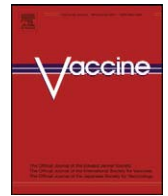




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Survey of the prevalence of immunization non-compliance due to needle fears in children and adults

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ABSTRACT

Needle fears are a documented barrier to immunization in children and adults. There is a paucity of data, however, regarding the prevalence of needle fears and their impact on immunization compliance. In this cross-sectional survey, a convenience sample of parents ($n=883$) and children ($n=1024$) attending a public museum in Toronto, Canada answered questions about needle fears and non-compliance with immunization due to needle fear. Altogether, 24% of parents and 63% of children reported a fear of needles. Needle fear was the primary reason for immunization non-compliance for 7% and 8% of parents and children, respectively. Interventions aimed at improving education about, and access to, analgesic interventions during immunization injections performed in childhood are recommended in order to prevent the development of needle fears and vaccine non-compliance.

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1. Introduction

Routine immunization plays a key role in maintaining global public health. Despite its proven success, numerous individuals either refuse or delay immunization. Concern about potential harms is one of the reasons for immunization non-compliance. Parents perceive that the most common vaccine-related harm is a child's pain from multiple injections [1].

Injection-induced anxiety and pain are the most frequent adverse effect following immunization [2]. Over 90% of young children exhibit severe distress during immunization [3] and both parents and vaccinators admit they are non-compliant with childhood immunization schedules in an effort to reduce pain and distress [4,5]. Compliance has been shown to decrease as the number of separate vaccine injections being administered increases [6]. Negative experiences with injections lead to the development of needle fears in some children which are carried into adulthood, and contribute to health care avoidance behaviors in adults, including immunization non-compliance [7]. Outbreaks of vaccine-preventable

diseases have been documented to begin in individuals that refused immunization [8] or, due to reduced herd immunity, among infants too young to be immunized [9]. Thus, the success of immunization programs is compromised, in part, because fear-induced avoidance of immunization leads to sub-optimal coverage rates [10].

At present, there are no prevalence estimates of needle fears among children and adults undergoing immunization and the specific impact of needle fears on immunization compliance. We undertook this study to address this knowledge gap given the continual increase in the number of vaccines being recommended and the potential for needle fear to negatively impact vaccine uptake. The primary objectives were to determine the prevalence of needle fears in adults and children undergoing immunization and the reported impact of needle fear on vaccine compliance. Secondary objectives were to describe parental attitudes about, and experiences with, immunization in their children.

2. Methods

Participants included a convenience sample of adults and children attending the Ontario Science Centre (OSC) in Toronto, Ontario, Canada (<http://www.ontariosciencecentre.ca>) between June 18 and August 30, 2011. The OSC is an interactive science-based museum open to the public. The OSC was selected as the

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setting for recruitment because it provided access to a large and diverse sample of parents and children (~4000/day). Individuals were eligible if: (1) they resided in the Greater Toronto Area (GTA); (2) spoke English; and (3) had experience with immunization. One or more individuals from the same family, aged 6 years or older, were eligible to participate. Participants comprised 2 groups: parents and children (6–17 years). The OSC designated space in the section of the museum that explores aspects of the human brain and communication, *MindWorks*, adjacent to the cafeteria. Advertising consisted of signage, 5-min stage presentations, stickers, and verbal descriptions of the study to individuals walking by the designated study area.

Different interviewer-administered surveys were used for children and parents. Both surveys were prepared in accordance with published guidelines [11] and consisted mainly of questions with categorical (yes/no or Likert scale) responses to pre-set response alternatives, with the ability to provide open-ended responses (i.e., partially closed-ended questions). Items included: participant characteristics [age, sex, and number of children (parent survey) or siblings (child survey)]; region of residence within the GTA (Toronto, Halton, Durham, Peel, York); education level achieved (parent survey); needle fear; non-compliance with immunization as a result of needle fear; compliance with influenza vaccination specifically and willingness to comply if given in a non-painful way; and willingness to learn methods of reducing immunization pain. For needle fear, the specific question asked to parents and children was “Are you afraid of getting immunizations/shots?” For immunization non-compliance due to needle fear, the question used for parents was “Did you ever delay or miss getting an immunization/shot because you were afraid?” and for children, it was “Did you ever miss getting a shot/needle because you were afraid/scared?” For willingness to comply with influenza vaccination if given in a non-painful way, parents were asked separately about themselves and their children. For their children, they were asked: “Would you make sure your children got the flu shot if it was given in a non-painful way (that is, without a needle prick or with pain-relieving methods)?” and for themselves, they were asked “Would you get the flu shot yourself if you could be assured it would be painless (that is, without a needle prick or given with pain-relieving methods)?” Parents were also asked about their attitudes about, and experiences with, immunization in their children, including: education about pain management; challenges with immunization; pain-relieving strategies employed; confidence in ability to mitigate injection-related pain; anxiety about childhood immunization; interest in learning methods to manage pain and willingness to pay to reduce pain during immunization. Willingness to pay was queried by the question “Would you be willing to pay to make immunizations/shots less painful and less frightening for your children?” Separately, children rated how painful immunization injections were (0 = none, 1 = a little, 2 = moderate, 3 = a lot). The specific word used throughout the interview to refer to immunization injections was tailored to the participant’s usual vocabulary; most commonly, it was either immunization, shot, injection, or needles.

Content validity of the surveys was established by an interdisciplinary panel with expertise in pediatrics, immunization, and pain. Input was sought from OSC researchers as well as parents and children from the community. Interviewers underwent training and inter-rater reliability was established. Surveys were pilot-tested at the OSC on June 18, 2011 and changes were made in the order and wording of questions in response to participant and interviewer feedback. The study was approved by the Research Ethics Boards of the University of Toronto and York University. Informed written consent was obtained for all participants ≥ 13 years old. For children 6–12 years old, both parent consent and child assent were obtained.

Table 1Characteristics of survey participants ($n = 1907$).

	Parents ($n = 883$)	Children ($n = 1024$)
Age in years, mean (SD)	40 (7) ^a	10 (3)
Female sex, frequency (%)	641 (73) ^b	513 (50)
Number of children or siblings, median (range)	Children 2 (1–7) ^a	Siblings 1 (0–11) ^d
University or college education level, frequency (%)	807 (92) ^b	–
Resides in city of Toronto, frequency (%)	446 (51) ^c	718 (70) ^e

^a $n = 880$.^b $n = 881$.^c $n = 876$.^d $n = 1023$.^e $n = 1017$.

2.1. Sample size calculation and data analysis

Assuming a prevalence rate of needle fear of at least 25% [12] a sample size of 2000 (1000/group) provided a precision of less than 3% for each group [13]. Data were analyzed descriptively and presented as frequency (percent), median (range), or mean (SD). Differences in proportions between groups and within groups were compared using Chi square test and McNemar test, respectively. Logistic regression was used to identify factors associated with needle fear (yes/no). Parent self-reported needle fear was modeled with following independent variables: age; sex; education level; GTA region. For parent-reported needle fear in their children, the following variables were included: child age; child sex; parent anxiety about childhood immunization injections (yes/no) and parent fear of immunization injections (yes/no). For the purposes of analysis, child age was re-coded into 6 categories: <1 year, 1–3 years, 4–8 years, 9–12 years, 13–17 years and ≥ 18 years. A hierarchical random effects model that clustered the child within the family (i.e., parent report) was used for this specific regression analysis. In children, self-reported fear was modeled with the following independent variables: age; sex; perceived pain intensity during immunization. In addition, parent willingness to pay (yes/no) to reduce childhood immunization pain was modeled using the following variables: GTA region; education level; number of children; presence of needle fear in any child, needle fear in parent; parent attitudes toward managing pain, parental anxiety during childhood immunization injections, and parental dissatisfaction with previous pain management in children. For each regression analysis, the independent variables were selected a priori based on clinical relevance. Data were analyzed using SAS version 9.2. A p -value of ≤ 0.05 was considered significant.

3. Results

In total, 1973 individuals participated. Of these, 949 were parents and 1024 were children. Parents reported on 1761 children. Responses from 40 individuals that participated in the pilot were included in the analysis. Both parents from the same family each completed a survey for 132 interviews – the responses from only 1 parent, selected at random, were included from the 66 couples. Thus, 883 parents were included. Participant characteristics are displayed in Table 1.

Two hundred and five parents (24%) and 636 children (63%) reported having a fear of needles. Parents reported needle fears in 50% of their children. For the 812 cases in which a parent and child from the same family participated, the rate of needle fear was higher for children’s self-report (64%) compared to parental report (51%), ($p < 0.001$).

Parent and child self-reported needle fear, according to age of participant, is shown in Table 2. For parents, logistic regression

Table 2Self-reported needle fears in children ($n = 1024$) and Parents ($n = 883$).

	Children ^a			Parents ^b
	6–8 years	9–12 years	13–17 years	≥18 years
Number with needle fear				
A little bit	133 (48)	131 (58)	76 (58)	133 (65)
Moderate	54 (19)	55 (24)	29 (22)	38 (19)
A lot	92 (33)	41 (18)	25 (19)	34 (17)
Overall	279 (68)	227 (65)	130 (51)	205 (24)

Values are frequency (percent) reporting any level of fear

^a $n = 1014$.^b $n = 875$.

revealed a significant positive association between needle fear and female sex (OR = 2.1, 95% CI: 1.4–3.2; $p < 0.001$). For children, a significant positive association was found between needle fear and female sex (OR = 1.9, 95% CI: 1.4–2.5; $p < 0.001$) and increasing perceived pain intensity during immunization ($p < 0.001$). Using 'a lot of pain' as the reference standard, ORs were 0.04 (95% CI: 0.02–0.07), 0.13 (95% CI: 0.07–0.2), and 0.45 (95% CI: 0.2–0.8) for needle fear when compared to 'no pain', 'a little', and 'moderate' pain, respectively.

Parent-reported needle fear in their children, according to child age, is shown in Table 3. A significant association between parent-reported needle fear in their children and the following factors was found: child age ($p < 0.001$), parental anxiety about child immunization ($p < 0.001$), and parent fear of needles ($p = 0.004$). Greater needle fear was reported in children aged 1–12 years (age categories 2–4) when compared to children ≥ 18 years (age category 6), and for parents with anxiety about childhood immunization (OR 2.0, 95% CI: 1.5–2.7) and needle fear (OR 1.8, 95% CI: 1.2–2.6).

Self-reported immunization non-compliance due to needle fear was reported by 58 (7%) of parents and 79 (8%) of children. There was a significant relationship between level of needle fear and vaccine non-compliance for parents ($p < 0.001$) and children ($p = 0.001$). Forty-five (5%) parents reported having avoided or delayed immunization in one or more of their children due to child needle fear.

Regarding influenza immunization specifically, an absolute increase of 10% in willingness to be immunized was reported overall by parents if the vaccine could be administered in a non-painful way compared to self-reported usual practices (43% vs. 33%; $p < 0.0001$). Similarly, overall, more parents reported they would be willing to immunize their children (43% vs. 31%) if they could be assured administration of the vaccine was painless ($p < 0.0001$).

Common challenges experienced by parents during immunization of their children are shown in Table 4. Methods employed by parents to manage immunization pain and distress in their children are shown in Table 5. While 46% of parents reported being very confident in their ability to make their children's immunization injections less painful and frightening, 70% reported they had never received any education on how to reduce pain, and 79% reported they would like to learn ways to do so. Furthermore, 70% of parents reported they would be less anxious about their children getting immunizations if they were given in a non-painful way.

Parent attitudes about immunization pain are shown in Table 6. Half of parents reported they would pay to reduce immunization

Table 3Parent-reported needle fears in their children, according to child age ($n = 1761$).^a

	<1 year	1–3 years	4–8 years	9–12 years	13–17 years	≥18 years
Number with needle fear	6 (30)	127 (51)	408 (56)	199 (49)	68 (40)	24 (26)

Values are frequency (percent)

^a Data were excluded from 70 parents who responded "don't know" and 28 with "missing" data.**Table 4**Challenges reported by parents during routine childhood immunization ($n = 883$).

Challenges	Frequency (%)
Crying	752 (85)
Screaming	338 (38)
Flailing	288 (33)
Having to use restraint to carry out procedure	206 (23)
Running away	173 (20)
Kicking	136 (15)
Light headedness	37 (4)
Threatening	31 (4)
Shortness of breath	33 (4)
Soil self	15 (2)
Fainting	14 (2)

These data correspond to the following survey item: "I am going to read a list of things that some people have told us were challenges during immunization injections in their children. Can you tell me if you faced any of these challenges? Remember there are no right or wrong answers. Just choose the items that match your experiences."

Table 5Strategies reported by parents to manage pain and distress in children during routine immunization ($n = 883$).

Strategies	Frequency (%)
Holding	738 (84)
Reassurance	641 (73)
Preparation	603 (68)
Distraction	593 (67)
Acting calm	574 (65)
Empathy	550 (62)
Oral analgesics (acetaminophen, ibuprofen)	433 (49)
Offer reward	405 (46)
Apologizing	209 (24)
Tell child it will not hurt	170 (19)
Pacifier	164 (19)
Deep breathing	154 (17)
Rubbing/massaging	153 (17)
Breastfeeding	146 (17)
Topical anesthetics	94 (11)
Ice	66 (7)
Bottle feeding	56 (6)
Sugar water	36 (4)

These data correspond to the following survey item: "I am going to read a list of things that some people have told us they have used in the past to comfort their children during immunization injections. Can you tell me if you did any of these same things? Remember there are no right or wrong answers. Just tell me about your experiences."

pain in their children: three-quarters would pay between \$5 and \$50 (CAD). Of those offering reasons they would not pay, 28% said pain treatment/medication should be included as a part of the immunization process; not as an extra parental expense. Willingness to pay was positively associated with: presence of needle fear in at least one child (OR 1.9, 95% CI: 1.4–2.6; $p < 0.001$); presence of parental anxiety during child immunization (OR 3.0, 95% CI: 2.2–4.3; $p < 0.001$); positive attitudes toward managing immunization pain (OR 1.5, 95% CI: 1.3–1.7; $p < 0.001$); increasing education level (OR 1.4, 95% CI: 1.1–1.8; $p = 0.02$), and dissatisfaction with how pain was managed in children in the past (OR 1.2, 95% CI: 1.0–1.5; $p = 0.05$).

Table 6Attitudes held by parents regarding pain during immunization ($n = 883$).

	Strongly agree	Agree	No opinion	Disagree	Strongly disagree
Immunization injections cause the same amount of pain in everybody ^a	18 (2)	166 (19)	57 (6)	526 (60)	115 (13)
We do not need to do anything about children's pain during immunization because pain is a normal part of the procedure ^b	33 (4)	245 (28)	75 (9)	449 (51)	79 (9)
Doctors and nurses should help make immunizations less painful for children ^b	194 (22)	545 (62)	64 (7)	74 (8)	4 (0)
Parents should be given information about how to make immunizations less painful for their children ^a	263 (30)	577 (65)	23 (3)	18 (2)	1 (0)

^a $n = 882$.^b $n = 881$.

4. Discussion

In a convenience sample of 1024 children and 883 parents, needle fears were reported by about two-thirds of children and one-quarter of adults. Immunization non-compliance due to needle fear was reported by about one out of every dozen children and adults alike. Together, these data provide evidence that needle fears are both commonplace and a significant barrier to routine immunization.

The observed prevalence of needle fears among children in the present study is comparable to a previous survey conducted in the U.S. involving 1011 parents. In that study, parents reported that 70% of children under the age of 10 years experienced fear, anxiety, or stress during a visit to the doctor or hospital for any needle-stick procedure (<http://www.painfoundation.org/media/resources/pain-surveys.html>). The prevalence of needle fears among adults in the present study is similar to prior estimates from a general practice and a travellers' health clinic (22% for both) [7,14].

The finding of a high prevalence of needle fears among children fits with studies demonstrating that needle procedures are one of the most fearful aspects of medical care for children [15,16] and that the majority of young children are quite distressed during needle procedures [3,17]. Also consistent with previous studies, correlates of needle fear included younger age and female sex [18,19]. We found that parents under-reported needle fear in their children when compared to children's self-report. Similar results have been observed in studies of children's pain [20]. It is generally accepted that children's self-report is the primary source of information when judging pain. The results of the present study suggest that the same approach be used when judging needle fear in children.

Inadequate vaccine uptake levels in the U.S. have resulted in recurrent outbreaks of vaccine-preventable diseases [9]. Needle fear in both adults and children is one documented source of vaccine non-compliance. Needle fear not only causes anxiety in individuals undergoing immunization, their anxiety contributes to distress in vaccinators carrying out the procedure and attending caregivers, and leads to dissatisfaction with the immunization experience for everyone involved [2]. If fear is sufficiently severe, procedures may be aborted, and serious injury has resulted from fainting-induced falls [21]. Traumatic memories of past procedures lead to the development of negative attitudes about immunization, avoidance, and outright refusal of subsequent procedures [2]. Effective management of anxiety and pain or development of non-painful approaches to immunization may therefore reduce outbreaks of vaccine-preventable diseases among those who refuse to be immunized due to fear and, by increasing herd immunity.

The magnitude of immunization non-compliance due to needle fears has not been well studied, and may depend in part, on

the nature of the vaccine being administered [7]. For influenza vaccine specifically, a review of studies of vaccine uptake in healthcare workers concluded that 4–26% of individuals refused vaccination because of fear of injections [22]. In a recent study, we documented that at least 5% of adults undergoing H1N1 vaccination did so because they were guaranteed administration of an analgesic agent for the needle poke [23]. These data provided the first evidence that managing injection pain improves vaccination compliance. In the present study, we examined this notion further by asking parents about their willingness to be immunized against influenza in the future if a non-painful administration method was available and we compared this to their current practices with injectable influenza vaccine. Parents reported a 30% increase in willingness to be vaccinated themselves and a 40% increase in willingness to vaccinate their children if influenza was administered in a non-painful manner. Together, these data further support the hypothesis that vaccine uptake can be improved if pain is abolished.

Parents reported challenges during their children's immunization injections, including; crying, screaming, flailing, and having to restrain children in order to successfully carry out the procedure. Although the majority reported they had not received education about mitigating pain, they employed a variety of techniques that were either ineffective or increase children's distress. Examples of ineffective strategies include; administering acetaminophen or ibuprofen prior to immunization, applying ice, or telling children the injection will not hurt [24]. Examples of strategies that increase distress include; apologizing, providing reassurance, and empathy [2]. Any attempt to mitigate pain and distress during immunization must begin with knowledge about effective techniques. At present, parents employing these ineffective strategies may be under the false impression that what they do helps their children to cope.

It has been consistently documented that parents are not educated about pain management during childhood immunization injections [25]. The paucity of effective needle/immunization anxiety and pain education programs is alarming in light of the fact that children bear a large burden of pain from immunization injections due to their repeated occurrence and that the risk of developing needle fears is greatest in this age group [2]. It is also contrary to efforts to promote discourse between physicians and parents regarding understanding the reasons parents resist vaccination and adopting strategies to overcome these hurdles [9]. In the present study, most individuals reported they would like to learn ways to effectively manage injection-related anxiety and pain; hence, efforts should be made to incorporate this information within current immunization education systems. Various stakeholder organizations are beginning to provide tools for parents and vaccinators (e.g., pamphlets, videos, analgesic documentation charts), which should facilitate the required knowledge transfer [26]. In addition, the Brighton

Collaboration (<https://brightoncollaboration.org>), an international collaboration whose primary aim is to develop standardized global case definitions of adverse events following immunization (AEFI) is incorporating acute vaccine injection pain as a reportable AEFI [27], which will bring increased international attention to injection-induced anxiety and pain. It is important to note that most evidence-based pain-relieving interventions can be incorporated into routine immunization in any clinical setting, as they cost little or no money and fit within usual waiting times [28]. This includes modalities from all of the domains of pain management, including: pharmacological (e.g., sugar water for infants), physical (e.g., upright positioning and/or holding), and psychological (e.g., distraction) methods. Furthermore, in settings where education about analgesic interventions has been implemented, increased utilization of analgesics and improved satisfaction has been documented for both parents and vaccinators [29].

There are some limitations that warrant discussion. First, responses of children and adults were not validated, raising the possibility of reporting bias. Observed rates of influenza vaccine uptake, however, were consistent with published provincial and national rates [30] making it unlikely that the results were grossly inaccurate. In addition, self-report is an accepted method of ascertaining both influenza vaccine uptake statistics [31] and information about pain and fear in individuals. Second, the chosen study site (i.e., OSC) may have led to recruitment of a study sample with limited applicability to the general population. Although individuals from a wide geographic region (i.e., GTA, including ~6 million inhabitants) were included, we did note that average education level in study participants was higher than the regional average. However, there was no evidence of an association between education level and needle fear. In addition, reported patterns of needle fear, influenza vaccine uptake and utilization of analgesic interventions were consistent with studies undertaken in individuals in other settings [7,14,25,30] suggesting applicability to other populations and settings. Under-reporting of needle fears and immunization compliance may have occurred due to the use of interviewers to administer surveys instead of using self-administered surveys and resulting social desirability bias. Underreporting was also possible due to exclusion of individuals who did not have experience with immunization in their children or themselves and exclusion of families in which, when the study was being explained to them, one or more children began screaming and/or running away because they feared they would be given an injection. Finally, under-reporting of immunization non-compliance may have been present in children, particularly younger children, who may not be aware of instances when parents refused immunization on their behalf. Conversely, there is a potential that the overall prevalence of needle fears was over-estimated slightly because more mothers participated than fathers, and mothers were more likely to self-report needle fears.

Strengths of the study include: involving children and parents from a wide sampling region, and using interviewers to administer the survey. Conducting the study at the OSC allowed investigators to have access to large numbers of children and parents from a large geographical region. This facilitated inclusion of diverse cultural and ethnic backgrounds, perspectives and practices. Having interviewers administer questions rather than having respondents answer questions on their own maximized comprehension and response rates for individual questions.

In conclusion, this survey demonstrated that needle fears are pervasive and contribute to vaccine non-compliance. Proven strategies exist to manage anxiety and pain during immunization, but knowledge and use of these interventions are low and not consistent. Incorporating analgesic interventions in the vaccination process should address this unmet gap in optimal patient care. Managing injection-induced anxiety and pain will improve

the quality of care of individuals undergoing vaccination, and potentially improve vaccination compliance rates; this will support immunization programs on a global level. Additional benefits include improving the experience of immunization for children, parents, and immunizers.

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