (n = 206)



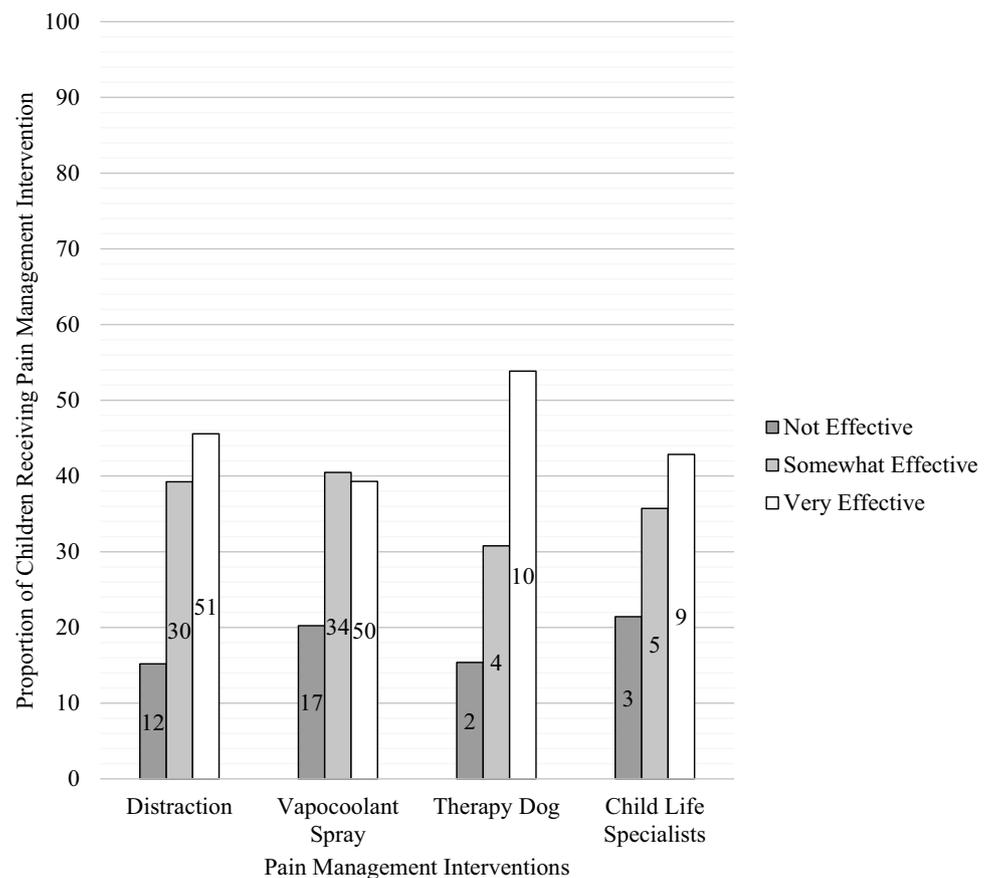
or somewhat effective by 100% of parents who used them; however, these results should be interpreted with caution since there were only 6 infants in our study. Distraction and vapocoolant spray were the most commonly used, both of which are practical interventions that vaccinators can apply to the majority of the children receiving influenza vaccination. Distraction is recommended as effective for children ages 2 years and above [10, 12]. Vapocoolant spray however has less evidence of effectiveness and, as per the clinical practice guideline on vaccination pain management [12], is not recommended as an effective treatment for any age of children. Yet, it is an intervention that is readily available, easy and quick to use and therefore preferred by the vaccinators as well as many children who are offered this treatment by vaccinators, and choose to use the spray.

Despite many parents reporting that the interventions used were effective, nearly half still said they perceived their child to be in distress at some point during the vaccination procedure. These results are consistent with another study that showed the majority of parents were satisfied with pain

management during their child's hospitalization, despite many of them also reporting their child to be in moderate to severe pain [25]. This disconnect may be explained by parents assuming prior to the procedure that vaccines are always painful, and thus being satisfied with the use of pain management regardless of their children's distress. Literature shows that parents also experience anxiety and distress when their children receive immunization [6], which may impact their perception of their children's distress and explain the disconnect between distress levels and satisfaction with the pain management used at the FFC. This is also consistent with the findings from our team's QA survey on hospital staff's needle fear, which found 22% of respondents fearful of needles, regardless of whether their children were fearful or not [16].

Parent surveys indicated that a few children showed signs of distress but did not receive any pain management intervention at all. While vaccinators administering the vaccines at the FFC are informed on pharmacological and non-pharmacological interventions for needle-related procedures,

Fig. 4 Perceived effectiveness of pain and distress management interventions, as reported by parents (n = 206)



there are several potential barriers that may explain the lack of use of pain treatment for all children during vaccination. For example, previous studies have identified barriers such as lack of knowledge and uncertainty regarding effectiveness of pharmacological interventions, responsibility for educating parents [7], cost, time constraints [26] and persistent attitudes surrounding pain that prevent best practice implementation [1]. This may also indicate a need for more education regarding pain management interventions for all vaccinators and increased knowledge translation surrounding these strategies. In our study, the reasons these children did not receive any pain treatment during vaccination are unknown, and future work to explore vaccinators' perceptions of facilitators and barriers to utilizing pain treatment at the FFC is currently being planned.

Strengths and Limitations

This study took place in a large, high volume public vaccination clinic, ensuring representation of children across most age groups and parental survey responses covering the majority of children in attendance. A naturalistic observation design allowed the research team to discretely observe children in their natural state without influencing their behaviour or level of distress. In addition, the use of parental surveys

provided vital information on parents' perceptions of their children's pain and distress and the effectiveness of pain treatment used. This data contributes important information to inform the planning and conduct of future vaccination clinics.

The inability to link the data on children from the naturalistic observations to the parent surveys prevented us from comparing the observed and perceived distress with the pain management strategies used. Further, due to the different age groups used for the observation checklists and for the parent surveys, it was also not possible to directly compare distress levels from the independent observers and the parents when analyzing the data. Nonetheless, the two independent sets of data provide valuable information and future evaluations of the FFC will use data collection tools that offer identical precise definitions for age groups, as well as vaccination procedure time periods.

Another potential limitation is that pain treatment usage and effectiveness was only assessed by parents during the FFC, relying on their memory of what their children received and their interpretation of its effectiveness. For future clinics, it may be worthwhile to consider having objective observers also watching and tracking the use and effectiveness of pain management interventions. This would provide additional data that could then be compared

to parents' perceptions and identify any variances between the two datasets.

Implications for Clinical Practice

This study will inform the design of future public vaccination clinics. Toddlers and children were perceived to be the most distressed in both observations and parent surveys, which suggests that there should be greater focus on health-care providers using effective age and developmentally appropriate pain management techniques prior to and during vaccinations from early infancy to reduce pain and distress at the time of injections, and minimize the risk of development of needle fears. Although many of the children at the FFC received pain management treatment, further work should be done to reach 100% use of interventions during future clinics to reduce distress levels and prevent the development of needle-related fears.

Implications for Research

The impact of education of the vaccination staff to adopt and implement specific pain management techniques should be assessed. Given that not all children perceived to be distressed in our study received pain management interventions despite them being available for use, it is also important to continue ongoing knowledge translation efforts to help develop evidence-based strategies for implementing pain treatment best practices during pediatric painful procedures. Conducting a survey on the barriers and facilitators to using pain management interventions may also provide insight to what can be improved to increase usage in clinical settings. In addition, considering the number of children distressed prior to vaccination, continued interprofessional collaboration with other allied health providers such as CLS and psychology is required to better understand the source of needle-related fears and how to best support parents and pediatric patients during vaccinations.

Conclusion

The results of this study demonstrate that despite the use of evidence-based pain management strategies, many children were distressed before, during, and after vaccination at the large public FFC. Further research is required to determine whether introducing these interventions in infancy and continuously using them throughout childhood can reduce pain and distress surrounding needle-related procedures, as well as the best strategies to increase implementation of pain management interventions. The results from this study increased our understanding of the time periods that are most distressing for children attending a public vaccination

clinic. This information will help to improve the implementation of age-appropriate evidence-based supports given to children and families during vaccination procedures at future influenza vaccination clinics.

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Compliance with Ethical Standards

Conflict of interest The authors declare they have no actual or potential conflict of interest. The authors alone are responsible for the content and writing of the paper.

Ethical Approval The Children's Hospital of Eastern Ontario Research Ethics Board approved this study (#17/152X). All procedures involving human participants were performed in accordance with ethical standards of the institutional research committee.

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